Prior Authorization Approval Criteria

Effective Date: 01/01/2025

Prior authorization criteria are developed following evidence-based criteria including:

i. Safety, including concurrent drug utilization review (cDUR) when applicable
ii. Efficacy: the potential outcome of treatment under optimal circumstances
iii. Strength of scientific evidence and standards of practice through review of relevant information from the peer-reviewed medical literature, accepted national treatment guidelines, and expert opinion where necessary
iv. Cost-Effectiveness: the actual outcome of treatment under real life conditions including consideration of total health care costs, not just drug costs, through utilization of pharmacoeconomic principles and/or published pharmacoeconomic or outcomes research evaluations where available
v. Relevant benefits of current formulary agents of similar use
vi. Any restrictions that should be delineated to assure safe, effective, or proper use of the drug.

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This document contains Prior Authorization Approval Criteria for the following medications:

1. Aimovig (erenumab)
2. Ajovy (fremanezumab)
3. Austedo (deutetrabenazine)
4. Benlysta (belimumab)
5. Cimzia (certolizumab)
6. Bydureon Bcise(exenatide extended release)
7. Byetta (exenatide)
8. Cimzia (certolizumab)
9. Continuous Glucose Monitors
10. Cosentyx (secukinumab)
11. Dupixent (dupilumab)
12. Emgality (galcanezumab)
13. Forteo (teriparatide)
14. Gilenya (fingolimod)
15. Gleevec (imatinib)
16. Hepatitis C Virus (HCV) Non-Preferred Medications (Mavyret, Zepatier)
17. Horizant (gabapentin enacarbil)
18. Ingrezza (valbenazine)
19. Insulin Pump
20. Jakafi (ruxolitinib)
21. Kalydeco (ivacaftor)
22. Kesimpta (ofatumumab)
23. Kineret (anakinra)
24. Lupron, Lupron Depot, Lupron Depot-Ped (leuprolide)

25. Nurtec ODT (rimegepant)
26. Opioid Benzodiazepine Concurrent Use [Applies to Medicaid Choice Only]
27. Opioid Morphine Equivalent Dose (MED) Limit [Applies to Medicaid Choice Only]
28. Opioid Naïve Day Supply Limit [Applies to Medicaid Choice Only]
29. Orencia (abatacept)
30. Orkambi (lumacaftor/ivacaftor)
31. Otezla (apremilast)
32. Ozempic (semaglutide)
33. Reyvow (lasmiditan)
34. Rinvoq (upadacitinib)
35. Rubraca (rucaparib)
36. Rybelsus (semaglutide)
37. Sensipar (cinalcalcet)
38. Simponi (golimumab)
39. Somatropin
40. Stelara (ustekinumab)
41. Synagis (palivizumab)
42. Tasigna (nilotinib)
43. Tecfidera (dimethyl fumarate)
44. Tobi Podhaler (tobramycin inhalation powder)
45. Tolvaptan
46. Trikafta (elexacaftor/tezacaftor/ivacaftor)
47. Trulicity (dulaglutide)
48. Tymlos (abaloparatide)
49. Ubrelvy (ubrogepant)
50. Valchlor (mechlorethamine)
51. Victoza (liraglutide)
52. Xeljanz (tofacitinib)
53. Xolair (omalizumab)
54. Xyrem (sodium oxybate)
55. Zejula (niraparib)
56. Pharmacy Benefit Formulary Exception Protocol

Prior Authorization Approval Criteria

Aimovig (erenumab)

Generic name: erenumab injection
Brand name: Aimovig
Medication class: Calcitonin gene related peptide receptor (CGRP) antagonist

FDA-approved uses:

- Migraine prophylaxis

Usual dose range:

- Migraine prophylaxis
  - 70 mg – 140 mg subcutaneously once monthly

Criteria for use:

Initiation Criteria

Migraine prophylaxis

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond or intolerance to an adequate trial of **two** of the following:
  - An anti-epileptic drug (such as divalproex sodium or topiramate)
  - A beta-blocker (such as propranolol extended-release)
  - An antidepressant (such as venlafaxine or a TCA, such as amitriptyline)
  - Botox (PA Required)

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 140 mg once per month
- Avoid use if allergic to latex

Approval time frames:

- Initial – 6 months with MDL of 0.04/day (1 mL per 28 days)
- Renewal – 1 year with MDL of 0.04/day (1 mL per 28 days)

References:

- Aimovig Prescribing Information; Thousand Oaks, CA; Amgen, Inc.; 2023.
- American Headache Society (AHS) Consensus Statement. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache 2019;59:1-18.
- Buse DC, Lipton RB, Hallström Y, et al. Migraine-related disability, impact, and health-related quality of life among patients with episodic migraine receiving preventive treatment with erenumab. Cephalalgia 2018
- Dodick DW, Ashina M, Brandes JL, et al. ARISE: A Phase 3 randomized trial of erenumab for episodic migraine. Cephalalgia 2018.
- Edvinsson L, Haanes K, Warfvinge K, and Krause DN. CGRP as the target of new migraine therapies – successful translation from bench to clinic. Nat Rev Neurol 2018; 14(6):338-350.
- Goadsby PJ, Reuter U, Hallström Y, et al. A Controlled Trial of Erenumab for Episodic Migraine. N Engl J Med 2017; 377:2123-2132.
- MacGregor EA. Migraine in the Clinic. ACP Ann Intern Med 2013.
- Shamliyan TA, Choi J, Ramakrishnan R, et al. Preventive Pharmacologic Treatments for Episodic Migraine in Adults. J Gen Intern Med 2013; 28(9):1225-1237.
- Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78:1337-1345.
- Sussman M, Benner J, Neumann P, and Menzin J. Cost-effectiveness analysis of erenumab for the preventive treatment of episodic and chronic migraine: Results from the US societal and payer perspectives. Cephalalgia 2018.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2018
Revision: December 2019, December 2020, January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Ajovy (fremanezumab)

Generic name: fremanezumab
Brand name: Ajovy
Medication class: Calcitonin gene related peptide receptor (CGRP) antagonist

FDA-approved uses:

- Migraine prophylaxis

Usual dose range:

- 225 mg once monthly or 675 mg once every 3 months

Criteria for use:

Initiation Criteria

Migraine prophylaxis

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond or intolerance to an adequate trial of Aimovig
- Failure to respond or intolerance to an adequate trial of **two** of the following:
  - An anti-epileptic drug (such as divalproex sodium or topiramate)
  - A beta-blocker (such as propranolol extended-release)
  - An antidepressant (such as venlafaxine or a TCA, such as amitriptyline)
  - Botox (PA Required)

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 225 mg per month or 675 mg once every 3 months (given as 3 consecutive 225 mg injections)

Approval time frames:

- Initial – 6 months with MDL of 0.06/day (1.5 mL per 28 days)
- Renewal – 1 year with MDL of 0.06/day (1.5 mL per 28 days)

References:

- Ajovy Prescribing Information; North Wales, PA; Teva Pharmaceuticals USA, Inc: 2022.
- American Headache Society (AHS) Consensus Statement. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache 2019;59:1-18.
- Edvinsson L, Haanes K, Warfvinge K, and Krause DN. CGRP as the target of new migraine therapies – successful translation from bench to clinic. Nat Rev Neurol 2018; 14(6):338-350.
- Dodick DW, Silberstein SD, Bigal ME, et al. Effect of Fremanezumab Compared With Placebo for Prevention of Episodic Migraine: A Randomized Clinical Trial. JAMA 2018; 319(19):1999-2008.
- MacGregor EA. Migraine in the Clinic. ACP Ann Intern Med 2013.
- Shamliyan TA, Choi J, Ramakrishnan R, et al. Preventive Pharmacologic Treatments for Episodic Migraine in Adults. J Gen Intern Med 2013; 28(9):1225-1237.
- Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78:1337-1345.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022

Prior Authorization Approval Criteria

Austedo (deutetrabenazine)

Generic name: deutetrabenazine
Brand name: Austedo
Medication class: Vesicular Monoamine Transporter 2 (VMAT2) inhibitor

FDA-approved uses:

- Tardive dyskinesia, moderate to severe
- Huntington's disease

Usual dose range:

- 6 mg to 24 mg twice daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Huntington's disease

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a neurologist or movement disorder specialist

Tardive dyskinesia

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a neurologist, movement disorder specialist, psychiatrist or provider specializing in psychiatric care
- Confirmation that moderate to severe tardive dyskinesia has been present for at least 3 months
- Documentation of prior use of antipsychotic medications or metoclopramide for at least 3 months if under the age of 60 or 1 month if 60 years of age or older (can also be determined by prescription claim history)

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 48 mg per day

Approval time frames:

- Initial: 1 year for all strengths with MDL as follows:
  - 6 mg tablet: 2/day
  - 9 mg tablet: 4/day
  - 12 mg tablet 4/day
- Renewal: 1 year for all strengths with MDL as follows:
  - 6 mg tablet: 2/day
  - 9 mg tablet: 4/day
  - 12 mg tablet 4/day

References:

- Austedo Prescribing Information; North Wales, PA; Teva Pharmaceuticals, Inc.: 2023.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: June 2023
Revision:

Prior Authorization Approval Criteria

Benlysta (belimumab)

Generic name: belimumab
Brand name: Benlysta
Medication class: Monoclonal antibody

FDA-approved uses:

- Systemic lupus erythematosus (SLE), autoantibody-positive
- Lupus nephritis, active

Usual dose range:

- 200 mg subcutaneously once weekly

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Systemic Lupus Erythematosus

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Confirmation that the patient has not responded to antimalarial treatment

Lupus nephritis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a nephrologist or rheumatologist
- Confirmation that the patient is receiving standard immunosuppressive therapy

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 200 mg weekly (maintenance dosing)

Approval time frames:

- Systemic lupus erythematosus
  - Initial: 6 months with MDL 0.15/day (4 mL per 28 days)
  - Renewal: 1 year with MDL 0.15/day (4 mL per 28 days)
- Lupus nephritis
  - Initial: 5 months starting in 3 weeks with MDL 0.15/day (4 mL per 28 days)
    - Additional override for 1 month starting today with MDL 0.29/day (8 mL every 28 days)
  - Renewal: 1 year with MDL 0.15/day (4 mL every 28 days)

References:

- Benlysta Prescribing Information; Philadelphia, PA; GlaxoSmithKline LLC: 2023.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: June 2023
Revision:

Prior Authorization Approval Criteria

Bydureon BCise (exenatide, extended release)

Generic name: exenatide, extended release
Brand name: Bydureon BCise
Medication class: GLP-1 receptor agonist

FDA-approved uses:

- Type 2 Diabetes Mellitus (adults and pediatric patients)

Usual dose range:

- Indication—adult 2mg weekly
- Indication – pediatric (10 years and older) 2mg weekly

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Type 2 Diabetes:

Adults

- FDA indicated diagnosis

Pediatric (10 years and older)

- FDA indicated diagnosis

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Contraindications:

- Multiple endocrine neoplasia syndrome type 2 or personal or family history of medullary thyroid carcinoma

Not approved if:

- No FDA diagnosis of Type 2 Diabetes Mellitus
- Use is for weight loss
- Under 10 years of age

Additional considerations:

Adults and Pediatrics:

- Maximum weekly dose 2mg per week

Approval time frames:

Adults and Pediatrics

- Initial:
  - 1 year with MDL of 0.13/day (max 4 pen per 28 days), by GPID
- Renewal
  - 1 year with MDL of 0.13/day (max 4 pen per 28 days), by GPID

References:

1. AstraZeneca Pharmaceuticals LP (per FDA). *Bydureon BCise® subcutaneous extended -release injection, Wilmington, DE; 2023.* https://den8dhaj6zs0e.cloudfront.net/50fd68b9-106b-4550-b5d0-12b045f8b184/df5ddbd6-546b-43da-b794-56f711189aba/df5ddbd6-546b-43da-b794-56f711189aba_viewable_rendition__v.pdf. Accessed: May 6, 2024.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: May 2024
Revision:

Prior Authorization Approval Criteria

Byetta (exenatide)

Generic name: exenatide
Brand name: Byetta
Medication class: GLP-1 receptor agonist

FDA-approved uses:

- Type 2 Diabetes Mellitus (adults)

Usual dose range:

- Indication—adult, immediate release 5mcg – 10mcg twice daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Type 2 Diabetes:

Adults

- FDA indicated diagnosis

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Contraindications:

- Multiple endocrine neoplasia syndrome type 2 or personal or family history of medullary thyroid carcinoma

Not approved if:

- No FDA diagnosis of Type 2 Diabetes Mellitus
- Use is for weight loss
- Under 18 years of age

Additional considerations:

Adults:

- Maximum daily dose is 1.8mg/day

Approval time frames:

Adults

- Initial:
  - 1 year with MDL of 0.08/day (max 1 pen per 30 days), by GPID for all strengths
- Renewal
  - 1 year with MDL of 0.08/day (max 1 pen per 30 days), by GPID for all strengths

References:

1. AstraZeneca Pharmaceuticals LP (per FDA). *Byetta® subcutaneous immediate-release injection, Wilmington, DE; 2022.* https://den8dhaj6zs0e.cloudfront.net/50fd68b9-106b-4550-b5d0-12b045f8b184/ce8afab9-2b45-436d-957c-a73978d09e93/ce8afab9-2b45-436d-957c-a73978d09e93_viewable_rendition__v.pdf. Accessed: May 6, 2024.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: May 2024
Revision:

Prior Authorization Approval Criteria

Cimzia (certolizumab)

Generic name: certolizumab
Brand name: Cimzia
Medication class: TNF inhibitor

FDA-approved uses:

- Ankylosing spondylitis, active
- Non-radiographic axial spondyloarthritis
- Crohn's disease, active, moderate to severe
- Plaque psoriasis, moderate to severe
- Psoriatic arthritis, active
- Rheumatoid arthritis, active, moderate to severe

Usual dose range:

- Ankylosing spondylitis/Non-radiographic axial spondyloarthritis/Plaque psoriasis/Psoriatic arthritis/Rheumatoid arthritis
  - 400 mg subcutaneously at weeks 0, 2 and 4; then 200 mg every 2 weeks or 400 mg every 4 weeks
- Crohn's disease
  - 400 mg subcutaneously at weeks 0, 2 and 4; then 400 mg every 4 weeks

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Ankylosing spondylitis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond (or contraindication) to an NSAID (such as ibuprofen, naproxen, meloxicam, etc. Please refer to the formulary for all available NSAIDs)
- Confirmation of **one** of the following:
  - Patient is pregnant, breastfeeding or trying to become pregnant
  - Failure to respond (or contraindication) to two of the following:
    - Cosentyx
    - Enbrel
    - Humira
    - Xeljanz (IR/XR)

Crohn's disease

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a gastroenterologist
- Failure to respond to one conventional therapy (such as budesonide, methylprednisolone, azathioprine, mercaptopurine, methotrexate or mesalamine)
- Confirmation of **one** of the following:
  - Patient is pregnant, breastfeeding or trying to become pregnant
  - Failure to respond (or contraindication) to Humira

Non-radiographic axial spondyloarthritis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond (or contraindication) to an NSAID (such as ibuprofen, naproxen, meloxicam, etc. Please refer to the formulary for all available NSAIDs)
- Confirmation of **one** of the following objective signs of inflammation:
  - C-reactive protein (CRP) levels above the upper limit of normal
  - Sacroiliitis on magnetic resonance imaging (MRI)

Plaque psoriasis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a dermatologist
- Documentation that patient has one of the following:
  - Psoriasis covering 3% or more of body surface area (BSA)
  - Psoriatic lesions affecting the hands, feet, genital area or face
- Failure to respond to one conventional therapy (such as, methotrexate, calcipotriene, cyclosporine, acitretin, topical corticosteroids, phototherapy ultraviolet light A [PUVA], ultraviolet light B [UVB])
- Confirmation of **one** of the following:
  - Patient is pregnant, breastfeeding or trying to become pregnant
  - Failure to respond (or contraindication) to two of the following:
    - Cosentyx
    - Enbrel
    - Humira
    - Otezla
    - Stelara

Psoriatic arthritis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist or dermatologist
- Failure to respond (or contraindication) to one DMARD (such as methotrexate, hydroxychloroquine, leflunomide or sulfasalazine)
- Confirmation of **one** of the following:
  - Patient is pregnant, breastfeeding or trying to become pregnant
  - Failure to respond (or contraindication) to two of the following:
    - Cosentyx
    - Enbrel
    - Humira
    - Otezla
    - Stelara
    - Xeljanz (IR/XR)

Rheumatoid arthritis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond (or contraindication) to one DMARD (such as methotrexate, hydroxychloroquine, leflunomide or sulfasalazine)
- Confirmation of **one** of the following:
  - Patient is pregnant, breastfeeding or trying to become pregnant
  - Failure to respond (or contraindication) to two of the following:
    - Enbrel
    - Humira
    - Xeljanz (IR/XR)

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 400 mg every 14 days for plaque psoriasis and 400 mg every 28 days for all other diagnoses (maintenance dosing)

Approval time frames:

- Ankylosing spondylitis
  - Initial: 5 months starting in 3 weeks with MDL 0.04/day (1 kit per 28 days)
    - Additional override for 1 month starting today with MDL 0.11/day (1 starter kit or 3 regular kits per 28 days)
  - Renewal: 1 year with MDL 0.04/day (1 kit per 28 days)
- Crohn's disease
  - Initial: 5 months starting in 3 weeks with MDL 0.04/day (1 kit per 28 days)
    - Additional override for 1 month starting today with MDL 0.11/day (1 starter kit or 3 regular kits per 28 days)
  - Renewal: 1 year with MDL 0.04/day (1 kit per 28 days)
- Non-radiographic axial spondyloarthritis
  - Initial: 5 months starting in 3 weeks with MDL 0.04/day (1 kit per 28 days)
    - Additional override for 1 month starting today with MDL 0.11/day (1 starter kit or 3 regular kits per 28 days)
  - Renewal: 1 year with MDL 0.04/day (1 kit per 28 days)
- Plaque psoriasis
  - Initial: 6 months with MDL 0.08/day (2 kits per 28 days)
  - Renewal: 1 year with MDL 0.08/day (2 kits per 28 days)
- Psoriatic arthritis
  - Initial: 5 months starting in 3 weeks with MDL 0.04/day (1 kit per 28 days)
    - Additional override for 1 month starting today with MDL 0.11/day (1 starter kit or 3 regular kits per 28 days)
  - Renewal: 1 year with MDL 0.04/day (1 kit per 28 days)
- Rheumatoid arthritis
  - Initial: 5 months starting in 3 weeks with MDL 0.04/day (1 kit per 28 days)
    - Additional override for 1 month starting today with MDL 0.11/day (1 starter kit or 3 regular kits per 28 days)
  - Renewal: 1 year with MDL 0.04/day (1 kit per 28 days)

References:

- Cimzia Prescribing Information; Smyrna, GA; UCB, Inc.: 2023.
- Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic non-biological therapies. J Am Acad of Dermatol 2020;0(0).
- Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad of Dermatol 2019;80(4):1029-1072.
- Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoritatic arthritis. Arthritis Rheum 2019; 71(1):5-32.
- Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol 2018;113(4):481-517.
- Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken) 2016; 68:1.

- Ward MM, Deodhar A, Akl EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheum 2016; 68:282.
- Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009; 61:451.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: May 2020
Revision: June 2021, June 2022, June 2023

Prior Authorization Approval Criteria

Continuous Glucose Monitor

Formulary Products:

- FreeStyle Libre 14 Day Reader
- FreeStyle Libre 14 Day Sensor
- FreeStyle Libre 2 Reader
- FreeStyle Libre 2 Sensor
- FreeStyle Libre 3 Reader
- FreeStyle Libre 3 Sensor
- Dexcom G6 Receiver
- Dexcom G6 Sensor
- Dexcom G6 Transmitter

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

1. The beneficiary has Elevate Child Health Plan *Plus* or Elevate Medicaid Choice (**age 20 years or younger**); **and**
2. The beneficiary has diabetes mellitus; **and**
3. The beneficiary is insulin-treated with multiple (three or more) daily administrations of insulin or a continuous subcutaneous insulin infusion (CSII) pump; **and**
4. The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results; **and**
5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or telehealth visit with the beneficiary to evaluate their diabetes control and determines that criteria (2-3) above are met; **and**
6. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person or telehealth visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan; **and**
7. Receipt of, or documented plan to receive, diabetes education specific to the use of CGMs; **and**
8. Attestation that the beneficiary is able to hear and view the CGM alerts and respond accordingly, or have a caregiver who is able to do so, **and**
9. Providers should verify that the patient meets the manufacturer's recommendations for appropriate age range, testing and calibration requirements, etc. before prescribing the CGM device; **or**
10. Has an otherwise qualifying circumstance or is otherwise deemed medically necessary.

Renewal Criteria

1. Individual meets all the initial criteria; **and**
2. In-person or telehealth visit with treating practitioner within at least six (6) months of CGM renewal prescription; **and**

3. Provider determines that the individual is regularly utilizing the device; **and**
4. Individual receives ongoing instruction and evaluation of technique, results, and their ability to use data from CGM to adjust therapy; **or**
5. Has an otherwise qualifying circumstance or is otherwise deemed medically necessary.

An upgrade to a new model or different brand of CGM may be deemed medically necessary in the following situations:

- There is documentation that the current device is no longer functional either partially or entirely, and therefore is no longer clinically effective; **or**
- The requested upgrade is different in its capability and would be expected to provide better clinical outcomes than the current device; **and**
- The member has been using their current device for at least three years.
- If the current CGM requires repair or replacement that is no longer possible because it is obsolete, requests may be approved in cases where use is less than three years. PARs may be pended to gather additional details regarding the device being obsolete.

Additional Considerations:

- **Continuous glucose monitors for Elevate Medicaid Choice members that are 21 years old and older are managed directly by the Colorado Department of Healthcare Policy and Finance (HCPF). Please submit the prior authorization request to the Provider Portal with HCPF ColoradoPar Health First Colorado Prior Authorization Request Program | Colorado Department of Health Care Policy & Financing at: https://hcpf.colorado.gov/par#forms**

Approval time frames:

Initial and Renewal: based the product requested

- FreeStyle Libre 14 Day, FreeStyle Libre 2, FreeStyle Libre 3
  - Reader: Approve for 12 months by GPID with max quantity of 1 (1 per 365 days)
  - Sensor: Approve for 12 months by GPID with MDL of 0.08/day (2 per 28 days)
- Dexcom G6
  - Receiver: Approve for 12 months by GPID with max quantity of 1 (1 per 365 days)
  - Transmitter: Approve for 12 months by GPID with MDL of 0.02/day (1 per 90 days)
  - Sensor: Approve for 12 months by GPID with MDL of 0.1/day (3 per 30 days)

References:

- American Diabetes Association. Diabetes Technology: Standards of Care in Diabetes - 2023. Diabetes Care 2024;47(Supplement_1):S126–S144
- Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) | Colorado Department of Health Care Policy & Financing. Accessed August 19, 2024. https://hcpf.colorado.gov/DMEPOS-manual#Therapeutic%20Continuous%20Glucose%20Monitor%20(CGM)%20Benefit%20Coverage.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: August 2024
Revision:

Prior Authorization Approval Criteria

Cosentyx (secukinumab)

Generic name: secukinumab
Brand name: Cosentyx
Medication class: Anti-interleukin 17A monoclonal antibody

FDA-approved uses:

- Ankylosing spondylitis
- Juvenile idiopathic arthritis, enthesitis-related
- Non-radiographic axial spondyloarthritis
- Psoriatic arthritis
- Plaque psoriasis

Usual dose range:

- Initial
  - 75 mg – 300 mg subcutaneously at weeks 0, 1, 2, 3, and 4, then every 4 weeks thereafter
- Maintenance
  - 75 mg – 300 mg subcutaneously every 4 weeks

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Ankylosing spondylitis/Non-radiographic axial spondyloarthritis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond to an NSAID (such as ibuprofen, naproxen, meloxicam, etc. Please refer to the formulary for all available NSAIDs)

Juvenile idiopathic arthritis, enthesitis-related

Pediatric and Adult

- FDA indicated diagnosis
- 4 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond to one of the following:
  - An oral DMARD (such as methotrexate, leflunomide or sulfasalazine)

- An NSAID (such as ibuprofen, naproxen, meloxicam, etc. Please refer to the formulary for all available NSAIDs)

Psoriatic arthritis

Pediatric and Adult

- FDA indicated diagnosis
- 2 years of age or older
- Prescribed by or in consultation with a dermatologist or rheumatologist
- Failure to respond to one oral DMARD (such as methotrexate, leflunomide or sulfasalazine)

Plaque psoriasis

Pediatric and Adult

- FDA indicated diagnosis
- 6 years of age or older
- Prescribed by or in consultation with a dermatologist
- Documentation that patient has one of the following:
  - Psoriasis covering 3% or more of body surface area (BSA)
  - Psoriatic lesions affecting the hands, feet, genital area or face
- Failure to respond to one conventional therapy (such as, methotrexate, calcipotriene, cyclosporine, acitretin, topical corticosteroids, phototherapy ultraviolet light A [PUVA], ultraviolet light B [UVB])

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Approval time frames:

- Initial – 6 months, MDL 0.08/day (2 pens or syringes/month)
  – 1st month: 75 mg - MDL 0.09/day (5 syringes)
  – 1st month: 150 mg - MDL 0.17/day (5 pens/syringes)
  – 1st month: 300 mg - MDL 0.34/day (10 pens/syringes)
- Renewal – 1 year, MDL 0.08/day

References:

- Cosentyx Prescribing Information. Novartis Pharmaceuticals Corporation, East Hanover, NJ: 2022.
- Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic non-biological therapies. J Am Acad of Dermatol 2020; 82(6):1445-1486.
- Menter A, Strober BE, Kaplan DH, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad of Dermatol 2019; 80(4):1029-1072.
- Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheum 2019; 71:846.

- Ward MM, Deodhar A, Genslar LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheum 2019; 71(10):1599-1613.
- Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoritatic Arthritis. Arthritis Rheum 2019; 71(1):5-32.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: March 2020
Revision: March 2021, March 2022, May 2023

Prior Authorization Approval Criteria

Dupixent (dupilumab)

Generic name: dupilumab injection
Brand name: Dupixent
Medication class: IL-4 receptor antagonist

FDA-approved uses:

- Moderate to severe atopic dermatitis
- Moderate to severe asthma
- Chronic sinusitis with nasal polyps
- Eosinophilic esophagitis
- Prurigo nodularis

Usual dose range:

- Moderate to severe atopic dermatitis
  - Pediatric (6 months to 5 years of age): No initial loading dose is recommended
    - 5 kg - <15 kg: 200 mg subcutaneously every 4 weeks
    - 15 kg - <30 kg: 300 mg subcutaneously every 4 weeks
  - Pediatric (6 years to 17 years of age):
    - 15 kg – <30 kg: 600 mg subcutaneously followed by 300 mg subcutaneously every 4 weeks
    - 30 kg - <60 kg: 400 mg subcutaneously followed by 200 mg subcutaneously every other week
    - 60 kg or more: 600 mg subcutaneously followed by 300 mg subcutaneously every other week
  - Adults:
    - 600 mg subcutaneously followed by 300 mg subcutaneously every other week
- Moderate to severe asthma
  - Pediatric (6 months to 11 years of age): No initial loading dose is recommended
    - 15 kg - <30 kg: 300 mg subcutaneously every 4 weeks
  - Adults and Pediatric Patients 12 years and older ≥30 kg:
    - 200 mg subcutaneously every other week 400 mg subcutaneously followed by 200 mg subcutaneously every other week OR *600 mg subcutaneously followed by 300 mg subcutaneously every other week

*Also used in patients with oral corticosteroid-dependent asthma or with comorbid moderate-to-severe atopic dermatitis or adults with co-morbid chronic rhinosinusitis with nasal polyposis.

- Chronic sinusitis with nasal polyps
  - 300 mg subcutaneously every other week

- Eosinophilic esophagitis
  - Pediatric (1 year of age and older weighing at least 15 kg):
    - 15 kg - <30 kg: 200 mg subcutaneously every other week
    - 30 kg - <40 kg: 300 mg subcutaneously every other week
  - Adults and pediatric patients 12 years of age and ≥40 kg:
    - 300 mg subcutaneously every week

- Prurigo nodularis
  - 600 mg subcutaneously followed by 300 mg subcutaneously every other week

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Moderate-to-severe atopic dermatitis

Adolescents and adults

- FDA indicated diagnosis
- 6 months of age or older
- Prescribed by (or in consultation with) a dermatologist or allergist
- Failure to respond, intolerance, or contraindication to an adequate trial of one of the following:
  - A medium to very-high potency formulary topical corticosteroid
  - Topical tacrolimus

Moderate-to-severe asthma

Adolescents and adults

- FDA indicated diagnosis
- 6 years of age or older
- Prescribed by (or in consultation with) a pulmonologist or allergist
- Confirmation of one of the following:
  - Asthma with eosinophilic phenotype with eosinophil count greater than or equal to 300 cells/mcL in the past 12 months
  - Oral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use in the last 3 months
- Failure to respond, intolerance, or contraindication to an adequate trial of all the following:
  - A formulary inhaled corticosteroid (i.e., Alvesco, fluticasone, Pulmicort, QVAR)

- An additional formulary controller medication (i.e., fluticasone-salmeterol, Spiriva, Symbicort)
- Medication is being prescribed as add-on therapy to existing asthma regimen

Chronic sinusitis with nasal polyps

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by (or in consultation with) an allergist or ears, nose and throat specialist
- Failure to respond, intolerance, or contraindication to an adequate trial of the following:
  - Two formulary intranasal corticosteroid sprays (i.e., fluticasone, flunisolide nasal spray)

Eosinophilic esophagitis

Adolescents and adults

- FDA indicated diagnosis
- Adults and pediatric patients aged 1 year and older (weighing at least 15 kg)
- Prescribed by (or in consultation with) a gastroenterologist, allergist or immunologist
- Diagnosis has been confirmed by an esophagogastroduodenoscopy (EGD) with biopsy
- Failure to respond, intolerance, or contraindication to an adequate trial of ALL the following:
  - Proton pump inhibitor (i.e., esomeprazole, lansoprazole, omeprazole, pantoprazole)
  - Swallowed topical steroids (i.e., MDI fluticasone or budesonide sprayed into mouth then swallowed)
  - Dietary therapy

Prurigo nodularis

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by (or in consultation with) a dermatologist or allergist
- Documentation that the patient has chronic pruritis (i.e., itch lasting longer than 6 weeks), presence of multiple pruriginous lesions (localized or general), and a history or sign of a prolonged scratching behavior
- Failure to respond, intolerance, or contraindication to an adequate trial of at least TWO of the following:

- A formulary topical corticosteroid
- An intralesional corticosteroid
- A topical calcineurin inhibitor (i.e., tacrolimus ointment)
- A topical calcipotriol (i.e., calcipotriene cream/ointment)

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Avoid administration of live vaccines
- No known drug-drug interactions, but monitor narrow therapeutic index medications as dupilumab can potentially alter CYP enzyme formation
- Increased risk of conjunctivitis and arthralgia
- First line therapy for patients with eosinophilic esophagitis with a strong preference to avoid dietary restriction or swallowed topical steroids
- Patients with eosinophilic esophagitis who have multiple atopic conditions (i.e., moderate, persistent, or difficult to control asthma, atopic dermatitis and/or chronic sinusitis with nasal polyps) may benefit significantly

Approval time frames:

- **Initial – based on diagnosis and strength prescribed as follows:**
- Moderate to severe atopic dermatitis –
    - Pediatric (6 months to 5 years of age):
        - 5 kg - <15 kg: 200 mg/1.14 mL: MDL 0.05/day (1.14 mL per 28 days)
        - 15 kg - <30 kg: 300 mg/2 mL: MDL 0.08/day (2 mL per 28 days)
    - Pediatric (6 years to 17 years of age): - enter 2 separate approvals as follows:
        - 15 kg – <30 kg - Approve for 1 month:
            - 300 mg/2 mL: MDL 4/day (4 mL one-time loading dose)
        - 15 kg – <30 kg: Approve for 5 months after the end of the first approval:
            - 300 mg/2 mL: MDL 0.08/day (2 mL per 28 days)
        - 30 kg - <60 kg - Approve for 1 month:
            - 200 mg/1.14 mL: MDL 0.17/day (4.56 mL per 28 days)
        - 30 kg - <60 kg - Approve for 5 months after the end of the first approval:
            - 200 mg/1.14 mL: MDL 0.09/day (2.28 mL per 28 days)
    - Adults and Pediatric patients ≥60 kg: - enter 2 separate approvals as follows:
        - Approve for 1 month:
            - For 300 mg/2 mL: MDL 0.29/day (8 mL per 28 days)
        - Approve for 5 months after the end of the first approval:
            - For 300 mg/2 mL: MDL 0.15/day (4 mL per 28 days)

- Moderate to severe asthma –
    - Pediatric (6 months to 11 years of age):

- 15 kg - <30 kg: 300 mg/2 mL: MDL 0.08/day (2 mL per 28 days)
- ≥30 kg: 200 mg/1.14 mL: MDL 0.09/day (2.28 mL per 28 days)

- Adults and pediatric patients 12 years and older: - enter 2 separate approvals as follows:
  - Approve for 1 month:
    - For 200 mg/1.14 mL: MDL 0.17/day (4.56 mL per 28 days)
    - For 300 mg/2 mL: MDL 0.29/day (8 mL per 28 days)
  - Approve for 3 months after the end of the first approval:
    - For 200 mg/1.14 mL: MDL 0.09/day (2.28 mL per 28 days)
    - For 300 mg/2 mL: MDL 0.15/day (4 mL per 28 days)

- Chronic sinusitis with nasal polyps – for 300 mg/2 mL strength only, approve as follows:
  - Approve for 6 months with MDL 0.15/day (4 mL per 28 days)

- Eosinophilic esophagitis – Approve for 6 months
  - Pediatric (1 year of age and older weighing at least 15 kg):
    - 15 kg - <30 kg: 200 mg/1.14 mL: MDL 0.09/day (2.28 mL per 28 days)
    - 30 kg – <40 kg: 300 mg/2 mL: MDL 0.15/day (4 mL per 28 days)
  - Adults and pediatric patients 12 years of age and ≥40 kg:
    - 300 mg/2 mL: MDL 0.29/day (8 mL per 28 days)

- Prurigo nodularis – for 300 mg/2 mL strength only, enter 2 separate approvals as follows:
  - Approve for 1 month with MDL 0.29/day (8 mL per 28 days)
  - Approve for 5 months after the end of the first approval with MDL 0.15/day (4 mL per 28 days)

- **Renewal – Approve for 1 year with MDL based on diagnosis and strength as follows:**

  - Moderate to severe atopic dermatitis –
    - Pediatric (6 months to 5 years of age):
      - 5 kg - <15 kg: 200 mg/1.14 mL: MDL 0.05/day (1.14 mL per 28 days)
      - 15 kg - <30 kg: 300 mg/2 mL: MDL 0.08/day (2 mL per 28 days)
    - Pediatric (6 years to 17 years of age):
      - 15 kg – <30 kg: 300 mg/2 mL: MDL 0.08/day (2 mL per 28 days)
      - 30 kg - <60 kg: 200 mg/1.14 mL: MDL 0.09/day (2.28 mL per 28 days)
    - Adults and Pediatric patients ≥60 kg:
      - For 300 mg/2 mL: MDL 0.15/day (4 mL per 28 days)

  - Moderate to severe asthma –
    - Pediatric (6 months to 11 years of age):
      - 15 kg - <30 kg: 300 mg/2 mL: MDL 0.08/day (2 mL per 28 days)
      - ≥30 kg: 200 mg/1.14 mL: MDL 0.09/day (2.28 mL per 28 days)
    - Adults and pediatric patients 12 years and older

- For 200 mg/1.14 mL: MDL 0.09/day (2.28 mL per 28 days)
- For 300 mg/2 mL: MDL 0.15/day (4 mL per 28 days)

- Chronic sinusitis with nasal polyps – for 300 mg/2 mL strength only, approve as follows:
  - For 300 mg/2 mL: MDL 0.15/day (4 mL per 28 days)

- Eosinophilic esophagitis –
  - Pediatric (1 year of age and older weighing at least 15 kg):
    - 15 kg - <30 kg: 200 mg/1.14 mL: MDL 0.09/day (2.28 mL per 28 days)
    - 30 kg – <40 kg: 300 mg/2 mL: MDL 0.15/day (4 mL per 28 days)
  - Adults and pediatric patients 12 years of age and ≥40 kg:
    - For 300 mg/2 mL: MDL 0.29/day (8 mL per 28 days)

- Prurigo nodularis –
  - For 300 mg/2 mL: MDL 0.15/day (4 mL per 28 days)

References:

- Aceves SS, Dellon ES, Greenhawt M, et al. Clinical guidance for the use of dupilumab in eosinophilic esophagitis; A yardstick; Ann Allergy Asthma Immunol. 2023 Mar;130(3):371-378. PubMed PMID: 36521784.
- Dupixent® (package insert); Tarrytown, NY; Regeneron Pharmaceuticals, Inc.; 2024.
- Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis. J Am Acad Dermatol 2014; 71:116-32.
- Elmariah S, Kim B, Berger T, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. J Am Acad Dermatol. 2021;84(3):747-60.
- Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from www.ginasthma.org. Accessed December 29, 2022.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: August 2019
Revision: November 2020, January 2022, March 2023, March 2024, April 2024

Prior Authorization Approval Criteria

Emgality (galcanezumab)

Generic name: galcanezumab
Brand name: Emgality
Medication class: Calcitonin gene related peptide receptor (CGRP) antagonist

FDA-approved uses:

- Migraine prophylaxis
- Episodic cluster headache

Usual dose range:

- Migraine prophylaxis
  - 240 mg once as loading dose, then 120 mg subcutaneously once monthly
- Episodic cluster headache
  - 300 mg subcutaneously once monthly

Criteria for use:

Initiation Criteria

Migraine prophylaxis

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond or intolerance to an adequate trial of Aimovig
- Failure to respond or intolerance to an adequate trial of **two** of the following:
  - An anti-epileptic drug (such as divalproex sodium or topiramate)
  - A beta-blocker (such as propranolol extended-release)
  - An antidepressant (such as venlafaxine or a TCA, such as amitriptyline)
  - Botox (PA Required)

Episodic cluster headache

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a neurologist
- Failure to respond or intolerance to an adequate trial of verapamil

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 300 mg once per month

Approval time frames:

- Migraine prophylaxis
  - Initial: 6 months with MDL 0.04/day (1 syringe/pen every 28 days)
    - Loading dose: 1 month with MDL 0.08/day (2 syringes/pens)
  - Renewal: 1 year with MDL 0.04/day (1 syringe/pen every 28 days)
- Episodic cluster headache
  - Initial: 6 months with MDL 0.11/day (3 x 100mg/mL syringes every 28 days)
  - Renewal: 1 year with MDL 0.11/day

References:

- Emgality Prescribing Information; Indianapolis, IN; Eli Lilly and Company: 2021.
- American Headache Society (AHS) Consensus Statement. Update on integrating new migraine treatments into clinical practice. Headache 2021;61(7):1021-1039.
- American Headache Society (AHS) Consensus Statement. The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache 2019;59:1-18.
- Edvinsson L, Haanes K, Warfvinge K, and Krause DN. CGRP as the target of new migraine therapies – successful translation from bench to clinic. Nat Rev Neurol 2018; 14(6):338-350.
- Robbins MS, Starling, AJ, Pringsheim TM, et al. Treatment of cluster headache: the American Headache Society evidence-based guidelines. Headache 2016;56:1093-1106.
- MacGregor EA. Migraine in the Clinic. ACP Ann Intern Med 2013.
- Shamliyan TA, Choi J, Ramakrishnan R, et al. Preventive Pharmacologic Treatments for Episodic Migraine in Adults. J Gen Intern Med 2013; 28(9):1225-1237.
- Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78:1337-1345.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: April 2020
Revision: April 2021, April 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Forteo (teriparatide)

Generic name: teriparatide
Brand name: Forteo
Medication class: Parathyroid hormone receptor agonist

FDA-approved uses:

- Postmenopausal osteoporosis
- Osteoporosis in men
- Osteoporosis due to corticosteroid use

Usual dose range:

- 20 mcg daily

Criteria for use:

Initiation Criteria

Postmenopausal osteoporosis/Osteoporosis in men/Osteoporosis due to corticosteroid use

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Confirmation that the patient has not received a total of 24 months cumulative treatment with any parathyroid hormone therapy (i.e. Forteo, Tymlos, teriparatide)
- Confirmation of one of the following:
  - High risk for fractures defined as one of the following:
    - History of osteoporosis related (i.e., fragility, low trauma) fracture
    - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs)
    - No prior treatment for osteoporosis AND FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
  - Failure to respond, intolerance or contraindication to oral bisphosphonates, such as Fosamax or Actonel

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response
- Confirmation that the patient has not received a lifetime total of 24 months cumulative treatment with any parathyroid hormone therapy (i.e. Forteo, Tymlos, teriparatide)

Additional considerations:

- Maximum daily dose of 20 mcg, which is 1 pen kit (2.4 mL) per 28-days
- Maximum total course of treatment with any parathyroid hormone therapy (Forteo, teriparatide, and/or Tymlos) is 24 months cumulative in a lifetime. Exceptions to exceed 24 months of treatment may be considered if a patient remains at or has returned to having a high risk for fracture.

Approval time frames:

- Initial
  - 24 months with MDL of 0.09/day (2.4 mL per 28 days)
- Renewal
  - Up to 24 months to complete a maximum total of 24 months in a lifetime; with MDL of 0.09/day (2.4 mL per 28 days)
  - Note: only the number of months remaining will be approved to achieve 24 total months in a lifetime

References:

- Forteo Prescribing Information; Indianapolis, IN; Eli Lilly and Company; 2021.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Gilenya (fingolimod)

Generic name: fingolimod
Brand name: Gilenya
Medication class: Spinogosine 1-phosphate receptor modulator

FDA-approved uses:

- Relapsing forms of multiple sclerosis (MS)

Usual dose range:

- Relapsing forms of multiple sclerosis – child ≤ 40kg — 0.25 mg daily
- Relapsing forms of multiple sclerosis – child > 40kg — 0.5 mg once daily
- Relapsing forms of multiple sclerosis – adults — 0.5 mg once daily

Criteria for use:

Initiation Criteria

Relapsing forms of multiple sclerosis:

Children and Adolescents

- FDA indicated diagnosis
- Prescribed by (or in consultation with) a neurologist
- 10 to 17 years of age

Adults

- FDA indicated diagnosis
- Prescribed by (or in consultation with) a neurologist
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial (6 months) of dimethyl fumarate (PA required)

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Contraindications:

- Patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure
- History or presence of Mobitz Type II second-degree or third-degree atrioventricular (AV) block or sick sinus syndrome, unless patient has a functioning pacemaker

- Baseline QTc interval ≥500 msec; Baseline QTc interval ≥450 msec in males and >470 msec in females should not be dosed in a 6 hour observation and should be referred back to neurologist to arrange 24 hour continuous monitoring
- Treatment with Class Ia or Class III anti-arrhythmic drugs

Not approved if:

- Combined with Copaxone, Aubagio, Tecfidera, Tysabri, Rituxan or an interferon product
- Patient has any contraindications

Additional considerations:

- Patient must be observed for 6 hours after the initial dose and all other doses where the patient has not received the medication for two weeks or more.
- Use with caution in individuals with cardiovascular disease

Approval time frames:

- Initial – 6 months with MDL 1/day
- Renewal – 1 year with MDL 1/day

References:

- Gilenya ® [package insert], East Hanover, NJ: Novartis.; 2023.
- Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology 2018; 90(17):777-788.
- Calabresi PA, Radue EW, Goodin D, et al. Safety and efficacy of fingolimod in patients with relapsing-remitting multiple sclerosis (FREEDOMS II): a double-blind, randomised, placebo-controlled, phase 3 trial. Lancet Neurol. 2014;13(6):545-56.
- National Institute for Health and Care Excellence (2014) Multiple sclerosis in adults: management. Clinical Guideline CG186. London: National Institute for Health and Care Excellence.
- Cohen JA, Barkhof F, Comi G, et al. Oral fingolimod or intramuscular interferon for relapsing multiple sclerosis. N Engl J Med. 2010;362(5):402-15.
- Kappos L, Radue EW, O'connor P, et al. A placebo-controlled trial of oral fingolimod in relapsing multiple sclerosis. N Engl J Med. 2010;362(5):387-401.
- Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002; 58(2):169-78.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: November 2014
Revision: November 2015, November 2016, November 2017, November 2018, November 2019, December 2020, January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Gleevec (imatinib mesylate)

Generic name: imatinib mesylate
Brand name: Gleevec
Medication class: Tyrosine kinase inhibitor

FDA-approved uses:

- Eosinophilic leukemia
- Dermatofibrosarcoma protuberans
- Gastrointestinal stromal tumor
- Hypereosinophilic syndrome
- Myelodysplastic syndrome
- Myeloproliferative disorder
- Philadelphia chromosome-positive acute lymphoblastic leukemia
- Philadelphia chromosome-positive chronic myelogenous leukemia
- Systemic mast cell disease

Usual dose range:

- Up to 600 mg once daily or 400 mg twice daily, depending on diagnosis

Criteria for use:

Initiation Criteria

Eosinophilic leukemia
Dermatofibrosarcoma protuberans
Gastrointestinal stromal tumor
Hypereosinophilic syndrome
Myelodysplastic syndrome
Myeloproliferative disorder

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an oncologist

Systemic mast cell disease

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an immunologist or oncologist

Philadelphia chromosome-positive acute lymphoblastic leukemia
Philadelphia chromosome-positive chronic myelogenous leukemia

Pediatrics and Adults

- FDA indicated diagnosis
- 1 year of age or older
- Prescribed by or in consultation with an oncologist

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum total daily dose of 800 mg

Approval time frames:

- Initial – 6 months; MDL 3/day (100 mg) or 2/day (400 mg)
- Renewal – 1 year; MDL 3/day (100 mg) or 2/day (400 mg)

References:

- Gleevec Prescribing Information; East Hanover, NJ; Novartis Pharmaceuticals Corporation; 2022.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Zepatier

(Hepatitis C Virus Non-Preferred Medications)

Non-Preferred Formulary agents: Zepatier

Criteria for use:

Initiation Criteria (PLEASE CHECK BOX or write N/A to confirm that point has been addressed)

- ☐ If new request, must have a contraindication to preferred formulary alternatives (Epclusa, Harvoni) documented on the PA request form or listed here:
  _____
- ☐ Hepatitis C virus (HCV) infection with a confirmed genotype (GT) obtained within the last year:
  - ☐ GT1
  - ☐ GT2
  - ☐ GT3
  - ☐ GT4
  - ☐ GT5
  - ☐ GT6
- ☐ 3 years of age or older for Mavyret; 12 years of age or older for Zepatier
- ☐ Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist or HIV specialist
- ☐ Confirmation that prescriber and patient understand that patients who terminated previous HCV treatment with a direct-acting antiviral (DAA) medication due to nonmedical reasons will not be considered for retreatment
- ☐ Confirmation that the patient does not have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- ☐ Confirmation that patient is willing to adhere to treatment requirements
- Confirmation of one of the following:
  - ☐ No cirrhosis
  - ☐ Compensated cirrhosis
- Confirmation of one of the following:
  - ☐ Treatment-naïve
    - ☐ If no cirrhosis
      - ☐ Mavyret for 8 weeks is preferred for all genotypes
    - ☐ If compensated cirrhosis
      - ☐ GT1a
        - ○ If NS5A RAS present, then Mavyret for 12 weeks is preferred

- If NS5A RAS absent, then Zepatier for 12 weeks is preferred
- GT1b
  - Zepatier for 12 weeks is preferred
- GT2
  - Mavyret for 12 weeks is preferred
- GT3
  - Mavyret for 12 weeks is preferred
- GT4
  - Zepatier for 12 weeks is preferred
- GT5
  - Mavyret for 12 weeks is preferred
- GT6
  - Mavyret for 12 weeks is preferred

- Treatment-experienced
  - If previously failed PEG-IFN/ribavirin and/or Sovaldi and confirmation of one of the following
    - No cirrhosis
      - For GT1, GT2, GT4, GT5 or GT6: Mavyret for 8 weeks is preferred
      - For GT3: Mavyret for 16 weeks is preferred
    - Compensated cirrhosis
      - For GT1, GT2, GT4, GT5 or GT6: Mavyret for 12 weeks is preferred
      - For GT3: Mavyret for 16 weeks is preferred
  - If previously failed Harvoni or Daklinza/PEG-IFN/ribavirin
    - For GT1: Mavyret for 16 weeks is preferred
  - If previously failed Olysio/Sovaldi or Olysio/PEG-IFN/ribavirin or Victrelis/PEG-IFN/ribavirin or Incivek/PEG-IFN/ribavirin
    - For GT1: Mavyret for 12 weeks is preferred

Contraindications:

- Severe hepatic impairment (Child-Pugh C)
- Concomitant use with atazanavir or rifampin

Not approved if:

- Less than 12 months since the last attempt of HCV treatment

- Evidence of medication non-adherence to treatment of concurrent medical diseases (e.g. poorly controlled DM, severe HTN, heart failure, significant CAD, COPD, thyroid disease)
- Concurrent psychiatric illness without strong primary care physician and psychiatric support
- Known hypersensitivity to drugs used to treat HCV

Additional considerations:

- May not be required when there are confirmed major drug-drug interactions that prevent its use and changing current medications is not appropriate
- Treatment-experienced patients with previous failure of a DAA (i.e. Daklinza, Epclusa, Harvoni, Mavyret, Olysio, Sovaldi, Technivie, Viekira Pak, Viekira XR, Vosevi, Zepatier) that do not meet the initiation criteria above will only be considered on a case-by-case basis and must be in accordance with the AASLD/IDSA HCV guidelines
- Treatment of patients with decompensated cirrhosis will be considered on a case-by-case basis and must be in accordance with the AASLD/IDSA HCV guidelines
- Mavyret maximum daily limit (MDL) is 3 tablets per day (or up to 6 pediatric pellet packets per day)
- Zepatier MDL is 1 tablet per day

Approval time frames:

- Up to 16 weeks with MDL 1/day for Zepatier

References:

- Mavyret Prescribing Information. AbbVie Inc.., North Chicago, IL: 2021.
- Zepatier Prescribing Information. Merck & Co., Inc., Whitehouse Station, NJ: 2022.
- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed December 28, 2022.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: September 2017
Revision: May 2018, July 2019, December 2019, December 2020, November 2021, November 2023

Prior Authorization Approval Criteria

Horizant (gabapentin enacarbil)

Generic name: gabapentin enacarbil
Brand name: Horizant
Medication class: Anticonvulsant

FDA-approved uses:

- Postherpetic neuralgia
- Restless legs syndrome

Usual dose range:

- 300 mg – 600 mg once or twice daily

Criteria for use:

Initiation Criteria

Postherpetic neuralgia

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a neurologist
- Failure to respond to an adequate trial of gabapentin (generic Neurontin)
- Failure to respond to an adequate trial of **two** of the following:
  - Pregabalin
  - Lidocaine patch
  - A formulary TCA, such as amitriptyline

Restless legs syndrome

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a neurologist
- Failure to respond or intolerance to an adequate trial of **all** of the following:
  - Gabapentin (generic Neurontin)
  - Pramipexole
  - Pregabalin

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 600 mg twice daily

Approval time frames:

- Initial – 6 months with MDL 2 tablets per day
- Renewal – 1 year with MDL of up to 2 tablets per day

References:

- Horizant Prescribing Information; Atlanta, GA; Arbor Pharmaceuticals, LLC: 2022.
- Lin CS, Lin YC, Lao HC, Chen CC, Interventional treatments for postherpetic neuralgia: a systematic review. Pain Physician 2019; 22:209-228.
- Winkelman JW, Armstrong MJ, Allen RP, et al. Report of the guideline development, dissemination, and implementation subcommittee of the American Academy of Neurology; Practice guideline summary: Treatment of restless legs syndrome in adults. Neurology 2016;87(24):2585-2593.
- Dubinsky RM, Kabbani H, El-Chami Z, Boutwell C, Ali H. Practice Parameter: Treatment of postherpetic neuralgia. An evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology September 28, 2004 vol. 63 no. 6 959-965.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Ingrezza (valbenazine)

Generic name: valbenazine
Brand name: Ingrezza
Medication class: Vesicular Monoamine Transporter 2 (VMAT2) inhibitor

FDA-approved uses:

- Tardive dyskinesia, moderate to severe

Usual dose range:

- 40 mg to 80 mg once daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Tardive dyskinesia

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a neurologist, movement disorder specialist, psychiatrist or provider specializing in psychiatric care
- Confirmation that moderate to severe tardive dyskinesia has been present for at least 3 months
- Documentation of prior use of antipsychotic medications or metoclopramide for at least 3 months if under the age of 60 or 1 month if 60 years of age or older (can also be determined by prescription claim history)
- Failure to respond (or contraindication) to Austedo

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 80 mg per day

Approval time frames:

- Initial: 1 year for all strengths with MDL 1/day
  - First month: one fill for initiation dose pack with MDL 1/day
- Renewal: 1 year for all strengths with MDL 1/day

References:

- Ingrezza Prescribing Information; San Diego, CA; Neurocrine Biosciences, Inc.: 2022.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: June 2023
Revision:

Prior Authorization Approval Criteria

Insulin Infusion Pump

Formulary Products:

- Omnipod Dash Pods (Gen 4)
- Omnipod 5 G6 Intro Kit (Gen 5)
- Omnipod 5 G6 Pods (Gen 5)

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

- Diagnosis of diabetes mellitus
  - If diagnosis of type 2 diabetes mellitus, then documentation of requiring 4 or more insulin injections per day
- Documentation of one of the following:
  - Monitors blood glucose 4 or more times per day
  - Uses a continuous glucose monitor
- Documentation of being educated on the use of insulin infusion pump

Renewal Criteria

- Documentation of positive clinical response

Approval time frames:

Initial and Renewal: based on the product requested

- Omnipod Dash Pods (Gen 4): Approve for 12 months by GPID with MDL 0.34/day (10 per 30 days)
- Omnipod 5 G6 Intro Kit (Gen 5): Approve for 12 months by GPID with max quantity of 1 (1 per 365 days)
- Omnipod 5 G6 Pods (Gen 5): Approve for 12 months by GPID with MDL 0.34/day (10 per 30 days)

References:

- American Diabetes Association. Diabetes Technology: Standards of Care in Diabetes - 2023. Diabetes Care 2024;47(Supplement_1):S126–S144

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: August 2024
Revision:

Prior Authorization Approval Criteria

Jakafi (ruxolitinib)

Generic name: ruxolitinib
Brand name: Jakafi
Medication class: Janus associated kinase (JAK) inhibitor

FDA-approved uses:

- Polycythemia vera
- Intermediate or high-risk myelofibrosis
- Steroid-refractory acute or chronic graft-versus-host disease (GVHD)

Usual dose range:

- 5 mg – 25 mg twice daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Polycythemia vera

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or contraindication) to hydroxyurea

Intermediate or high-risk myelofibrosis

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Confirmation of one of the following:
  - Primary myelofibrosis
  - Post-polycythemia vera myelofibrosis
  - Post-essential thrombocythemia myelofibrosis

Steroid-refractory acute or chronic graft-versus-host disease

Adolescents and adults

- FDA indicated diagnosis
- 12 years of age or older

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 25 mg twice daily

Approval time frames:

- Initial – 6 months with MDL of 2 tablets per day
- Renewal – 1 year with MDL of 2 tablets per day

References:

- Jakafi Prescribing Information; Wilmington, DE; Incyte Corporation: 2023.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: May 2020
Revision: June 2021, June 2022, June 2023

Prior Authorization Approval Criteria

Kalydeco (ivacaftor)

Generic name: ivacaftor
Brand name: Kalydeco
Medication class: Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator

FDA-approved uses:

- Cystic fibrosis with an ivacaftor-responsive mutation in the CFTR gene

Usual dose range:

- 25 mg – 150 mg orally every 12 hours

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Cystic fibrosis with an ivacaftor-responsive mutation in the CFTR gene

Pediatric and Adult

- FDA indicated diagnosis
- 4 months of age or older
- Prescribed by or in consultation with a pulmonologist or cystic fibrosis (CF) specialist
- Documentation that confirms appropriate genetic mutation
- Confirmation that patient is not on concurrent therapy with Orkambi, Symdeko or Trikafta

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 150 mg twice daily

Approval time frames:

- Initial – 6 months with MDL of 2 packets/day or 2 tablets/day
- Renewal – 1 year with MDL of 2 packets/day or 2 tablets/day

References:

- Kalydeco Prescribing Information. Vertex Pharmaceuticals Inc., Boston, MA: 2022.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: March 2020
Revision: March 2021, March 2022, March 2023

Prior Authorization Approval Criteria

Kesimpta (ofatumumab)

Generic name: ofatumumab
Brand name: Kesimpta
Medication class: Anti-CD20 monoclonal antibody

FDA-approved uses:

- Multiple sclerosis, relapsing forms

Usual dose range:

- 20 mg subcutaneously at week 0, 1 and 2, then 20 mg every 4 weeks starting at week 4

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Multiple sclerosis, relapsing forms

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a neurologist
- Confirmation that the patient has clinically isolated syndrome, relapsing-remitting disease or active secondary progressive disease

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 20 mg every 4 weeks (maintenance dosing)

Approval time frames:

- Initial: 11 months starting 3 weeks from today with MDL 0.02/day (0.4 mL per 28 days)
  - Additional approval for first month starting today with MDL 0.05/day (1.2 mL per 28 days)
- Renewal: 1 year with MDL 0.02/day (0.4 mL per 28 days)

References:

- Kesimpta Prescribing Information; East Hanover, NJ; Novartis Pharmaceuticals Corporation: 2022.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: June 2023
Revision:

Prior Authorization Approval Criteria

Kineret (anakinra)

Generic name: anakinra
Brand name: Kineret
Medication class: Interleukin-1 (IL-1) Receptor Antagonist

FDA-approved uses:

- Neonatal-onset multisystem inflammatory disease (NOMID)
- Deficiency of Interleukin-1 Receptor Antagonist (DIRA
- Rheumatoid arthritis

Usual dose range:

- Chronic infantile neurological, cutaneous and articular syndrome / Deficiency of interleukin-1 receptor antagonist
  - 1 to 2 mg/kg subcutaneously once daily
- Rheumatoid arthritis
  - 100 mg subcutaneously once daily

Criteria for use:

Initiation Criteria

Rheumatoid arthritis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond, intolerance, or contraindication to all the following:
  - One oral DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine)
  - Humira or Enbrel
  - Xeljanz (IR/XR)

Neonatal-onset multisystem inflammatory disease (NOMID)

Pediatric and Adult

- FDA indicated diagnosis

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

Pediatric and Adult

- FDA indicated diagnosis

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Approval time frames:

- Rheumatoid arthritis
  - Initial: 6 months with MDL 0.67/day
  - Renewal: 12 months with MDL 0.67/day
- Neonatal-onset multisystem inflammatory disease (NOMID)
  - Initial: 12 months; MDL is weight-based per request
  - Renewal: 12 months; MDL is weight-based per request
- Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
  - Initial: 12 months; MDL is weight-based per request
  - Renewal: 12 months; MDL is weight-based per request

References:

Kineret [Prescribing Information]. SE-112 76 Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); December 2020.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: September 2023
Revision:

Prior Authorization Approval Criteria

Lupron, Lupron Depot, Lupron Depot-Ped (Leuprolide)

Generic name: leuprolide
Brand names: Lupron, Lupron Depot, Lupron Depot-Ped
Medication class: Gonadotropin-releasing hormone (GnRH) agonist

FDA-approved uses:

- Preoperative anemia for patients with uterine leiomyoma
- Central precocious puberty
- Endometriosis
- Palliative treatment of advanced prostate cancer

Usual dose range:

- Central precocious puberty
  - 7.5 mg – 15 mg intramuscularly once monthly (1-month formulation)
  - 11.25 – 30 mg intramuscularly once every 3 months (3-month formulation)
- Preoperative anemia for patients with uterine leiomyoma
  - 3.75 mg intramuscularly once monthly for up to 3 months
  - 11.25 mg intramuscularly once (3-month formulation)
- Endometriosis
  - 3.75 mg intramuscularly once monthly for 6 months
  - 11.25 mg intramuscularly every 3 months (3-month formulation) for 2 doses
- Palliative treatment of advanced prostate cancer
  - 7.5 mg intramuscularly once monthly (1 month formulation)
  - 22.5 mg intramuscularly every 3 months (3-month formulation)
  - 30 mg intramuscularly every 4 months (4-month formulation)
  - 45 mg intramuscularly every 6 months (6-month formulation)

Criteria for use:

Initiation Criteria

Central precocious puberty

Pediatrics

- FDA indicated diagnosis
- 1 year of age or older
- Prescribed by or in consultation with an endocrinologist
- Confirmation that the patient was younger than 9 years of age when the condition started

- Confirmation of <u>one</u> of the following:
  - Baseline luteinizing hormone (LH) level greater than 0.3 mIU/mL
  - Leuprolide-stimulated LH level greater than 8 mIU/mL at 3 hours
  - For female, leuprolide-stimulated estradiol level greater than 5.5 ng/mL at 24 hours
  - For male, leuprolide-stimulated testosterone level greater than 20 ng/mL at 24 hours

Endometriosis

<u>Adults</u>

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an obstetrician/gynecologist
- Previous failure (or contraindication) to all of the following:
  - A non-steroidal anti-inflammatory drug (NSAID)
  - A progestin-containing contraceptive

Preoperative anemia for patients with uterine leiomyoma

<u>Adults</u>

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an obstetrician/gynecologist

Palliative treatment of advanced prostate cancer

<u>Adults</u>

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an oncologist

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

<u>Additional considerations</u>:

- Pediatric dosing is weight-based

<u>Approval time frames</u>:

- Initial – 1 year with MDL based on duration of depot kit
- Renewal – 1 year with MDL based on duration of depot kit

References:

- Lupron Depot Prescribing Information; North Chicago, IL; AbbVie Inc: 2023.
- Lupron Depot-Ped Prescribing Information; North Chicago, IL; AbbVie Inc: 2023.
- Lupron Prescribing Information; Lake Forest, IL; TAP Pharmaceutical Products Inc: 2008.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Nurtec ODT (rimegepant)

Generic name: rimegepant
Brand name: Nurtec ODT
Medication class: Calcitonin gene related peptide receptor (CGRP) antagonist

FDA-approved uses:

- Migraine (acute treatment)
- Migraine prophylaxis

Usual dose range:

- Migraine (acute treatment)
  - 75 mg once as needed, not to exceed 1 dose in a 24-hour period
- Migraine prophylaxis
  - 75 mg once every other day

Criteria for use:

Initiation Criteria

Migraine (acute treatment)

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond to an adequate trial of **two** the following:
  - Eletriptan
  - Rizatriptan
  - Sumatriptan
  - Zolmitriptan

Migraine prophylaxis

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond or intolerance to an adequate trial of **three** of the following:
  - An anti-epileptic drug (such as divalproex sodium or topiramate)
  - A beta-blocker (such as propranolol extended-release)
  - An antidepressant (such as venlafaxine or a TCA, such as amitriptyline)

- Botox (PA Required)
- Aimovig (PA Required)

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 75 mg in a 24-hour period

Approval time frames:

- Initial – 1 year with MDL of 0.5/day (15 tablets per 30 days)
- Renewal – 1 year with MDL of 0.5/day (15 tablets per 30 days)

References:

- Nurtec ODT Prescribing Information; New Haven, CT; Biohaven Pharmaceuticals, Inc; 2023.
- The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache: The Journal of Head and Face Pain. 2019:59; 1-18.
- Edvinsson L, Haanes K, Warfvinge K, and Krause DN. CGRP as the target of new migraine therapies – successful translation from bench to clinic. Nat Rev Neurol 2018; 14(6):338-350.
- Marmura MJ1, Silberstein SD, Schwedt TJ. The acute treatment of migraine in adults: the American headache society evidence assessment of migraine pharmacotherapies. Headache. 2015 Jan;55(1):3-20.
- Shamliyan TA, Choi J, Ramakrishnan R, et al. Preventive Pharmacologic Treatments for Episodic Migraine in Adults. J Gen Intern Med 2013; 28(9):1225-1237.
- Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78:1337-1345.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, December 2023

Prior Authorization Approval Criteria
Opioid-Benzodiazepine Concurrent Use

Medication class: Opioids and Benzodiazepines

Criteria:

Members will not be allowed to have a prescription for an opioid and a benzodiazepine concurrently if exceeding seven (7) days of overlap. This will be allowed if being prescribed by one prescriber.

Exceptions:

- Patient has a diagnosis of active cancer
- Patient is in hospice care
- Patient is receiving palliative care or end-of-life care
- Patient is a resident of a long-term care facility
- Patient has a diagnosis of sickle cell disease
- All other exceptions will be reviewed on a case-by-case basis

Approval time frames:

- One year

References:

- Dowell D, Ragan K, et al. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2022. MMWR Recomm Rep 2022; 71(3):1–95.
- Washington State Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf [Accessed September 15, 2017].
- Ballas SK. Pain Management of Sickle Cell Disease. Hematol Oncol Clin North Am 2005; 19(5):785-802.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: October 2019
Reviewed: December 2022, November 2023

Prior Authorization Approval Criteria
Opioid Morphine Equivalent Dose (MED) Limit

Medication class: Opioids

Usual dose range:

- No prior authorization needed if < 200 MED per day

Criteria for use:

If daily dose ≥ 200 MED, then must have confirmation of one of the following:

- Diagnosis of cancer
- Diagnosis of palliative care
- Diagnosis of sickle cell disease
- Enrolled in hospice

–OR—

- Intent to taper down to < 200 MED

Renewal Criteria:

- Confirmation of approvable diagnosis
- Documentation of effectiveness of therapy
- If previous approval was for a taper, confirmation of attempt to taper dose down to <200 MED

Not approved if:

- No approvable diagnosis
- No attempt to taper down dose
- Concomitant use of opioid antagonist (i.e. Suboxone)

Approval time frames:

- For intent to taper down to < 200 MED
  - Initial – 6 months
  - Renewal – 6 months if requesting more time to taper
- For approved diagnosis or hospice
  - Initial – One year
  - Renewal – One year

References:

- Dowell D, Ragan K, et al. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2022. MMWR Recomm Rep 2022; 71(3):1–95.
- Washington State Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf [Accessed September 15, 2017].
- Ballas SK. Pain Management of Sickle Cell Disease. Hematol Oncol Clin North Am 2005; 19(5):785-802.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2017
Revision: December 2022, November 2023

Prior Authorization Approval Criteria
Opioid Naïve Day Supply Limit

Medication class: Opioids

Criteria:

Members who have not filled a prescription for an opioid within the past *180* days will be identified as "opioid naïve" and will be limited to a seven (7) day supply for the first opioid prescription. This restriction will also limit the number of opioid fills to **three claims within the first 30-day period.**

Exceptions:

Members will be exempt from this limitation if they meet ONE of the following:

- Diagnosis of cancer
- Diagnosis of palliative care
- Diagnosis of sickle cell disease
- Enrolled in hospice
- Patient is NOT opioid naïve (has had opioids in the past 180 days)
- All other exceptions will be reviewed on a case-by-case basis

Approval time frames:

- One year

References:

- Dowell D, Ragan K, et al. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2022. MMWR Recomm Rep 2022; 71(3):1–95.
- Colorado Department of Regulatory Agencies. 2019. Guidelines for the Safe Prescribing and Dispensing of Opioids. [Online]. Accessed from https://www.colorado.gov/pacific/dora/opioid_guidelines

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: May 2019
Reviewed: September 2020, September 2021, January 2022, December 2022, November 2023

Prior Authorization Approval Criteria

Orencia (abatacept)

Generic name: abatacept
Brand name: Orencia
Medication class: Selective T-cell costimulation blocker

FDA-approved uses:

- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis
- Rheumatoid arthritis

Usual dose range:

- Polyarticular juvenile idiopathic arthritis
  - 50 - 125 mg subcutaneously once weekly
- Psoriatic arthritis/Rheumatoid arthritis
  - 125 mg subcutaneously once weekly

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Psoriatic arthritis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond (or intolerance) to all of the following:
  - One oral DMARD (such as methotrexate, leflunomide or sulfasalazine)
  - Humira or Enbrel
  - Otezla (PA required)

Rheumatoid arthritis/Polyarticular juvenile idiopathic arthritis

Pediatric and adult

- FDA indicated diagnosis
- 2 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond (or intolerance) to all of the following:
  - One oral DMARD (such as methotrexate, leflunomide or sulfasalazine)
  - Humira or Enbrel

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Approval time frames:

- Initial – 6 months, MDL 0.15/day (1 pen or syringe/week)
- Renewal – 1 year, MDL 0.15/day (1 pen or syringe/week)

References:

- Orencia Prescribing Information. Bristol-Myers Squibb Company, Princeton, NJ: 2021.
- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res 2021; 73(7):924-939.
- Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Arthritis Rheum 2019; 71:846.
- Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoritatic Arthritis. Arthritis Rheum 2019; 71(1):5-32.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: March 2020
Revision: March 2021, March 2022, May 2023

Prior Authorization Approval Criteria

Orkambi (lumacaftor/ivacaftor)

Generic name: lumacaftor/ivacaftor
Brand name: Orkambi
Medication class: Cystic fibrosis transmembrane conductance regulator (CFTR) corrector/potentiator

FDA-approved uses:

- Cystic fibrosis, homozygous for the F508del mutation of the CFTR gene

Usual dose range:

- 75 mg/94 mg – 400 mg/250 mg orally twice daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Cystic fibrosis

Pediatric and Adult

- FDA indicated diagnosis
- 1 year of age or older
- Prescribed by or in consultation with a pulmonologist or cystic fibrosis (CF) specialist
- Documentation that confirms appropriate genetic mutation
- Confirmation that patient is not on concurrent therapy with Kalydeco, Symdeko or Trikafta

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 400 mg/250 mg twice daily

Approval time frames:

- Initial – 6 months with MDL of 2 packets/day or 4 tablets/day
- Renewal – 1 year with MDL of 2 packets/day or 4 tablets/day

References:

- Orkambi Prescribing Information. Vertex Pharmaceuticals Inc., Boston, MA: 2023.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: March 2020
Revision: March 2021, March 2022, March 2023

Prior Authorization Approval Criteria

Otezla (apremilast)

Generic name: apremilast
Brand name: Otezla
Medication class: PDE4 inhibitor

FDA-approved uses:

- Plaque psoriasis
- Psoriatic arthritis
- Oral ulcers associated with Behçet's syndrome

Usual dose range:

- All FDA-approved diagnoses – 30 mg orally twice daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Plaque psoriasis

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by (or in consultation with) a dermatologist
- Confirmation the patient has **one** of the following:
  - Psoriasis covering 2% of body surface area (BSA)
  - Static Physician Global Assessment (sPGA) score of 2
  - Psoriasis Area and Severity Index (PASI) score of 2 to 9
  - Psoriatic lesions affecting the hands, feet, genital area or face
- Failure to respond to one conventional therapy (such as, methotrexate, calcipotriene, cyclosporine, acitretin, topical corticosteroids, phototherapy ultraviolet light A [PUVA], ultraviolet light B [UVB])

Psoriatic arthritis

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by (or in consultation with) a dermatologist or rheumatologist
- Failure to respond (or contraindication) to one DMARD (such as methotrexate, hydroxychloroquine, leflunomide or sulfasalazine)

Oral ulcers associated with Behçet's syndrome

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by (or in consultation with) a rheumatologist or specialist in oral diseases
- Failure to respond (or contraindication) to an adequate trial of **one** of the following:
  - Triamcinolone dental paste
  - Colchicine
  - Azathioprine

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Avoid concomitant use with strong CYP450 inducers (e.g. rifampin, phenobarbital, carbamazepine, phenytoin)
- Max dose of 1 tablet twice daily

Approval time frames:

- Initial: 1 year with MDL of 2/day
  - If a starter pack is requested, enter additional override as follows:
    - For Two Week Starter Pack: 14 days with MDL 2/day
    - For 28-day Starter Pack: 28 days with MDL 2/day
- Renewal: 1 year with MDL of 2/day

References:

- Otezla® (package insert); Thousand Oaks, CA; Amgen Inc: 2021.
- Menter A, Gelfand JM, Connor C, et al. Joint AAD-NPF guidelines of care for the management of psoriasis with systemic nonbiologic therapies. Journal of the American Academy of Dermatology 2020;82(6):1445-1486.
- Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology 2019;80(4):1029-1072.
- Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis & Rheumatology 2019;71(1):5-32.
- Hatemi G, Christensen R, Bang D, et al. 2018 update of the EULAR recommendations for the management of Behçet's syndrome. Annals of the Rheumatic Diseases 2018;77:808-818.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: August 2019
Revision: November 2020, January 2022, December 2022, June 2023

Prior Authorization Approval Criteria

Ozempic (Semaglutide)

Generic name: Semaglutide
Brand name: Ozempic
Medication class: GLP-1 receptor agonist

FDA-approved uses:

- Type 2 Diabetes Mellitus (adults only)
- Disorder of cardiovascular system; prophylaxis – Type 2 Diabetes Mellitus (adults only)

Usual dose range:

- Indication – adult 0.25mg – 2mg weekly
  - Titration Dosing: 0.25mg weekly for 4 weeks
  - Maintenance Dosing: 0.5mg – 2mg weekly

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Type 2 Diabetes with or without disorder of cardiovascular system prophylaxis:

Adults

- FDA indicated diagnosis

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Contraindications:

- Multiple endocrine neoplasia syndrome type 2 or personal or family history of medullary thyroid carcinoma

Not approved if:

- No FDA diagnosis of Type 2 Diabetes Mellitus
- Use is for weight loss
- Under 18 years of age

Additional considerations:

Adults:

- Maximum dose is 2mg/week

Approval time frames:

Adults

- Initial:
  - 1 year with MDL of 0.11/day (max 3 per 28 days), by GPID

- Renewal
  - 1 year with MDL of 0.11/day (max 3 per 28 days), by GPID

References:

1. Novo Nordisk Inc (per FDA). *Ozempic(R) subcutaneous injection, semaglutide subcutaneous injection,* Plainsboro, NJ, 2023. https://www.novo-pi.com/ozempic.pdf. Accessed May 8, 2024.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: May 2024
Revision:

Prior Authorization Approval Criteria

Reyvow (lasmiditan)

Generic name: lasmiditan
Brand name: Reyvow
Medication class: Serotonin (5-HT) 1F receptor agonist

FDA-approved uses:

- Migraine (acute treatment)

Usual dose range:

- Migraine (acute treatment)
  - 50 – 200 mg once as needed, not to exceed 1 dose in a 24-hour period

Criteria for use:

Initiation Criteria

Migraine (acute treatment)

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond to an adequate trial of **two** the following:
  - Eletriptan
  - Rizatriptan
  - Sumatriptan
  - Zolmitriptan

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 200 mg in a 24-hour period

Approval time frames:

- Initial – 1 year MDL of 0.27/day (8 tablets per 30 days)
- Renewal – 1 year with of 0.27/day (8 tablets per 30 days)

References:

- Reyvow Prescribing Information; Indianapolis, IN; Eli Lilly and Company; 2022.

- The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache: The Journal of Head and Face Pain. 2019:59; 1-18.
- Marmura MJ1, Silberstein SD, Schwedt TJ. The acute treatment of migraine in adults: the American headache society evidence assessment of migraine pharmacotherapies. Headache. 2015 Jan;55(1):3-20.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Rinvoq (upadacitinib)

Generic name: upadacitinib
Brand name: Rinvoq
Medication class: Janus kinase (JAK) inhibitor

FDA-approved uses:

- Ankylosing spondylitis
- Atopic dermatitis, moderate to severe
- Crohn's disease, moderate to severe
- Non-radiographic axial spondyloarthritis
- Psoriatic arthritis
- Rheumatoid arthritis, moderate to severe
- Ulcerative colitis, moderate to severe

Usual dose range:

- Initial
  - 45 mg once daily for 8 to 12 weeks, depending on diagnosis
- Maintenance
  - 15 mg – 30 mg once daily, depending on diagnosis

Criteria for use:

Initiation Criteria

Ankylosing spondylitis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond, intolerance, or contraindication to all the following:
  - An NSAID (such as ibuprofen, naproxen, meloxicam, etc. Please refer to the formulary for all available NSAIDs)
  - Humira or Enbrel
  - Xeljanz (IR/XR)

Atopic dermatitis, moderate to severe

Pediatric and Adult

- FDA indicated diagnosis
- 12 years of age or older

- Prescribed by or in consultation with a dermatologist, allergist, or immunologist
- Failure to respond, intolerance, or contraindication to one of the following:
  - A formulary topical corticosteroid
  - Topical pimecrolimus or tacrolimus

Crohn's disease, moderate to severe

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a gastroenterologist
- Failure to respond, intolerance, or contraindication to all the following:
  - One conventional therapy (such as budesonide, methylprednisolone, azathioprine, mercaptopurine, methotrexate or mesalamine)
  - Humira

Non-radiographic axial spondyloarthritis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond to an NSAID (such as ibuprofen, naproxen, meloxicam, etc. Please refer to the formulary for all available NSAIDs)

Psoriatic arthritis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a dermatologist or rheumatologist
- Failure to respond, intolerance, or contraindication to all the following:
  - One oral DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine)
  - Humira or Enbrel
  - Xeljanz (IR/XR)

Rheumatoid arthritis, moderate to severe

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond, intolerance, or contraindication to all the following:

- One oral DMARD (such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine)
- Humira or Enbrel
- Xeljanz (IR/XR)

Ulcerative colitis, moderate to severe

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a gastroenterologist
- Failure to respond, intolerance, or contraindication to all the following:
  - One conventional therapy (such as budesonide, methylprednisolone, azathioprine, mercaptopurine, methotrexate or mesalamine)
  - Humira
  - Xeljanz (IR/XR)

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Approval time frames:

- Ankylosing spondylitis
  - Initial: Rinvoq 15 mg for 6 months with MDL 1/day
  - Renewal: Rinvoq 15 mg for 12 months with MDL 1/day
- Atopic dermatitis, moderate to severe
  - Initial: Rinvoq 15 mg and Rinvoq 30 mg for 6 months with MDL 1/day
  - Renewal: Rinvoq 15 mg and Rinvoq 30 mg for 12 months with MDL 1/day
- Crohn's disease, moderate to severe
  - Initial: Rinvoq 15 mg and Rinvoq 30 mg for 6 months with MDL 1/day
    - Additional override for Rinvoq 45 mg for 12 weeks starting today with MDL 1/day
  - Renewal: Rinvoq 15 mg and Rinvoq 30 mg for 12 months with MDL 1/day
- Non-radiographic axial spondyloarthritis
  - Initial: Rinvoq 15 mg for 6 months with MDL 1/day
  - Renewal: Rinvoq 15 mg for 12 months with MDL 1/day
- Psoriatic arthritis
  - Initial: Rinvoq 15 mg for 6 months with MDL 1/day
  - Renewal: Rinvoq 15 mg for 12 months with MDL 1/day
- Rheumatoid arthritis, moderate to severe
  - Initial: Rinvoq 15 mg for 6 months with MDL 1/day
  - Renewal: Rinvoq 15 mg for 12 months with MDL 1/day
- Ulcerative colitis, moderate to severe
  - Initial: Rinvoq 15 mg and Rinvoq 30 mg for 6 months with MDL 1/day

- Additional override for Rinvoq 45 mg for 8 weeks starting today with MDL 1/day
- Renewal: Rinvoq 15 mg and Rinvoq 30 mg for 12 months with MDL 1/day

References:

- Rinvoq [Prescribing Information]. North Chicago, IL: AbbVie Inc.; May 2023.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: September 2023
Revision:

Prior Authorization Approval Criteria

Rubraca (rucaparib)

Generic name: rucaparab
Brand name: Rubraca
Medication class: Poly ADP-ribose polymerase (PARP) inhibitor

FDA-approved uses:

- Epithelial ovarian, Fallopian tube or primary peritoneal cancer with deleterious BRCA (germline and/or somatic) after 2 or more previous chemotherapies
- Maintenance therapy for epithelial ovarian, Fallopian tube or primary peritoneal cancer with recurrent disease after complete or partial response to platinum-based chemotherapy
- Metastatic castration resistant prostate cancer

Usual dose range:

- 600 mg twice daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Recurrent epithelial ovarian, Fallopian tube or primary peritoneal cancer

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an oncologist
- Confirmation of a deleterious BRCA mutation (germline and/or somatic)
- Documentation that the patient is in complete or partial response to platinum-based chemotherapy

Metastatic castration resistant prostate cancer

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an oncologist
- Confirmation of a deleterious BRCA mutation (germline and/or somatic) by an FDA-approved diagnostic test for Rubraca
- Documentation of both of the following:
  - Disease progression on androgen-receptor directed therapy
  - Disease progression on a taxane-based chemotherapy regimen
- Documentation of **one** of the following:

- Patient previously had a bilateral orchiectomy
- Patient has a castrate level of testosterone (less than 50 ng/dL)
- Rubraca will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (such as leuprolide, goserelin, histrelin)

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 600 mg twice daily

Approval time frames:

- Initial – 6 months with MDL of 4 tablets per day
- Renewal – 1 year with MDL of 4 tablets per day

References:

- Rubraca Prescribing Information; Boulder, CO; Clovis Oncology, Inc: 2022.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: May 2020
Revision: June 2021, June 2022, June 2023

Prior Authorization Approval Criteria

Rybelsus (Semaglutide)

Generic name: Semaglutide
Brand name: Rybelsus
Medication class: GLP-1 receptor agonist

FDA-approved uses:

- Type 2 Diabetes Mellitus (adults only)

Usual dose range:

- Indication – adult — 3mg – 14mg
  - Titration Dosing: — 3mg daily for 30 days
  - Maintenance Dosing: — 7mg – 14mg daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Type 2 Diabetes:

Adults

- FDA indicated diagnosis

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Contraindications:

- Multiple endocrine neoplasia syndrome type 2 or personal or family history of medullary thyroid carcinoma

Not approved if:

- No FDA diagnosis of Type 2 Diabetes Mellitus
- Use is for weight loss
- Under 18 years of age

Additional considerations:

Adults:

- Maximum dose is 14mg per day

Approval time frames:

Adults

- Initial:
  - 1 year with MDL of 1/day (max 30 for 30), by GPID
- Renewal
  - 1 year with MDL of 1/day (max 30 per 30 days), by GPID

References:

1. Colorado Department of Health Care Policy and Financing. Preferred Drug List (PDL). Department of Health Care Policy and Financing. https://hcpf.colorado.gov/sites/hcpf/files/04-01-24%20PDL%20V3.pdf. April 4, 2024. Accessed May 8, 2024.

2. Novo Nordisk Inc (per FDA). *Rybelsus, semaglutide oral tablet,* Plainsboro, NJ, 2023. https://www.novo-pi.com/rybelsus.pdf. Accessed May 8, 2024.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: May 2024
Revision:

Prior Authorization Approval Criteria

Sensipar (cinacalcet)

Generic name: cinacalcet
Brand name: Sensipar
Medication class: Calcimimetic

FDA-approved uses:

- Primary hyperparathyroidism / Parathyroid Carcinoma
- Secondary hyperparathyroidism

Usual dose range:

- Primary hyperparathyroidism/Parathyroid carcinoma:
  - Up to 90 mg four times daily
- Secondary hyperparathyroidism:
  - Up to 180 mg once daily

Criteria for use:

Initiation Criteria

Primary hyperparathyroidism/Parathyroid carcinoma:

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by endocrinologist or oncologist
- Documentation of hypercalcemia associated with parathyroid carcinoma confirmed by a serum calcium level ≥ 8.4 mg/dL
- Confirmation that patient is not a candidate for parathyroidectomy

Secondary hyperparathyroidism:

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by endocrinologist or nephrologist
- Confirmation that the patient is on dialysis
- Documentation of iPTH > 300 pg/mL and serum calcium ≥ 8.4 mg/dL

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Contraindications:

- Hypersensitivity to any ingredients
- Patients with hypocalcemia

Additional considerations:

- Lowers seizure threshold
- Maximum total daily dose is 360 mg/day

Approval time frames:

- Initial – 6 months with MDL of 4/day
- Renewal – 1 year with MDL of 4/day

References:

- Sensipar Prescribing Information. Amgen Inc. Thousand Oaks, CA: 2022.
- Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO 2017 clinical practice guideline update for the diagnosis, evaluation, prevention, and treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney Int Suppl 2017;7:1-59.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: June 2014
Revision: June 2015, June 2016, June 2017, June 2018, June 2019, September 2020, January 2022, December 2022, November 2023

Prior Authorization Approval Criteria

Simponi (golimumab)

Generic name: golimumab
Brand name: Simponi
Medication class: TNF-inhibitor

FDA-approved uses:

- Ankylosing spondylitis
- Psoriatic arthritis
- Rheumatoid arthritis
- Ulcerative colitis

Usual dose range:

- Ankylosing spondylitis/Psoriatic arthritis/Rheumatoid arthritis
  - 50 mg subcutaneously once a month
- Ulcerative colitis
  - 100 mg subcutaneously once a month
    - Induction: 200 mg at week 0, 100 mg at week 2, then 100 mg every 4 weeks

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Ankylosing spondylitis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond to all of the following:
  - An NSAID (such as ibuprofen, naproxen, meloxicam, etc. Please refer to the formulary for all available NSAIDs)
  - Humira
  - Enbrel

Psoriatic arthritis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a dermatologist or rheumatologist
- Failure to respond to all of the following:

- One oral DMARD (such as methotrexate, leflunomide or sulfasalazine)
- Humira
- Enbrel

Rheumatoid arthritis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond to all of the following:
  - One oral DMARD (such as methotrexate, leflunomide or sulfasalazine)
  - Humira
  - Enbrel

Ulcerative colitis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a gastroenterologist
- Failure to respond to one conventional therapy (such as budesonide, methylprednisolone, azathioprine, mercaptopurine, methotrexate or mesalamine)
- Failure to respond to Humira

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Approval time frames:

- Initial – 6 months; MDL 0.04/day (1 pen or syringe/month)
  – Ulcerative colitis: 1st month; MDL 0.11/day
- Renewal – 1 year; MDL 0.04/day

References:

- Simponi Prescribing Information. Janssen Biotech, Inc., Horsham, PA: 2019.
- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res 2021; 73(7):924-939.
- Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019; 114(3):384-413.
- Ward MM, Deodhar A, Genslar LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheum 2019; 71(10):1599-1613.

- Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoritatic Arthritis. Arthritis Rheum 2019; 71(1):5-32.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: March 2020
Revision: March 2021, March 2022, May 2023

Prior Authorization Approval Criteria

Somatropin

Generic name: somatropin
Brand name: Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Zomacton
Medication class: Pituitary Hormone/ Growth Hormone Modifier

FDA-approved uses:

- Growth hormone deficiency
- Noonan's syndrome
- Prader-Willi syndrome
- Renal function impairment with growth failure
- Short stature disorder, Idiopathic
- Short stature disorder - Turner syndrome
- Short-stature homeobox-containing gene (SHOX) deficiency
- Small for gestational age baby, with no catch-up growth by age 2 to 4 years

Usual dose range:

Adult Dosing

- **Growth hormone deficiency**: weight-based dosing schedule: initial, not more than 0.04 mg/kg/week SUBQ given as a daily divided dose; increase at 4 to 8 week intervals
- **Growth hormone deficiency**: alternative dosing schedule: initial, 0.2 mg/day (range, 0.15 to 0.3 mg/day) SUBQ; increase by 0.1 to 0.2 mg/day every 1 to 2 months according to patient response

Pediatric Dosing

- **Growth hormone deficiency:** 0.15 to 0.3 mg/kg/week SUBQ, divided into equal daily doses given 6 or 7 days/week
- **Noonan's syndrome:** up to 0.462 mg/kg/week SUBQ, divided into equal daily doses
- **Prader-Willi syndrome:** 0.24 mg/kg/week SUBQ, divided into equal daily doses given 6 to 7 days/week
- **Renal function impairment with growth failure:** up to 0.35 mg/kg/week SUBQ, divided into equal daily doses; may continue up to time of renal transplantation
- **Short stature disorder, Idiopathic:** up to 0.47 mg/kg/week SUBQ, divided into equal daily doses given 6 or 7 days/week
- **Short stature disorder - Turner syndrome:** up to 0.47 mg/kg/week SUBQ, divided into equal daily doses given 6 or 7 days/week
- **Short-stature homeobox-containing gene (SHOX) deficiency:** 0.35 mg/kg/week SUBQ, divided into equal daily doses given 6 to 7 days/week

- **Small for gestational age baby, with no catch-up growth by age 2 to 4 years:** up to 0.48 mg/kg/week SUBQ, divided into equal daily doses given 6 or 7 days/week

Criteria for use:

Initiation Criteria

Growth hormone deficiency

[*Important consideration: Acquired growth hormone deficiency with confirmation of known etiology (e.g. brain tumor, pituitary/hypothalamus tumor, radiation therapy, etc.) may not require the following criteria to be met*]

Adult

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Confirmed panhypopituitarism (deficiencies of TSH, ACTH, and gonadotropins), pituitary or hypothalamic disease by documentation of one of the following:
  - Subnormal serum IGF-1 concentration based on age and sex

-OR-

  - Subnormal serum growth hormone response to potent stimuli
    - Preferred: Insulin tolerance test (ITT) (Peak GH≤5.0 µg/L)
    - GHRH + arginine (ARG) or the glucagon test
      - Peak GH ≤ 11.0 µg/L in patients with BMI < 25 kg/m2
      - Peak GH ≤ 8.0 µg/L in patients with BMI> 25 and < 30 kg/m2
      - Peak GH ≤ 4.0 µg/L in patients with BMI ≥ 30 kg/m2

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Signs of growth deficiency by confirmation of ≤10th percentile per pediatric growth chart
- Documentation of the following:
  - Failure of two standard growth hormone stimulation tests (with arginine, clonidine, glucagon, insulin, levodopa, or propranolol)
    - Failure defined as a peak measured GH level of less than 10 ng/ml after stimulation

-OR-

  - Documentation of both of the following:
    - Decrease in one of the following lab values:
      - Insulin-like growth factor-1 (IGF-I)
      - Insulin-like growth factor binding protein-3 (IGFBP-3)
      - Bone age

- Failure of one standard growth hormone stimulation test

Noonan's syndrome

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Prader-Willi syndrome

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Renal function impairment with growth failure

Pediatric

- FDA indicated diagnosis
- Prescribed by (or under the care of) a nephrologist
- Confirmation that patient is pre-transplant
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Short stature disorder, Idiopathic

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender
- Predicted height is <63 inches for male
- Predicted height is <59 inches for female
- Documentation of epiphyses not closed (X-ray)

Short stature disorder - Turner syndrome

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Short-stature homeobox-containing gene (SHOX) deficiency:

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Confirmed by genetic testing
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Small for gestational age baby, with no catch-up growth by age 2 to 4 years

Pediatric

- FDA indicated diagnosis
- Prescribed by an endocrinologist
- Height before initiation of therapy must be greater than 2 standard deviations below normal mean for age and gender

Renewal Criteria

Adult (only for the diagnosis of growth hormone deficiency)

- Improvement of IGF-1 levels to determine dose, waist/hip ratios, thyroid function tests, lipids, body weight
  - Therapy should be discontinued when:
    - Patient has reached satisfactory adult height
    - When the patient ceases to respond
  - Adults may require life-long therapy as determined by a GH ≤ 3 ng/ml after a year of therapy

Pediatric (for all FDA-approved indications)

- Documentation of improved growth velocity
  - Therapy should be discontinued when the patient ceases to respond
  - Growth of 5 cm/year or more is expected, if growth rate does not exceed 2.5 cm in a 6-month period, dose adjustments should be considered for an additional 6 months; if there is still no satisfactory response, discontinuation of therapy should be considered

Contraindications:

- Acute critical illness
- Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment, there have been reports of sudden death
  - Use may be appropriate if severe respiratory impairment is being treated
- Active proliferative or severe non-proliferative diabetic retinopathy
- Children with closed epiphyses (X-ray)
- Known hypersensitivity to somatropin or m-cresol
- Pregnancy/Breast feeding

Additional considerations:

- If patient meets the above "Initiation Criteria" for somatropin therapy for any diagnosis, the plan will only approve a preferred product. Other products may be considered if the patient has tried and failed, has intolerance, or has documented medical rationale to support why they are unable to use the plan-preferred product
- For pediatric growth hormone deficiency: once a maintenance dose has been reached, monitoring should be done every 6-12 months on IGF-1; thyroid lab values only need to be monitored for the first 6-12 months of therapy to ensure they remain within normal limits
- Bone age may be advanced in cases of concomitant precocious puberty, thus it would not be expected to be low as stated in the above initiation criteria for pediatric growth hormone deficiency
- Caution when using in the presence of active malignancy

Approval time frames:

- Initial – 6 months; MDL is weight-based per request
- Renewal – 6 months; MDL is weight-based per request

References:.

- Genotropin Prescribing Information. Pharmacia & Upjohn Company. New York, NY: 2020.
- Humatrope Prescribing Information. Eli Lilly and Company. Indianapolis, IN: 2021.
- Norditropin Prescribing Information. Novo Nordisk. Princeton, NJ: 2020.
- Nutropin Prescribing Information. Genentech, Inc. South San Francisco, CA: 2021.
- Omnitrope Prescribing Information. Sandoz Inc. Princeton, NJ: 2019.
- Zomacton Prescribing Information. Ferring Pharmaceuticals Inc. Parsippany, NJ: 2021.
- Yuen KCJ, Biller BMK, Radovick S, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Growth Hormone Deficiency in Adults and Patients Transitioning from Pediatric to Adult Care. *Endocr Pract*. 2019;25(11):1191-1232.
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Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:

Initial: November 2013
Revision: November 2014, November 2015, November 2016, November 2017, November 2018, November 2019, December 2020, January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Stelara (ustekinumab)

Generic name: ustekinumab
Brand name: Stelara
Medication class: Interleukin-12/interleukin-23 inhibitor

FDA-approved uses:

- Crohn's disease, moderate to severe
- Plaque psoriasis, moderate to severe
- Psoriatic arthritis, moderate to severe
- Ulcerative colitis, moderate to severe

Usual dose range:

- Crohn's disease
  - 90 mg subcutaneously every 8 weeks (start 8 weeks after IV induction dose)
- Plaque psoriasis
  - 0.75 mg/kg – 90 mg subcutaneously at weeks 0, 4 and then every 12 weeks
- Psoriatic arthritis
  - 45 mg – 90 mg subcutaneously at weeks 0, 4 and then every 12 weeks
- Ulcerative colitis
  - 90 mg subcutaneously every 8 weeks (start 8 weeks after IV induction dose)

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Crohn's disease

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a gastroenterologist
- Failure to respond to one conventional therapy (such as budesonide, methylprednisolone, azathioprine, mercaptopurine, methotrexate or mesalamine)

Plaque psoriasis

Pediatric and Adult

- FDA indicated diagnosis
- 6 years of age or older
- Prescribed by or in consultation with a dermatologist
- Documentation that patient has one of the following:

- Psoriasis covering 3% or more of body surface area (BSA)
- Psoriatic lesions affecting the hands, feet, genital area or face

- Failure to respond to one conventional therapy (such as, methotrexate, calcipotriene, cyclosporine, acitretin, topical corticosteroids, phototherapy ultraviolet light A [PUVA], ultraviolet light B [UVB])

Psoriatic arthritis

Pediatric and Adult

- FDA indicated diagnosis
- 6 years of age or older
- Prescribed by or in consultation with a rheumatologist or dermatologist
- Failure to respond (or contraindication) to one DMARD (such as methotrexate, hydroxychloroquine, leflunomide or sulfasalazine)

Ulcerative colitis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a gastroenterologist
- Failure to respond to one conventional therapy (such as budesonide, methylprednisolone, azathioprine, mercaptopurine, methotrexate or mesalamine)

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 90 mg every 8 weeks (maintenance dosing)

Approval time frames:

- Crohn's disease/Ulcerative colitis
  - Initial: 6 months with MDL 0.02/day (1 mL per 56 days)
  - Renewal: 1 year with MDL 0.02/day (1 mL per 56 days)
- Plaque psoriasis/Psoriatic arthritis
  - Initial: 5 months starting in 3 weeks with MDL 0.012/day (1 mL per 84 days)
    - Additional override for 1 month starting today with MDL 0.04/day (1 mL per 28 days)
  - Renewal: 1 year with MDL 0.012/day (1 mL per 84 days)

References:

- Stelara Prescribing Information; Horsham, PA; Janssen Biotech, Inc.: 2022.
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Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: May 2020
Revision: June 2021, June 2022, June 2023

Prior Authorization Approval Criteria

Synagis (palivizumab)

Generic name: palivizumab
Brand name: Synagis
Medication class: Monoclonal antibody

FDA-approved uses:

- Prophylaxis of respiratory syncytial virus (RSV) infection

Usual dose range:

- 15 mg/kg intramuscularly once monthly for maximum of 5 doses

Criteria for use:

Initiation Criteria

Prophylaxis of respiratory syncytial virus (RSV) infection

Infant in the first year of life, must have confirmation of one of the following:

- Born before 29 weeks 0 days gestation
- Born before 32 weeks 0 days AND with chronic lung disease (CLD) of prematurity AND requirements of >21% oxygen for at least 28 days after birth
- Hemodynamically significant heart disease (acyanotic heart disease who are receiving medication to control congestive heart failure (CHF) and will require cardiac surgical procedures or infants with moderate to severe pulmonary hypertension) AND born within 12 months of onset of the RSV season
- Cardiac transplantation during the RSV season
- Cyanotic heart defects AND in consultation with a pediatric cardiologist
- Neuromuscular disease or pulmonary abnormality AND is unable to clear secretions from the upper airways
- Profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy)
- Cystic fibrosis with clinical evidence of CLD AND/OR nutritional compromise

Child in the second year of life, must have confirmation of one of the following:

- Born before 32 weeks 0 days AND with CLD of prematurity AND requirements of >21% oxygen for at least 28 days after birth AND continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy)
- Profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy)
- Manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities of chest radiography or chest computed tomography that persist when stable) OR weight for length less than the 10th percentile
- Cardiac transplantation during the RSV season

Renewal Criteria

- Follow initiation criteria by age of child

Additional considerations:

- Maximum monthly dose is 15 mg/kg based on current weight
- Patients do not need treatment past the RSV season, therefore, some patients will not require all 5 doses if treatment was started mid-season.

Approval time frames:

- Initial
  - 1 dose monthly within the RSV season of August through April; maximum of 5 doses per RSV season
- Renewal
  - 1 dose monthly within the RSV season of August through April; maximum of 5 doses per RSV season

References:

- Synagis Prescribing Information; Gaithersburg, MD; MedImmune, LLC: 2021.
- American Academy of Pediatrics, Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infections. Pediatrics 2014:134:415-420.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, October 2023

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Prior Authorization Approval Criteria

Tasigna (nilotinib)

Generic name: nilotinib
Brand name: Tasigna
Medication class: Tyrosine kinase inhibitor

FDA-approved uses:

- Philadelphia chromosome-positive chronic myelogenous leukemia

Usual dose range:

- Up to 400 mg twice daily

Criteria for use:

Initiation Criteria

Philadelphia chromosome-positive chronic myelogenous leukemia

Pediatrics and Adults

- FDA indicated diagnosis
- 1 year of age and older
- Prescribed by or in consultation with an oncologist
- Previous failure or intolerance to imatinib

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum total daily dose of 800 mg

Approval time frames:

- Initial – 6 months with MDL 4/day
- Renewal – 1 year with MDL 4/day

References:

- Tasigna Prescribing Information; East Hanover, NJ; Novartis Pharmaceuticals Corporation; 2021.
- Gleevec Prescribing Information; East Hanover, NJ; Novartis Pharmaceuticals Corporation; 2022.
- National Comprehensive Cancer Network. Chronic Myeloid Leukemia 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf [Accessed December 13, 2023].

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Tecfidera (dimethyl fumerate)

Generic name: dimethyl fumerate
Brand name: Tecfidera
Medication class: immunomodulator

FDA-approved uses:

- Relapsing forms of multiple sclerosis (MS)

Usual dose range:

- Relapsing forms of multiple sclerosis – adults 240 mg twice daily

Criteria for use:

Initiation Criteria

Relapsing forms of multiple sclerosis:

Adults

- FDA indicated diagnosis
- Prescribed by (or in consultation with) a neurologist
- 18 years of age or older

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Not approved if:

- Combined with Copaxone, Aubagio, Gilenya, Tysabri, Rituxan or an interferon product

Additional considerations:

- Tecfidera has not been studied in patients with low lymphocyte counts
- Recommended titration schedule is 120 mg twice daily for 7 days, then 240 mg twice daily
    - Slower titration or premedication with nonenteric-coated aspirin (up to 325 mg 30 minutes prior to dose) may reduce the incidence of flushing

Approval time frames:

- Initial – 6 months with MDL 2/day
- Renewal – 1 year with MDL 2/day

References:

- Tecfidera ® [package insert], Cambridge, MA: Biogen Idec Inc.; 2023.
- Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology 2018; 90(17):777-788.
- National Institute for Health and Care Excellence (2014) Multiple sclerosis in adults: management. Clinical Guideline CG186. London: National Institute for Health and Care Excellence.
- Havrdova E, Hutchinson M, Kurukulasuriya NC, et al. Oral BG-12 (dimethyl fumarate) for relapsing-remitting multiple sclerosis: a review of DEFINE and CONFIRM. Evaluation of: Gold R, Kappos L, Arnold D, et al. Placebo-controlled phase 3 study of oral BG-12 for relapsing multiple sclerosis. N Engl J Med 2012;367:1098-107; and Fox RJ, Miller DH, Phillips JT, et al. Placebo-controlled phase 3 study of oral BG-12 or glatiramer in multiple sclerosis. N Engl J Med 2012;367:1087-97. Expert Opin Pharmacother. 2013;14(15):2145-56.
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- Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002;58(2):169-78.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: November 2014
Revision: November 2015, November 2016, November 2017, November 2018, November 2019, December 2020, January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Tobi Podhaler (tobramycin inhalation powder)

Generic name: tobramycin inhalation powder
Brand name: Tobi Podhaler
Medication class: Aminoglycoside antibiotic

FDA-approved uses:

- Cystic fibrosis with infection due to pseudomonas aeruginosa

Usual dose range:

- 112 mg (4 capsules) inhaled twice daily (28 days on, 28 days off)

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Cystic fibrosis with infection due to pseudomonas aeruginosa

Pediatric and Adult

- FDA indicated diagnosis
- 6 years of age or older
- Prescribed by or in consultation with a pulmonologist or cystic fibrosis (CF) specialist
- Documentation that the patient has infection due to pseudomonas aeruginosa by submission of a copy of the lab report
- Failure to respond (or intolerance) to tobramycin inhalation solution

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 112 mg twice daily

Approval time frames:

- Initial – 1 year with MDL of 8 capsules/day
- Renewal – 1 year with MDL of 8 capsules/day

References:

- Tobi Podhaler Prescribing Information. Novartis Pharmaceuticals Corporation, East Hanover, NJ: 2023.
- Mogayzel PJ, Naureckas ET, Robinson KA, et al and the Cystic Fibrosis Foundation Pulmonary Clinical Practice Guidelines Committee. Cystic Fibrosis Foundation pulmonary guideline. Pharmacologic approaches to prevention and eradication of initial Pseudomonas aeruginosa infection. Ann Am Thorac Soc. 2014; 11(10):1640-50.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: March 2020
Revision: March 2021, March 2022, March 2023

Prior Authorization Approval Criteria

Tolvaptan

Generic name: tolvaptan
Brand name: Jynarque, Samsca
Medication class: Vasopressin antagonist

FDA-approved uses:

- Autosomal dominant polycystic kidney disease
- Hypervolemic or euvolemic hyponatremia

Usual dose range:

- Autosomal dominant polycystic kidney disease
  - 45 mg – 90 mg upon waking and 15 mg – 30 mg 8 hours later
- Hypervolemic or euvolemic hyponatremia
  - 15 mg – 60 mg once daily for up to 30 days

Criteria for use:

Initiation Criteria

Autosomal dominant polycystic kidney disease (ADPKD)

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a nephrologist
- Confirmation that the patient does not have end-stage renal disease (ESRD)
- Confirmation that patient has polycystic kidney status via CT or MRI and **one** of the following:
  - Patient has a genotype causative of ADPKD
  - Patient has family history of confirmed polycystic kidney disease in one or both parents
  - Patient has evidence of 3 or more cysts in both kidneys
  - Patient has evidence of cysts present in the kidneys and the liver
- Physician attestation that the patient is at high risk of rapid progression of disease

Hypervolemic or euvolemic hyponatremia

Adults

- FDA indicated diagnosis

- 18 years of age or older
- Prescribed by or in consultation with a nephrologist
- Confirmation of all of the following:
  - Treatment on this medication was initiated in the hospital
  - No more than a 30 day course is being requested
  - There has been at least a 30 day lapse since the last course of therapy on this medication

Renewal Criteria

- **ADPKD**
  - Physician attestation that patient has not progressed to ESRD

- **Hypervolemic or euvolemic hyponatremia**
  - Follow initiation criteria

Additional considerations:

- Risk factors for rapid progression of ADPKD may include one or more of the following: PKD1 genotype, hypertension, early onset of symptoms including proteinuria and hematuria, male gender, increased kidney size, increased left ventricular mass index, dipstick detectable proteinuria, low birth weight, decreased renal blood flow, increased urinary sodium excretion, increased low-density lipoprotein (LDL) cholesterol, increased plasma copeptin, higher serum uric acid levels, high concentration of fibroblast growth factor (FGF)

Approval time frames:

ADPKD

- Initial – 6 months with MDL 2/day
- Renewal – 6 months with MDL 2/day

Hypervolemic or euvolemic hyponatremia

- Initial – 1 month with MDL 2/day
- Renewal – 1 month with MDL 2/day

References:

- Jynarque Prescribing Information; Rockville, MD; Otsuka America Pharmaceutical, Inc; 2022.
- Samsca Prescribing Information; Rockville, MD; Otsuka America Pharmaceutical, Inc; 2022.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, December 2023

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Prior Authorization Approval Criteria
Trikafta (elexacaftor/tezacaftor/ivacaftor)

Generic name: elexacaftor/tezacaftor/ivacaftor
Brand name: Trikafta
Medication class: Cystic fibrosis transmembrane conductance regulator (CFTR) corrector/potentiator

FDA-approved uses:
- Cystic fibrosis with at least one F508del mutation in the CTFR gene

Usual dose range:
- 2 tablets of (elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg) in the morning and 1 tablet of ivacaftor 75 mg in the evening OR 2 tablets of (elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg) in the morning and 1 tablet of ivacaftor 150 mg in the evening

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Cystic fibrosis with at least one F508del mutation in the CTFR gene

Pediatric and Adult
- FDA indicated diagnosis
- 6 years of age or older
- Prescribed by or in consultation with a pulmonologist or cystic fibrosis (CF) specialist
- Documentation that confirms appropriate genetic mutation
- Confirmation that patient is not on concurrent therapy with Kalydeco, Symdeko or Orkambi

Renewal Criteria
- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:
- Maximum of 3 tablets per day

Approval time frames:
- Initial – 6 months with MDL of 3 tablets per day
- Renewal – 1 year with MDL of 3 tablets per day

References:

- Trikafta Prescribing Information. Vertex Pharmaceuticals Inc., Boston, MA: 2023.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: March 2020
Revision: March 2021, March 2022, March 2023

Prior Authorization Approval Criteria

Trulicity (dulaglutide)

Generic name: Dulaglutide
Brand name: Trulicity
Medication class: GLP-1 receptor agonist

FDA-approved uses:

- Type 2 Diabetes Mellitus (adults and pediatrics)
- Disorder of cardiovascular system; prophylaxis – Type 2 Diabetes Mellitus (adults only)

Usual dose range:

- Indication – adult 0.75mg – 4.5mg weekly
- Indication – pediatric (10 years and older) 0.75mg – 1.5mg weekly

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Type 2 Diabetes:

Adults

- FDA indicated diagnosis

Pediatrics (10 years and older)

- FDA indicated diagnosis

Disorder of cardiovascular system; prophylaxis – Type 2 Diabetes Mellitus:

Adults

- FDA indicated diagnosis

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Contraindications:

- Multiple endocrine neoplasia syndrome type 2 or personal or family history of medullary thyroid carcinoma

Not approved if:

- No FDA diagnosis of Type 2 Diabetes Mellitus
- Use is for weight loss
- Under 10 years of age

Additional considerations:

Adults:

- Maximum weekly dose is 4.5mg/week

Pediatrics (10 years and older)

- Maximum weekly dose is 1.5mg/week

Approval time frames:

Adults

- Initial:
  - 1 year with MDL of 0.08/day for all the following strengths by GPID: 0.75mg/0.5mL, 1.5mg/0.5mL, 3mg/0.5mL, and 4.5mg/0.5mL
- Renewal
  - 1 year with MDL of 0.08/day for all the following strengths by GPID: 0.75mg/0.5mL, 1.5mg/0.5mL, 3mg/0.5mL, and 4.5mg/0.5mL

Pediatrics (10 years and older)

- Initial
  - 1 year with MDL of 0.08/day for the following strengths by GPID: 0.75mg/0.5mL, 1.5mg/0.5mL
- Renewal
  - 1 year with MDL of 0.08/day for the following strengths by GPID: 0.75mg/0.5mL, 1.5mg/0.5mL

References:

1. Product Information: TRULICITY(R) subcutaneous injection, dulaglutide subcutaneous injection. Eli Lilly and Company (per FDA), Indianapolis, IN, 2022.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 4/25/2024
Revision:

Prior Authorization Approval Criteria

Tymlos (abaloparatide)

Generic name: abaloparatide
Brand name: Tymlos
Medication class: Parathyroid hormone receptor agonist

FDA-approved uses:

- Postmenopausal osteoporosis
- Osteoporosis in men

Usual dose range:

- 80 mcg daily

Criteria for use:

Initiation Criteria

Postmenopausal osteoporosis/Osteoporosis in men

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond or intolerance to Forteo (PA required)
- Confirmation that the patient has not received a total of 24 months cumulative treatment with any parathyroid hormone therapy (i.e. Forteo, Tymlos, teriparatide)
- Confirmation of one of the following:
  - High risk for fractures defined as one of the following:
    - History of osteoporosis related (i.e., fragility, low trauma) fracture
    - 2 or more risk factors for fracture (e.g., history of multiple recent low trauma fractures, BMD T-score less than or equal to -2.5, corticosteroid use, or use of GnRH analogs)
    - No prior treatment for osteoporosis AND FRAX score ≥ 20% for any major fracture OR ≥ 3% for hip fracture
  - Failure to respond, intolerance or contraindication to oral bisphosphonates, such as Fosamax or Actonel

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response
- Confirmation that the patient has not received a total of 24 months cumulative treatment with any parathyroid hormone therapy (i.e. Forteo, Tymlos, teriparatide)

Additional considerations:

- Maximum daily dose of 80 mcg, which is 1 pen kit (1.56 mL) per 30 days
- Maximum total course of treatment with any parathyroid hormone therapy (Forteo, teriparatide, and/or Tymlos) is 24 months cumulative in a lifetime. Exceptions to exceed 24 months of treatment may be considered if a patient remains at or has returned to having a high risk for fracture.

Approval time frames:

- Initial
  - 24 months with MDL of 0.06/day (1.56 mL per 30 days)
- Renewal
  - Up to 24 months to complete a maximum total of 24 months in a lifetime; with MDL of 0.06/day (1.56 mL per 30 days)
  - Note: only the number of months remaining will be approved to achieve 24 total months in a lifetime

References:

- Tymlos Prescribing Information; Waltham, MA; Radius Health, Inc; 2023.
- Forteo Prescribing Information; Indianapolis, IN; Eli Lilly and Company; 2021.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Ubrelvy (ubrogepant)

Generic name: ubrogepant
Brand name: Ubrelvy
Medication class: Calcitonin gene related peptide receptor (CGRP) antagonist

FDA-approved uses:

- Migraine (acute treatment)

Usual dose range:

- Migraine (acute treatment)
  - 50 mg – 100 mg once; if needed, a second dose may be taken 2 hours after the first dose; not to exceed 200 mg in a 24-hour period

Criteria for use:

Initiation Criteria

Migraine (acute treatment)

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond to an adequate trial of **two** the following:
  - Eletriptan
  - Rizatriptan
  - Sumatriptan
  - Zolmitriptan

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum of 200 mg total in a 24-hour period

Approval time frames:

- Initial – 1 year with MDL of 0.54/day (16 tablets per 30 days)
- Renewal – 1 year with MDL of 0.54/day (16 tablets per 30 days)

References:

- Ubrelvy Prescribing Information; Madison, NJ; Allergan, Inc; 2023.

- The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. Headache: The Journal of Head and Face Pain. 2019:59; 1-18.
- Marmura MJ1, Silberstein SD, Schwedt TJ. The acute treatment of migraine in adults: the American headache society evidence assessment of migraine pharmacotherapies. Headache. 2015 Jan;55(1):3-20.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, December 2023

Prior Authorization Approval Criteria

Valchlor (mechlorethamine)

Generic name: mechlorethamine
Brand name: Valchlor
Medication class: Alkylating agent

FDA-approved uses:

- Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy

Usual dose range:

- Apply a thin film to affected area once daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an oncologist
- Failure to respond or intolerance to an adequate trial of one of the following skin-directed therapies:
  - Topical corticosteroids
  - Topical retinoids
  - Carmustine
  - Imiquimod
  - Local radiation therapy

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Approval time frames:

- Initial – 6 months with MDL in multiples of 60 g tube
- Renewal – 6 months with MDL in multiples of 60 g tube

References:

- Valchlor Prescribing Information; Iselin, NJ; Helsinn Therapeutics US, Inc: 2020.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: May 2020
Revision: June 2021, May 2022, June 2023

Prior Authorization Approval Criteria

Victoza (Liraglutide)

Generic name: Liraglutide
Brand name: Victoza
Medication class: GLP-1 receptor agonist

FDA-approved uses:

- Type 2 Diabetes Mellitus (adults and pediatrics)
- Disorder of cardiovascular system; prophylaxis – Type 2 Diabetes Mellitus (adults only)

Usual dose range:

- Indication – adult 0.6mg – 1.8mg daily
- Indication – pediatric (10 years and older) 0.6mg – 1.8mg daily

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Type 2 Diabetes:

Adults

- FDA indicated diagnosis

Pediatrics (10 years and older)

- FDA indicated diagnosis

Disorder of cardiovascular system; prophylaxis – Type 2 Diabetes Mellitus:

Adults

- FDA indicated diagnosis

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Contraindications:

- Multiple endocrine neoplasia syndrome type 2 or personal or family history of medullary thyroid carcinoma

Not approved if:

- No FDA diagnosis of Type 2 Diabetes Mellitus
- Use is for weight loss
- Under 10 years of age

Additional considerations:

Adults:

- Maximum daily dose is 1.8mg/day

Pediatrics (10 years and older)

- Maximum daily dose is 1.8mg/day

Approval time frames:

Adults

- Initial:
  - 1 year with MDL of 0.3/day (max 9 per 30 days), by GPID
- Renewal
  - 1 year with MDL of 0.3/day (max 9 per 30 days), by GPID

Pediatrics (10 years and older)

- Initial
  - 1 year with MDL of 0.3/day (max 9 per 30 days), by GPID
- Renewal
  - 1 year with MDL of 0.3/day (max 9 per 30 days), by GPID

References:

1. Product Information: VICTOZA(R) subcutaneous injection, liraglutide subcutaneous injection. Novo Nordisk Inc (per FDA), Plainsboro, NJ, 2023.

Prior Authorization Approval Criteria

Xeljanz and Xeljanz XR (tofacitinib)

Generic name: tofacitinib and tofacitinib extended-release
Brand name: Xeljanz and Xeljanz XR
Medication class: Janus kinase inhibitor

FDA-approved uses:

- Ankylosing spondylitis
- Polyarticular course juvenile idiopathic arthritis
- Psoriatic arthritis
- Rheumatoid arthritis, moderate to severe
- Ulcerative colitis, moderate to severe

Usual dose range:

- Ankylosing spondylitis/Psoriatic arthritis/Rheumatoid arthritis, moderate to severe
  - Xeljanz: 5 mg twice daily
  - Xeljanz XR: 11 mg daily
- Polyarticular course juvenile idiopathic arthritis
  - 3.2 mg to 5 mg twice daily depending on weight in kg
- Ulcerative colitis, moderate to severe
  - Xeljanz: 10 mg twice daily for 8 to 16 weeks, then 5 mg twice daily thereafter
  - Xeljanz XR: 22 mg daily for 8 to 16 weeks, then 11 mg daily thereafter

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Ankylosing spondylitis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond to an NSAID (such as ibuprofen, naproxen, meloxicam, etc. Please refer to the formulary for all available NSAIDs)
- Failure to respond (or intolerance) to Humira or Enbrel

Polyarticular course juvenile idiopathic arthritis

Pediatric and Adult

- FDA indicated diagnosis
- 2 years of age or older
- Prescribed by or in consultation with a rheumatologist

- Failure to respond (or contraindication) to one oral DMARD (such as methotrexate, leflunomide, hydroxychloroquine or sulfasalazine)
- Failure to respond (or intolerance) to Humira or Enbrel

Psoriatic arthritis

Pediatric and Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a dermatologist or rheumatologist
- Failure to respond (or contraindication) to one oral DMARD (such as methotrexate, leflunomide, hydroxychloroquine or sulfasalazine)
- Failure to respond (or intolerance) to Humira or Enbrel

Rheumatoid arthritis, moderate to severe

Pediatric and Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- Failure to respond to one oral DMARD (such as methotrexate, leflunomide, hydroxychloroquine or sulfasalazine)
- Failure to respond (or intolerance) to Humira or Enbrel

Ulcerative colitis, moderate to severe

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a gastroenterologist
- Failure to respond to one conventional therapy (such as budesonide, methylprednisolone, azathioprine, mercaptopurine, methotrexate or mesalamine)
- Failure to respond (or intolerance) to Humira

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of Xeljanz oral solution: 5 mg (5 mL) twice daily
- Maximum dose of Xeljanz: 10 mg twice daily
- Maximum dose of Xeljanz XR: 22 mg daily

Approval time frames:

- Ankylosing spondylitis/Psoriatic arthritis/Rheumatoid arthritis, moderate to severe
  - Initial:
    - Xeljanz 5mg: 6 months with MDL 2/day
    - Xeljanz XR 11 mg: 6 months with MDL 1/day
  - Renewal:
    - Xeljanz 5mg: 1 year with MDL 2/day
    - Xeljanz XR 11 mg: 1 year with MDL 1/day
- Polyarticular course juvenile idiopathic arthritis
  - Initial:
    - Xeljanz 5mg: 6 months with MDL 2/day
    - Xeljanz oral solution: 6 months with MDL 10/day
  - Renewal:
    - Xeljanz 5mg: 1 year with MDL 2/day
    - Xeljanz oral solution: 1 year with MDL 10/day
- Ulcerative colitis, moderate to severe
  - Initial:
    - Xeljanz 5 mg and 10 mg: 6 months with MDL 2/day
    - Xeljanz XR 11 mg and 22 mg: 6 months with MDL 1/day
  - Renewal:
    - Xeljanz 5 mg and 10 mg: 1 year with MDL 2/day
    - Xeljanz XR 11 mg and 22 mg: 1 year with MDL 1/day

References:

- Xeljanz and Xeljanz XR Prescribing Information; New York, NY; Pfizer Labs: 2023.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: June 2023
Revision:

Prior Authorization Approval Criteria

Xolair (omalizumab)

Generic name: omalizumab
Brand name: Xolair
Medication class: Monoclonal antibody

FDA-approved uses:

- Asthma, moderate to severe
- Chronic rhinosinusitis with nasal polyps
- Chronic spontaneous urticaria (also known as chronic idiopathic urticaria)

Usual dose range:

- Asthma, moderate to severe
  - 75 to 375 mg every 2 or 4 weeks based on serum total IgE level and bodyweight
- Chronic rhinosinusitis with nasal polyps
  - 75 mg to 600 mg every 2 or 4 weeks based on serum total IgE level and bodyweight
- Chronic spontaneous urticaria
  - 150 mg or 300 mg every 4 weeks

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Asthma

Pediatric and Adult

- FDA indicated diagnosis
- 6 years of age or older
- Prescribed by or in consultation with an allergist/immunologist or pulmonologist
- Documentation of a positive skin prick or blood test (e.g., ELISA, FEIA) to a perennial aeroallergen
- Documentation of baseline IgE serum level greater than or equal to 30 IU/mL
- Documentation that the patient is concurrently treated with all of the following:
  - A medium, high-dose, or maximally tolerated inhaled corticosteroid
  - At least one other maintenance medication (e.g., long-acting inhaled beta2-agonist such as salmeterol or formoterol, long-acting muscarinic antagonist such as tiotropium, a leukotriene receptor antagonist such as montelukast, theophylline, or oral corticosteroid)

- Confirmation that Xolair will NOT be used concurrently with Dupixent or an anti-IL5 biologic (e.g., Nucala, Cinqair, Fasenra) when these are used for the treatment of asthma
- Confirmation that patient has experienced **one** of the following:
  - An asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least one serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
  - Poor symptom control despite current therapy as evidenced by at least **three** of the following within the past 4 weeks:
    - Daytime asthma symptoms more than twice per week
    - Any night waking due to asthma
    - Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
    - Any activity limitation due to asthma

Chronic rhinosinusitis with nasal polyps

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an allergist/immunologist or otolaryngologist
- Confirmation that Xolair will be used as add-on maintenance treatment
- Failure to respond to a 90-day trial of one intranasal corticosteroid

Chronic spontaneous urticaria (also known as chronic idiopathic urticaria)

Adolescent and Adult

- FDA indicated diagnosis
- 12 years of age or older
- Prescribed by or in consultation with an allergist/immunologist or pulmonologist
- Confirmation that the patient experiences hives on most days of the week for at least 6 weeks
- Failure to respond to an adequate trial of all of the following:
  - High dose H1 antihistamine (such as four-fold dosing of Clarinex or Xyzal) for at least 2 weeks
  - Leukotriene antagonist (such as montelukast, zafirlukast) for at least 2 weeks

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose for asthma is 375 mg every 2 weeks
- Maximum dose for chronic rhinosinusitis with nasal polyps is 600 mg every 2 weeks
- Maximum dose for chronic spontaneous urticaria is 300 mg every 4 weeks

Approval time frames:

- Asthma, moderate to severe
  - Initial: 4 months with MDL as follows:
    - Xolair 75 mg/0.5 mL syringe: 0.18/day (5 mL per 28 days)
    - Xolair 150 mg/mL syringe: 0.18/day (5 mL per 28 days)
  - Renewal: 1 year with MDL as follows:
    - Xolair 75 mg/0.5 mL syringe: 0.18/day (5 mL per 28 days)
    - Xolair 150 mg/mL syringe: 0.18/day (5 mL per 28 days)
- Chronic rhinosinusitis with nasal polyps
  - Initial: 6 months with MDL as follows:
    - Xolair 75 mg/0.5 mL syringe: 0.29/day (8 mL per 28 days)
    - Xolair 150 mg/mL syringe: 0.29/day (8 mL per 28 days)
  - Renewal: 1 year with MDL as follows:
    - Xolair 75 mg/0.5 mL syringe: 0.29/day (8 mL per 28 days)
    - Xolair 150 mg/mL syringe: 0.29/day (8 mL per 28 days)
- Chronic spontaneous urticaria (also known as chronic idiopathic urticaria)
  - Initial: 6 months with MDL as follows:
    - Xolair 75 mg/0.5 mL syringe: 0.08/day (2 mL per 28 days)
    - Xolair 150 mg/mL syringe: 0.08/day (2 mL per 28 days)
  - Renewal: 6 months with MDL as follows:
    - Xolair 75 mg/0.5 mL syringe: 0.08/day (2 mL per 28 days)
    - Xolair 150 mg/mL syringe: 0.08/day (2 mL per 28 days)

References:

- Xolair Prescribing Information; South San Francisco, CA; Genentech, Inc.: 2023.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: June 2023
Revision:

Prior Authorization Approval Criteria

Xyrem (sodium oxybate)

Generic name: sodium oxybate
Brand name: Xyrem
Medication class: CNS depressant

FDA-approved uses:

- Cataplexy in patients with narcolepsy
- Excessive daytime sleepiness in patients with narcolepsy

Usual dose range:

- 4.5 - 9 mg in divided doses at bedtime and 4 hours later

Criteria for use: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Cataplexy in a patient with narcolepsy

Pediatric

- FDA indicated diagnosis
- 7 years of age or older
- Prescribed by or in consultation with a neurologist
- Confirmation that the patient will not drink alcohol or take sedative hypnotics while on this medication

Excessive daytime sleepiness in a patient with narcolepsy

Pediatric and adult

- FDA indicated diagnosis
- 7 years of age or older
- Prescribed by or in consultation with a neurologist
- Confirmation that the patient will not drink alcohol or take sedative hypnotics while on this medication
- Failure to respond (or intolerance) to modafinil or armodafinil
- Failure to respond (or intolerance) to a formulary amphetamine or methylphenidate product

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum dose of 9 grams daily

Approval time frames:

- Initial – 6 months, 18 mL/day (9 grams/day)
- Renewal – 1 year, MDL 18 mL/day (9 grams/day)

References:

- Xyrem Prescribing Information. Jazz Pharmaceuticals, Inc., Palo Alto, CA: 2023.
- National Institute of Neurological Disorders and Stroke. Narcolepsy Fact Sheet. NIH Publication No. 17-1637. Available at: https://www.ninds.nih.gov/Disorders/Patient-CaregiverEducation/Fact-Sheets/Narcolepsy-Fact-Sheet. Accessed March 18, 2022.
- Morgenthaler TI, Vishesh KK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin. Sleep 2007; 30(12):1705-11.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: March 2020
Revision: March 2021, March 2022, May 2023

Prior Authorization Approval Criteria

Zejula (niraparib)

Generic name: niraparab
Brand name: Zejula
Medication class: Poly ADP-ribose polymerase (PARP) inhibitor

FDA-approved uses:

- Recurrent epithelial ovarian, Fallopian tube or primary peritoneal cancer with deleterious BRCA (germline and/or somatic) after 2 or more previous chemotherapies
- Maintenance therapy for epithelial ovarian, Fallopian tube or primary peritoneal cancer with recurrent disease after complete or partial response to platinum-based chemotherapy

Usual dose range:

- Up to 300 mg once daily, depending on patient weight, platelet count and/or diagnosis

Criteria for use:

Initiation Criteria

Recurrent epithelial ovarian, Fallopian tube or primary peritoneal cancer/Maintenance therapy for epithelial ovarian, Fallopian tube or primary peritoneal cancer

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an oncologist
- Confirmation that the patient's cancer is associated with homologous recombination deficiency (HRD) positive status defined by **one** of the following:
  - Deleterious or suspected deleterious BRCA mutation
  - Genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy
- Documentation of one of the following:
  - Failure to respond to a trial of three or more previous chemotherapy regimens
    -OR-
  - The patient is in complete or partial response to platinum-based chemotherapy
- Failure to respond or intolerance to Rubraca

Renewal Criteria

- Provider attestation that the patient has experienced a positive clinical response

Additional considerations:

- Maximum total daily dose of 300 mg

Approval time frames:

- Initial – 6 months with MDL of 3 tablets per day
- Renewal – 1 year with MDL of 3 tablets per day

References:

- Zejula Prescribing Information; Triangle Park, NC; GlaxoSmithKline LLC: 2023.
- Rubraca Prescribing Information; Boulder, CO; Clovis Oncology, Inc: 2022.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2020
Revision: January 2022, December 2022, December 2023

ELEVATE CHILD HEALTH PLAN *PLUS*
Denver Health Medical Plan Inc.™

ELEVATE MEDICAID CHOICE
Denver Health Medical Plan Inc.™

Pharmacy Benefit Formulary Exception Protocol

Word/Term	Definition
Formulary	A formulary is a list of drugs or products, both generic and brand name, that are preferred by Denver Health Medical Plan, Inc. (DHMP).
Formulary Exceptions	A formulary exception should be requested to get coverage for a drug that is not on the DHMP formulary.
Tiering Exceptions (copay exception)	A tiering exception (sometimes called a copay exception) should be requested to get a non-preferred drug at the lower cost-share that applies to drugs in a preferred tier. If approved, this will allow the member to pay a lower copay amount.
Quantity Exception	For safety and cost reasons, plans may set quantity limits on the amount of drugs they cover over a certain period of time. This is called a quantity limit restriction. That means that DHMP will only cover the drug up to a certain quantity or amount. If your prescriber feels it is clinically necessary to go over the set limit, a quantity exception must be requested before the higher amount can be covered.
Step Exception	If a requested drug has a step therapy requirement, DHMP will ask that the member try step formulary drugs before the requested drug will be covered. If there are clinical reasons why the step therapy drug cannot be tried, then a step exception can be made to override the step therapy and allow the requested drug.
Medical Exception	When a member does not meet the plan's prior authorization criteria for the requested drug, but there are clinical reasons why the criteria should not apply to this member, a medical exception can be made to override the criteria.
Indication	In medicine, this is a valid reason to use a medication.

Purpose	This document sets procedures for members to obtain non-preferred drugs (formulary exceptions), lower copays (tiering exceptions), and higher quantities than are included within the DHMP formulary (quantity exceptions). This document also talks about the review process for exceptions to the step therapy requirements and prior authorization criteria requirements.

1. DHMP will review exceptions to the formulary including formulary exceptions, tiering exceptions, quantity exceptions, step exceptions and medical exceptions (see glossary above for definitions). The rules for these exception types are outlined below.

a. **Formulary Exceptions:** A member/prescriber may ask for a formulary exception if the following rules have been met:
    i. The requested drug is being used for an FDA approved indication **OR** the requested drug is for a medically accepted indication (health condition) supported by medical literature; **AND**
    ii. The prescribing provider must inform DHMP that at least two available therapeutic equivalents on the formulary (or medically appropriate medications, if no therapeutic equivalents exist) for treatment of the same condition either:
        1. Have been ineffective in the treatment of the disease or condition; **OR**
        2. Are reasonably expected to cause a harmful or adverse clinical reaction.

    AND

    iii. Drugs being considered for a formulary exception must meet any applicable utilization management requirements if they are in the same therapeutic class as formulary drugs that require such authorization.
        1. If the Denver Health Medical Plan does not have applicable utilization management requirements or prior authorization criteria, then the plan will utilize the criteria created by the Colorado Department of Health Care Policy and Financing.
    iv. Special Notes:
        1. Use of alternatives must be for a reasonable period. This is defined as one month of therapy or more, except in cases where the prescriber gives clinical reasons why alternatives are not effective, tolerable, or safe.
        2. If the prescriber's request for coverage of the non-formulary medication is only because prescriber or member is not willing to change to the plan's preferred alternative, the request will not be allowed.
        3. If criteria are met, the non-formulary drug will be approved allowing the prescription to process as a covered medication at the appropriate co-payment/cost share. Generic and brand name drugs will be covered at the non-preferred level of cost share (tier 2), and specialty drugs will be covered at the specialty level of cost share (tier 3).

b. **Quantity Exceptions:** If a member or prescriber requests a quantity exception to allow for a higher quantity of a drug than is listed on the plan formulary, they must meet the following rules:
    i. The drug is being used for an FDA approved indication, or a medically accepted indication.
    ii. The drug is being used within the recommended dosing guidelines in the

medical literature.

iii. The current quantity has not been effective in treating of the member's disease or medical condition.

iv. Based on clinical evidence and medical literature, the known relevant physical or mental characteristics of the member, and known characteristics of the drug regimen, the lower quantity is not likely to be effective.

v. No higher dosage strength can be used to get the same total daily dose (no dose consolidation is possible).

c. **Step Exception:** If a member or prescriber wishes to get a step exception to the formulary's existing step therapy requirements, the member or prescriber must give a clinical reason why the preferred formulary drug(s) will cause harm or be less effective than the requested drug or reasons why the guideline criteria cannot be applied to this member.

i. The drug is being used for an FDA approved indication, or a medically accepted indication.

d. **Medical Exception:** If a member or prescriber is requesting a medical exception to the formulary's prior authorization criteria, the member or prescriber must give clinical reasons why the criteria cannot be applied to the member.

i. The drug is being used for an FDA approved indication, or a medically accepted indication.

2. Processing Timeframes

a. **Timeframe Definitions**:

i. Pre-service: a request for coverage to be approved in advance of receiving services.

ii. Post-service: a request for coverage of services that have already been received. Reimbursements are categorized as post-service.

b. Requests are processed within the following timeframes:

i. Elevate Medicaid Choice and Child Health Plan

1. Urgent/Expedited:
   a. Pre-service: 24 hours
   b. Outreach Required: 72 hours from initial outreach or 24 hours after provider response
2. Non-Urgent:
   a. Pre-service: 24 hours
   b. Outreach Required: 72 hours from initial outreach or 24 hours after provider response
3. Post-service: 120 calendar days

COLORADO
Department of Health Care Policy & Financing

Health First COLORADO
Colorado's Medicaid Program

Colorado Department of Health Care Policy and Financing
Preferred Drug List (PDL)
Effective January 1, 2025

Prior Authorization Forms: Available online at https://hcpf.colorado.gov/pharmacy-resources

Prior Authorization (PA) Requests: Colorado Pharmacy Call Center Phone Number: 800-424-5725 | Fax Number: 800-424-5881

Electronic Prior Authorization (ePA): Electronic Prior Authorization Requests are supported by CoverMyMeds and may be submitted via Electronic Health Record (EHR) systems or through the CoverMyMeds provider portal.

The PDL applies to Medicaid fee-for-service members. It does not apply to members enrolled in Rocky Mountain Health HMO or Denver Health Medicaid Choice.

Initiation of pharmaceutical product subject to Prior Authorization: Please note that starting the requested drug, including a non-preferred drug, prior to a PA request being reviewed and approved, through either inpatient use, by using office "samples," or by any other means, does not necessitate Medicaid approval of the PA request.

Health First Colorado, at section 25.5-5-501, C.R.S., requires the generic of a brand name drug be prescribed if the generic is therapeutically equivalent to the brand name drug. Exceptions to this rule are: 1) If the brand name drug is more cost effective than the generic as determined by the Department, 2) If the patient has been stabilized on a brand name drug and the prescriber believes that transition to a generic would disrupt care, and 3) If the drug is being used for treatment of mental illness, cancer, epilepsy, or human immunodeficiency virus and acquired immune deficiency syndrome.

Please see the **Brand Favored Product List** for a list of medications where the brand name drug is more cost effective than the generic drug.

A provider may request a step therapy exception for the treatment of a serious or complex medical condition pursuant to section 25.5-4-428, C.R.S. Serious or complex medical condition means the following medical conditions: serious mental illness, cancer, epilepsy, multiple sclerosis, or human immunodeficiency virus (HIV)/ acquired immune deficiency syndrome (AIDS), or a condition requiring medical treatment to avoid death, hospitalization, or a worsening or advancing of disease progression resulting in significant harm or disability. The step therapy exception request form is available by visiting https://hcpf.colorado.gov/pharmacy-resources

Brand Name Required = BNR, Prior Authorization = PA, AutoPA = authorization can be automated at the point-of-sale transaction if criteria are met
Preferred drug list applies only to prescription (RX) products, unless specified.

Preferred Agents	Non-preferred Agents	Prior Authorization Criteria (All Non-preferred products will be approved for one year unless otherwise stated.)
I. Analgesics		
Therapeutic Drug Class: **NON-OPIOID ANALGESIA AGENTS - Oral -** *Effective 4/1/2024*		
No PA Required Duloxetine 20 mg, 30 mg, 60 mg capsule Gabapentin capsule, tablet, solution Pregabalin capsule SAVELLA (milnacipran) tablet, titration pack	**PA Required** CYMBALTA (duloxetine) capsule DRIZALMA (duloxetine DR) sprinkle capsules Duloxetine 40 mg capsule GRALISE (gabapentin ER) tablet Gabapentin ER tablet HORIZANT (gabapentin ER) tablet LYRICA (pregabalin) capsule, solution, CR tablet NEURONTIN (gabapentin) capsule, tablet, solution Pregabalin solution, ER tablet	Non-preferred oral non-opioid analgesic agents may be approved if member meets all of the following criteria: • Member has trialed and failed duloxetine (20mg, 30mg, or 60mg) AND has trialed and failed gabapentin OR pregabalin capsule (Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction) Prior authorization will be required for Lyrica (pregabalin) capsule dosages > 600mg per day (maximum of 3 capsules daily) and gabapentin dosages > 3600mg per day.
Therapeutic Drug Class: **NON-OPIOID ANALGESIA AGENTS - Topical -** *Effective 4/1/2024*		
No PA Required Lidocaine patch LIDODERM (lidocaine) patch	**PA Required** Lidocaine patch (Puretek) ZTLIDO (lidocaine) topical system	Non-preferred topical products require a trial/failure with an adequate 8-week trial of gabapentin AND pregabalin AND duloxetine AND a preferred lidocaine patch. Failure is defined as lack of efficacy with an 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction. **Lidocaine patch *(Puretek manufacturer only)*** may be approved if the following criteria are met: • Member is ≥ 18 years of age **AND** • Member has had an adequate 8-week trial and failure of: gabapentin **AND** pregabalin **AND** duloxetine **AND** a preferred lidocaine patch. Failure is defined as lack of efficacy with an 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction **AND** • Prescriber has provided a justification of clinical necessity indicating that an alternative generic lidocaine patch formulation cannot be used.

Therapeutic Drug Class: **NON-STEROIDAL ANTI-INFLAMMATORIES (NSAIDS) - Oral** - *Effective 4/1/2024*

No PA Required	**PA Required**	
Celecoxib capsule Diclofenac potassium 50 mg tablet Diclofenac sodium EC/DR tablet Ibuprofen suspension, tablet (RX) Indomethacin capsule, ER capsule Ketorolac tablet* Meloxicam tablet Nabumetone tablet Naproxen DR/ER, tablet (RX) Naproxen suspension Sulindac tablet	ARTHROTEC (diclofenac sodium/ misoprostol) tablet CELEBREX (celecoxib) capsule DAYPRO (oxaprozin) caplet Diclofenac potassium capsule, powder pack Diclofenac potassium 25 mg tablet Diclofenac sodium ER/SR tablet Diclofenac sodium/misoprostol tablet Diflunisal tablet DUEXIS (ibuprofen/famotidine) tablet ELYXYB (celecoxib) solution Etodolac capsule; IR, ER tablet FELDENE (piroxicam) capsule Fenoprofen capsule, tablet Flurbiprofen tablet Ibuprofen/famotidine tablet Ketoprofen IR, ER capsule LOFENA (diclofenac) tablet Meclofenamate capsule Mefenamic acid capsule Meloxicam submicronized capsule, suspension	**DUEXIS (ibuprofen/famotidine)** or **VIMOVO (naproxen/esomeprazole)** may be approved if the member meets the following criteria: • Trial and failure‡ of all preferred NSAIDs at maximally tolerated doses **AND** • Trial and failure‡ of three preferred proton pump inhibitors in combination with NSAID within the last 6 months **AND** • Has a documented history of gastrointestinal bleeding **Diclofenac potassium 25 mg immediate-release tablets** may be approved if the following criteria are met: • Member is ≥ 18 years of age **AND** • Member does not have any of the following medical conditions: o History of recent coronary artery bypass graft (CABG) surgery o History of myocardial infarction o Severe heart failure o Advanced renal disease o History of gastrointestinal bleeding **AND** • Member has trial and failure‡ of four preferred oral NSAIDs at maximally tolerated doses All other non-preferred oral agents may be approved following trial and failure‡ of four preferred agents. ‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions. *Ketorolac tablets quantity limits: 5-day supply per 30 days and 20 tablets per 30 days

	NALFON (fenoprofen) capsule, tablet NAPRELAN (naproxen CR) tablet Naproxen sodium CR, ER, IR tablet Naproxen/esomeprazole DR tablet Oxaprozin tablet Piroxicam capsule RELAFEN DS (nabumetone) tablet Tolmetin tablet VIMOVO (naproxen/esomeprazole) DR tablet	
Therapeutic Drug Class: **NON-STEROIDAL ANTI-INFLAMMATORIES (NSAIDS) - Non-Oral -** *Effective 4/1/2024*		
No PA Required Diclofenac 1.5% topical solution Diclofenac sodium 1% gel (OTC/Rx)	**PA Required** Diclofenac 1.3% topical patch, 2% pump FLECTOR (diclofenac) 1.3% topical patch Ketorolac nasal spray LICART (diclofenac) 1.3% topical patch PENNSAID (diclofenac solution) 2% pump, 2% solution packet	**SPRIX (ketorolac)** may be approved if meeting the following criteria: ● Member is unable to tolerate, swallow or absorb oral NSAID formulations **OR** ● Member has trialed and failed three preferred oral or topical NSAID agents (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) ● Quantity limit: 5-single day nasal spray bottles per 30 days All other non-preferred topical agents may be approved for members who have trialed and failed one preferred agent. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction. **Diclofenac topical patch** quantity limit: 2 patches per day Diclofenac 3% gel (generic Solaraze) prior authorization criteria can be found in the Antineoplastic agents, topical, section of the PDL.

Opioid Utilization Policy (long-acting and short-acting opioids):

It is highly encouraged that the healthcare team utilize the Prescription Drug Monitoring Program (PDMP) to aid in ensuring safe and efficacious therapy for members using controlled substances.

Total Morphine Milligram Equivalent Policy Effective 10/1/17:

- The maximum allowable morphine milligram equivalent (MME) is 200 MME. Prescriptions for short-acting (SA) and long-acting (LA) opioids are cumulatively included in this calculation. The prescription that exceeds the cumulative MME limit of 200 MME for a member will require prior authorization and may require a provider-to-provider telephone consultation with the pain management physician (free of charge and provided by Health First Colorado).
- Prior authorization will be granted to allow for tapering
- Prior authorization for 1 year will be granted for diagnosis of sickle cell anemia

- Prior authorization for 1 year will be granted for admission to or diagnosis of hospice or end of life care
- Prior authorization for 1 year will be granted for pain associated with cancer

MME calculation is conducted using conversion factors from the following link: https://pharmacypmp.az.gov/resources/mme-calculator

Only one long-acting opioid agent (including different strengths) and one short-acting opioid agent (including different strengths) will be considered for a prior authorization.

Medicaid provides guidance on the treatment of pain, including tapering, on our webpage under the heading Pain Management Resources and Opioid Use at: https://www.colorado.gov/pacific/hcpf/pain-management-resources-and-opioid-use

Opioid Naïve Policy Effective 8/1/17 (*Update effective 04/01/23 in Italics*):
Members who have not filled a prescription for an opioid within the past 180 days will be identified as "opioid treatment naïve" and have the following limitations placed on the initial prescription(s):

- The prescription is limited to short-acting opioid agents *or Butrans (buprenorphine)*. Use of other long-acting opioid agents will require prior authorization approval for members identified as opioid treatment naïve.
- The days' supply of the first, second, and third prescription for an opioid will be limited to 7 days, the quantity will be limited to 8 dosage forms per day (tablets, capsules), maximum #56 tablets/capsules for a 7-day supply
- The fourth prescription for an opioid will require prior authorization, filling further opioid prescriptions may require a clinical pharmacist review or provider to provider telephone consultation with a pain management physician (free of charge and provided by Health First Colorado).
- If a member has had an opioid prescription filled within the past 180 days, then this policy would not apply to that member and other opioid policies would apply as applicable.

Dental Prescriptions Opioid Policy Effective 11/15/18 (implemented in the claims system 01/07/19):
Members who receive an opioid prescribed by a dental provider will be subject to day supply limits and quantity per day limits for short acting opioids.

- The prescription is limited to short-acting opioid agents only. Use of long-acting opioid agents and short acting fentanyl agents will require prior authorization approval for members' prescriptions written by a dental provider.
- The days' supply of the first, second, and third prescription for an opioid will be limited to 4 days, the quantity will be limited to 6 dosage forms per day (tablets, capsules), maximum #24 tablets/capsules for a 4-day supply
- The fourth prescription for an opioid will require prior authorization. A prior authorization for the fourth fill may be approved for up to a 7-day supply and the quantity will be limited to 8 dosage forms per day (#56 tablets/capsules) for members with any of the following diagnoses/undergoing any of the following procedures:
    - Traumatic oro-facial tissue injury with major mandibular/maxillary surgical procedures
    - Severe cellulitis of facial planes
    - Severely impacted teeth with facial space infection necessitating surgical management
- Other potential exemptions that exceed the first 3 fill limits (day supply and quantity) may be evaluated with a provider-to-provider telephone consult with a pain management specialist (free of charge and provided by Health First Colorado)

If a member has had an opioid prescription prescribed by a non-dental provider, then this policy would not apply to that member and other opioid policies would apply as applicable. Dental prescriptions do not impact the opioid treatment naïve policy, but the prescriptions will be counted towards the Morphine Milligram Equivalent (MME) daily dose.

Opioid and Benzodiazepine Combination Effective 9/15/19:
Prior authorization will be required for members receiving long-term therapy with an opioid medication who are newly started on a benzodiazepine medication OR for members receiving long-term therapy with a benzodiazepine medication who are newly started on an opioid medication. Prior authorization may be approved if meeting the following:

- The member discontinued or is no longer taking either the opioid or benzodiazepine medication and will not be using these in combination **OR**
- The member will not be taking the prescribed opioid and benzodiazepine medications at the same time based on prescribed dosing interval (such as prn administration) for the regimen AND the prescriber attests that the member has received appropriate counseling* regarding the risks associated with combining opioid and benzodiazepine

medications including increased risk for sedation, respiratory depression, overdose, and overdose-related death and counseling regarding the FDA Boxed Warning for combining these medications **OR**

- The prescriber has evaluated the regimen and attests that it is appropriate for the member to continue use of the concomitant opioid and benzodiazepine medication regimen as prescribed AND the prescriber attests that the member has received appropriate counseling* regarding the risks associated with combining opioid and benzodiazepine medications including increased risk for sedation, respiratory depression, overdose, and overdose-related death and counseling regarding the FDA Boxed Warning for combining these medications **OR**
- Prior authorization may be approved for members receiving palliative or hospice care **OR**
- For benzodiazepine prior authorizations, approval may be granted if the benzodiazepine is being prescribed for seizure disorder or convulsions.

**If counseling has not been provided, the prescriber attests that a reasonable effort will be made to contact the member or the member's pharmacy to ensure that counseling is provided.*

Opioid and Quetiapine Combination Effective 9/15/19:
Pharmacy claims for members receiving opioid and quetiapine medications in combination will require entry of point-of-sale DUR service codes (Reason for Service, Professional Service, Result of Service) for override of drug-drug interaction (DD) related to risk of increased sedation from concomitant use of this drug combination.

Opioid and Buprenorphine-Containing substance use disorder (SUD) Product Combination Effective 06/01/21:
Opioid claims submitted for members currently receiving buprenorphine-containing SUD medications will require entry of point-of-sale DUR service codes (Reason for Service, Professional Service, Result of Service) for override of drug-drug interaction (DD) with use of this drug combination.

Therapeutic Drug Class: **OPIOIDS, Short Acting -** *Effective 4/1/2024*

Preferred No PA Required* (If criteria and quantity limit are met)	**Non-Preferred PA Required**	
*Acetaminophen/codeine tablets	Acetaminophen / codeine elixir	*Preferred codeine and tramadol products do not require prior authorization for adult members (18 years of age or greater) if meeting all other opioid policy criteria. Preferred codeine or tramadol products prescribed for members < 18 years of age must meet the following criteria: • **Preferred tramadol and tramadol-containing products** may be approved for members < 18 years of age if meeting the following: o Member is 12 years to 17 years of age **AND** o Tramadol is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure AND o Member's BMI-for-age is not > 95th percentile per CDC guidelines AND o Member does not have obstructive sleep apnea or severe lung disease OR o For members < 12 years of age with complex conditions or life-limiting illness who are receiving care under a pediatric specialist, tramadol and tramadol-containing products may be approved on a case-by-case basis • **Preferred Codeine and codeine-containing products** will receive prior authorization approval for members meeting the following criteria may be approved for members < 18 years of age if meeting the following: o Member is 12 years to 17 years of age AND o Codeine is NOT being prescribed for post-surgical pain following tonsil or adenoid procedure AND o Member's BMI-for-age is not > 95th percentile per CDC guidelines AND o Member does not have obstructive sleep apnea or severe lung disease AND o Member is not pregnant, or breastfeeding AND o Renal function is not impaired (GFR > 50 ml/min) AND
Hydrocodone/acetaminophen solution, tablet	ASCOMP WITH CODEINE (codeine/butalbital/aspirin/caffeine)	
Hydromorphone tablet	*Butalbital/caffeine/acetaminophen/codeine capsule	
Morphine IR solution, tablet	Butalbital/caffeine/aspirin/codeine capsule	
**NUCYNTA (tapentadol) tablet	Butalbital compound/codeine	
Oxycodone solution, tablet	Butorphanol tartrate (nasal) spray	
Oxycodone/acetaminophen tablet	Carisoprodol/aspirin/codeine	
*Tramadol 25mg, 50mg	Codeine tablet	
*Tramadol/acetaminophen tablet	Dihydrocodeine/acetaminophen/caffeine tablet	

	DILAUDID (hydromorphone) solution, tablet FIORICET/CODEINE (codeine/ butalbital/acetaminophen/caffeine) capsule Hydrocodone/ibuprofen tablet Hydromorphone solution Levorphanol tablet Meperidine solution, tablet Morphine concentrated solution, oral syringe NALOCET (oxycodone/acetaminophen) tablet Oxycodone capsule, syringe, concentrated solution Oxycodone/acetaminophen solution Oxycodone/acetaminophen tablet (generic PROLATE) Oxymorphone tablet Pentazocine/naloxone tablet PERCOCET (oxycodone/ acetaminophen) tablet ROXICODONE (oxycodone) tablet ROXYBOND (oxycodone) tablet SEGLENTIS (tramadol/celecoxib) tablet Tramadol 100mg tablet Tramadol solution	○ Member is not receiving strong inhibitors of CYP3A4 (such as erythromycin, clarithromycin, itraconazole, ketoconazole, posaconazole, fluconazole [≥200mg daily], voriconazole, delavirdine, and milk thistle) AND ○ Member meets <u>one</u> of the following: • Member has trialed codeine or codeine-containing products in the past with no history of allergy or adverse drug reaction to codeine • Member has not trialed codeine or codeine-containing products in the past and the prescriber acknowledges reading the following statement: "Approximately 1-2% of the population metabolizes codeine in a manner that exposes them to a much higher potential for toxicity. Another notable proportion of the population may not clinically respond to codeine. We ask that you please have close follow-up with members newly starting codeine and codeine-containing products to monitor for safety and efficacy." Non-preferred tramadol products may be approved following trial and failure of generic tramadol 50mg tablet AND generic tramadol/acetaminophen tablet. All other non-preferred short-acting opioid products may be approved following trial and failure of three preferred products. Failure is defined as allergy‡, lack of efficacy, intolerable side effects, or significant drug-drug interaction. ‡Allergy: hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema <u>Quantity Limits</u>: Short-acting opioids will be limited to a total of 120 tablets per 30 days (4/day) per member for members who are not included in the opioid treatment naive policy. • **Nucynta IR will have a maximum daily quantity of 6 tablets (180 tabs per 30 days). • Exceptions will be made for members with a diagnosis of a terminal illness (hospice or palliative care) or sickle cell anemia. • For members who are receiving more than 120 tablets currently and who do not have a qualifying exemption diagnosis, a 6-month prior authorization can be granted via the prior authorization process for providers to taper members. • Please note that if more than one agent is used, the combined total utilization may not exceed 120 units in 30 days. There may be allowed certain exceptions to this limit for acute situations (for example: post-operative surgery, fractures, shingles, car accident). <u>Maximum Doses:</u> Tramadol: 400mg/day Codeine: 360mg/day Butorphanol intranasal: 10ml per 30 days (four 2.5ml 10mg/ml package units per 30 days)

Therapeutic Drug Class: **FENTANYL PREPARATIONS (buccal, transmucosal, sublingual)** - *Effective 4/1/2024*		
	PA Required ACTIQ (fentanyl citrate) lozenge Fentanyl citrate lozenge, buccal tablet FENTORA (fentanyl citrate) buccal tablet	Fentanyl buccal, intranasal, transmucosal, and sublingual products: Prior authorization approval may be granted for members experiencing breakthrough cancer pain and those that have already received and are tolerant to opioid drugs for the cancer pain AND are currently being treated with a long-acting opioid drug. The prior authorization may be granted for up to 4 doses per day. For patients in hospice or palliative care, prior authorization will be automatically granted regardless of the number of doses prescribed.
Therapeutic Drug Class: **OPIOIDS, Long Acting** - *Effective 4/1/2024*		
Preferred **No PA Required** **(unless indicated by * criteria)** BELBUCA[BNR] (buprenorphine) buccal film BUTRANS[BNR] (buprenorphine) transdermal patch *Fentanyl 12mcg, 25mcg, 50mcg, 75mcg, 100mcg transdermal patch Morphine ER (generic MS Contin) tablet *NUCYNTA ER (tapentadol ER) **(will no longer be covered as of 1/1/25)** Tramadol ER (generic Ultram ER) tablet XTAMPZA ER (oxycodone) capsule **(will no longer be covered as of 1/1/25)**	**Non-Preferred** **PA Required** **OXYCONTIN (oxycodone ER) tablet Buprenorphine buccal film, transdermal patch CONZIP (tramadol ER) capsule Fentanyl 37mcg, 62mcg, 87mcg transdermal patch Hydrocodone ER capsule, tablet Hydromorphone ER tablet HYSINGLA (hydrocodone ER) tablet Methadone (all forms) Morphine ER capsule MS CONTIN (morphine ER) tablet Oxycodone ER tablet Oxymorphone ER tablet Tramadol ER capsule	***Belbuca (buprenorphine)** buccal film may be approved for members who have trialed and failed‡ treatment with Butrans (buprenorphine) patch at a dose of 20 mcg/hr **OR** with prescriber confirmation that the maximum dose of Butrans 20 mcg/hr will not provide adequate analgesia. Quantity limit: 60 films/30 days. **Oxycontin (oxycodone ER)** may be approved for members who have trialed and failed‡ treatment with TWO preferred agents. All other non-preferred products may be approved for members who have trialed and failed‡ three preferred products. ‡Failure is defined as lack of efficacy with 14-day trial, allergy (hives, maculopapular rash, erythema multiforme, pustular rash, intolerable application site skin reactions, severe hypotension, bronchospasm, and angioedema), intolerable side effects, or significant drug-drug interaction. Methadone: Members may receive 30-day approval when prescribed for neonatal abstinence syndrome without requiring trial and failure of preferred agents or opioid prescriber consultation. Methadone Continuation: Members who have been receiving methadone for pain indications do not have to meet non-preferred criteria. All new starts for methadone will require prior authorization under the non-preferred criteria listed above. *If a prescriber would like to discuss strategies for tapering off methadone or transitioning to other pain management therapies for a Health First Colorado member, consultation with the Health First Colorado pain management physician is available free of charge by contacting the pharmacy call center helpdesk and requesting an opioid prescriber consult.*

		Reauthorization: Reauthorization for a non-preferred agent may be approved if the following criteria are met: • Provider attests to continued benefit outweighing risk of opioid medication use AND • Member met original prior authorization criteria for this drug class at time of original authorization **Quantity/Dosing Limits: • **Oxycontin, Nucynta ER,** and **Hydrocodone ER (generic Zohydro ER)** will only be approved for twice daily dosing. • **Hysingla** will only be approved for once daily dosing. • **Fentanyl patches** will require a PA for doses of more than 15 patches/30 days (if using one strength) or 30 patches for 30 days (if using two strengths). For fentanyl patch strengths of 37mcg/hr, 62mcg/hr, and 87mcg/hr, member must trial and fail two preferred strengths of separate patches that will provide the desired dose (such as 12mcg/hr + 50mcg/hr = 62mcg/hr).

II. Anti-Infectives

Therapeutic Drug Class: **ANTIBIOTICS, INHALED** -*Effective 1/1/2025*

Preferred **No PA Required** **(*Must meet eligibility criteria)**	**Non-Preferred** **PA Required**	
Tobramycin inhalation solution (generic TOBI) *CAYSTON (aztreonam) inhalation solution	ARIKAYCE (amikacin liposomal) inhalation vial BETHKIS (tobramycin) inhalation ampule KITABIS (tobramycin) nebulizer pak TOBI (tobramycin) inhalation solution TOBI PODHALER (tobramycin) inhalation capsule Tobramycin inhalation ampule (generic Bethkis) Tobramycin nebulizer pak (generic Kitabis)	*__CAYSTON (aztreonam)__ inhalation solution may be approved if the following criteria are met: • Member has a history of trial and failure of preferred tobramycin solution for inhalation (failure is defined as lack of efficacy with a 4-week trial, intolerable side effects, or significant drug-drug interactions) **OR** provider attests that member cannot use preferred tobramycin solution for inhalation due to documented allergy or contraindication to therapy **AND** • The member has known colonization of *Pseudomonas aeruginosa* in the lungs **AND** • The member has been prescribed an inhaled beta agonist to use prior to nebulization of Cayston (aztreonam). **ARIKAYCE (amikacin)** may be approved if the following criteria are met: • Member has refractory mycobacterium avium complex (MAC) lung disease with limited or no alternative treatment options available **AND** • Member has trialed and failed 6 months of therapy with a 3-drug regimen that includes a macrolide (failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions). All other non-preferred inhaled antibiotic agents may be approved if the following criteria are met:

- The member has a diagnosis of cystic fibrosis with known colonization of *Pseudomonas aeruginosa* in the lungs **AND**
- Member has history of trial and failure of preferred tobramycin solution for inhalation (failure is defined as lack of efficacy with a 4-week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions).

Table 1: Minimum Age, Maximum Dose, and Quantity Limitations

Drug Name	Minimum Age	Maximum Dose	Quantity Limit (Based on day supply limitation for pack size dispensed)
ARIKAYCE (amikacin)	≥ 18 years	590 mg once daily	Not applicable
BETHKIS (tobramycin)	Age ≥ 6 years	300 mg twice daily	28-day supply per 56-day period
CAYSTON (aztreonam)	≥ 7 years	75 mg three times daily	28-day supply per 56-day period
KITABIS PAK (tobramycin)	Age ≥ 6 years	300 mg twice daily	28-day supply per 56-day period
TOBI † (tobramycin)	Age ≥ 6 years	300 mg twice daily	28-day supply per 56-day period
TOBI PODHALER (tobramycin)	Age ≥ 6 years	112 mg twice daily	28-day supply per 56-day period

† *Limitations apply to brand product formulation only*

Members currently stabilized on any inhaled antibiotic agent in this class may receive approval to continue that agent.

Therapeutic Drug Class: **ANTI-HERPETIC AGENTS - Oral -** *Effective 1/1/2025*

No PA Required	PA Required	
Acyclovir tablet, capsule *Acyclovir suspension (*members under 18 years or cannot swallow a solid dosage form*) Famciclovir tablet	Acyclovir suspension *(all other members)* SITAVIG (acyclovir) buccal tablet VALTREX (valacyclovir) tablet	Non-preferred products may be approved for members who have failed an adequate trial with two preferred products with different active ingredients. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction. **Sitavig** (acyclovir) buccal tablet may be approved for diagnosis of recurrent herpes labialis (cold sores) if member meets non-preferred criteria listed above AND has failed trial with oral acyclovir suspension. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

<table>
<tr>
<td>Valacyclovir tablet</td>
<td></td>
<td>*Acyclovir suspension does not require prior authorization for members < 18 years of age and may be approved for members ≥ 18 years of age who cannot swallow an oral dosage form.

<table>
<tr><th colspan="3">Maximum Dose Table</th></tr>
<tr><th></th><th>Adult</th><th>Pediatric</th></tr>
<tr><td>Acyclovir</td><td>4,000 mg/day</td><td>3,200 mg/day</td></tr>
<tr><td>Famciclovir</td><td>2,000 mg/day</td><td></td></tr>
<tr><td>Valacyclovir</td><td>4,000 mg/day</td><td>Age 2-11 years: 3,000 mg/day
Age ≥ 12 years: 4,000 mg/day</td></tr>
</table>
</td>
</tr>
<tr><td colspan="3">Therapeutic Drug Class: ANTI-HERPETIC AGENTS- Topical - Effective 1/1/2025</td></tr>
<tr>
<td>No PA Required

Acyclovir cream (Teva only)

Acyclovir ointment

DENAVIR (penciclovir) cream</td>
<td>PA Required

Acyclovir cream (all other manufacturers)

Penciclovir cream

XERESE (acyclovir/ hydrocortisone) cream

ZOVIRAX (acyclovir) cream, ointment</td>
<td>Non-Preferred Zovirax and acyclovir ointment/cream formulations may be approved for members who have failed an adequate trial with the preferred topical acyclovir ointment/cream product (diagnosis, dose and duration) as deemed by approved compendium. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction)

Xerese (acyclovir/hydrocortisone) prior authorization may be approved for members that meet the following criteria:

Documented diagnosis of recurrent herpes labialis AND
Member is immunocompetent AND
Member has failed treatment of at least 10 days with acyclovir (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects) AND
Member has failed treatment of at least one day with famciclovir 1500 mg OR valacyclovir 2 grams twice daily (Failure is defined as significant drug-drug interaction, lack of efficacy, contraindication to or intolerable side effects)

</td>
</tr>
<tr><td colspan="3">Therapeutic Drug Class: FLUOROQUINOLONES – Oral - Effective 1/1/2025</td></tr>
<tr>
<td>Preferred
No PA Required
(*if meeting eligibility criteria)

*CIPRO (ciprofloxacin) oral suspension[BNR]

Ciprofloxacin tablet

Levofloxacin tablet

Moxifloxacin tablet</td>
<td>Non-Preferred
PA Required

BAXDELA (delafloxacin) tablet

CIPRO (ciprofloxacin) tablet

Ciprofloxacin oral suspension

Levofloxacin oral solution

Ofloxacin tablet</td>
<td>*CIPRO suspension does not require prior authorization for members < 18 years of age and may be approved for members ≥ 18 years of age

Non-preferred products may be approved for members who have failed an adequate trial (7 days) with at least one preferred product. (Failure is defined as: lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

Levofloxacin solution may be approved for members with prescriber attestation that member:

is unable to take Cipro (ciprofloxacin) crushed tablet or suspension OR
is < 5 years of age and being treated for pneumonia OR
has failed† an adequate trial (7 days) of ciprofloxacin suspension

†Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy.</td>
</tr>
</table>

Therapeutic Drug Class: **HEPATITIS C VIRUS TREATMENTS -** *Effective 1/1/2025*

Direct Acting Antivirals (DAAs)

Preferred **No PA Required for initial treatment** **(*must meet eligibility criteria)**	**Non-Preferred** **PA Required**	
EPCLUSA (sofosbuvir/velpatasvir) 200 mg -50 mg, 150 mg-37.5 mg tablet, pellet pack HARVONI (ledipasvir/sofosbuvir) 45mg-200mg tablet, pellet pack Ledipasvir/Sofosbuvir 90 mg-400 mg tablet (*Asegua only)* MAVYRET (glecaprevir/pibrentasvir) tablet, pellet pack Sofosbuvir/Velpatasvir 400mg-100mg (*Asegua only)* *VOSEVI tablet (sofosbuvir/velpatasvir/voxilaprevir)	EPCLUSA 400 mg-100 mg (sofosbuvir/velpatasvir) tablet HARVONI 90 mg-400 mg (ledipasvir/sofosbuvir) tablet SOVALDI (sofosbuvir) tablet, pellet packet ZEPATIER (elbasvir/grazoprevir) tablet	Pharmacy claims for **preferred products** prescribed for initial treatment will be eligible for up to a 90-day supply fill allowing for the appropriate days' duration for completing the initial treatment regimen (with no PA required). Subsequent fills will require prior authorization meeting re-treatment criteria below. ***Second line preferred agents** (Vosevi) may be approved for members 18 years of age or older with chronic HCV infection who are non-cirrhotic or have compensated cirrhosis (Child-Pugh A) AND meet the following criteria: • GT 1-6 and has previously failed treatment with a regimen containing an NS5A inhibitor (such as ledipasvir, daclatasvir, or ombitasvir) **OR** • GT 1a or 3 and has previously failed treatment with a regimen containing sofosbuvir without an NS5A inhibitor **AND** • Request meets the applicable criteria below for re-treatment. **Re-treatment:** All requests for HCV re-treatment for members who have failed therapy with a DAA will be reviewed on a case-by-case basis. Additional information may be requested for re-treatment requests including: • Assessment of member readiness for re-treatment • Previous regimen medications and dates treated • Genotype of previous HCV infection • Any information regarding adherence to previously trialed regimen(s) and current chronic medications • Adverse effects experienced from previous treatment regimen • Concomitant therapies during previous treatment regimen • Vosevi regimens will require verification that member has been tested for evidence of active hepatitis B virus (HBV) infection and for evidence of prior HBV infection prior to initiating treatment. **Non-preferred** agents may be approved if documentation is provided indicating an acceptable rationale for not prescribing a preferred treatment regimen (acceptable rationale may include patient-specific medical contraindications to a preferred treatment or cases where a member has initiated treatment on a non-preferred drug and needs to complete therapy). Members currently receiving treatment with a non-preferred agent will receive approval to finish their treatment regimen, provided required documentation is sent via normal prior authorization request process.

Ribavirin Products		
No PA Required Ribavirin capsule Ribavirin tablet		Preferred products are eligible for up to a 90-day supply fill. Non-preferred ribavirin products require prior authorizations which will be evaluated on a case-by-case basis.

Therapeutic Drug Class: **HUMAN IMMUNODEFICIENCY VIRUS (HIV) TREATMENTS, ORAL** - *Effective 1/1/2025*

Oral products indicated for HIV pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) are eligible for coverage with a written prescription by an enrolled pharmacist. Additional information regarding pharmacist enrollment can be found at https://hcpf.colorado.gov/pharm-serv.

Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)		
No PA Required EDURANT (rilpivirine) tablet Efavirenz capsule, tablet Etravirine tablet INTELENCE (etravirine) tablet Nevirapine suspension, IR tablet, ER tablet PIFELTRO (doravirine) tablet		All products are preferred and do not require prior authorization.

Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)		
No PA Required Abacavir solution, tablet Didanosine DR capsule Emtricitabine capsule EMTRIVA (emtricitabine) capsule, solution EPIVIR (lamivudine) solution, tablet Lamivudine solution, tablet RETROVIR (zidovudine) capsule, syrup Stavudine capsule Tenofovir disoproxil fumarate (TDF) tablet		All products are preferred and do not require prior authorization.

VIREAD (TDF) oral powder, tablet ZIAGEN (abacavir) solution, tablet Zidovudine capsule, syrup, tablet		
Protease Inhibitors (PIs)		
No PA Required APTIVUS (tipranavir) capsule Atazanavir capsule Darunavir tablet Fosamprenavir tablet LEXIVA (fosamprenavir) suspension, tablet NORVIR (ritonavir) powder packet, tablet PREZISTA (darunavir) suspension, tablet REYATAZ (atazanavir) capsule, powder pack Ritonavir tablet VIRACEPT (nelfinavir) tablet		All products are preferred and do not require prior authorization.
Other Agents		
No PA Required ISENTRESS (raltegravir) chewable, powder pack, tablet ISENTRESS HD (raltegravir) tablet Maraviroc tablet RUKOBIA (fostemsavir tromethamine ER) tablet SELZENTRY (maraviroc) solution, tablet SUNLENCA (lenacapavir) tablet		All products are preferred and do not require prior authorization.

TIVICAY (dolutegravir) tablet TIVICAY PD (dolutegravir) tablet for suspension TYBOST (cobicistat) tablet VOCABRIA (cabotegravir) tablet		
Combination Agents		
No PA Required Abacavir/Lamivudine tablet ATRIPLA (efavirenz/Emtricitabine/TDF) tablet BIKTARVY (bictegravir/emtricitabine/TAF) tablet CIMDUO (lamivudine/TDF) tablet COMBIVIR (lamivudine/zidovudine) tablet COMPLERA (emtricitabine/rilpivirine/TDF) tablet DELSTRIGO (doravirine/lamivudine/TDF) tablet DESCOVY (emtricitabine/TAF) tablet DOVATO (dolutegravir/lamivudine) tablet Efavirenz/Emtricitabine/TDF tablet Efavirenz/Lamivudine/TDF tablet Emtricitabine/TDF tablet EPZICOM (abacavir/lamivudine) tablet EVOTAZ (atazanavir/cobicistat) tablet GENVOYA (elvitegravir/cobicistat/ emtricitabine/TAF) tablet		All products are preferred and do not require prior authorization.

JULUCA (dolutegravir/rilpivirine) tablet KALETRA (lopinavir/ritonavir) solution, tablet Lamivudine/Zidovudine tablet Lopinavir/Ritonavir solution, tablet ODEFSEY (emtricitabine/rilpivirine/TAF) tablet PREZCOBIX (darunavir/cobicistat) tablet STRIBILD (elvitegravir/cobicistat/ emtricitabine/TDF) tablet SYMFI/SYMFI LO (efavirenz/lamivudine/TDF) tablet SYMTUZA (darunavir/cobicistat/ emtricitabine/TAF) tablet TRIUMEQ (abacavir/dolutegravir/ lamivudine) tablet TRIUMEQ PD (abacavir/dolutegravir) tablet for suspension TRIZIVIR (abacavir/lamivudine/zidovudine) tablet *TRUVADA (emtricitabine/TDF) tablet		

Therapeutic Drug Class: **TETRACYCLINES -** *Effective 7/1/2024*		
No PA Required	**PA Required**	
Doxycycline hyclate capsules Doxycycline hyclate tablets Doxycycline monohydrate 50mg, 100mg capsule Doxycycline monohydrate tablets Minocycline capsules	Demeclocycline tablet DORYX (doxycycline DR) tablet Doxycycline hyclate DR tablet Doxycycline monohydrate 75mg, 150mg capsule Doxycycline monohydrate suspension	Prior authorization for non-preferred tetracycline agents may be approved if member has trialed/failed a preferred doxycycline product AND preferred minocycline. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Prior authorization for liquid oral tetracycline formulations may be approved if member is unable to take a solid oral dosage form. **Nuzyra** (omadacycline) prior authorization may be approved if member meets all of the following criteria: the above "non-preferred" prior authorization criteria and the following:

	Minocycline IR, ER tablet MINOLIRA (minocycline ER) tablet MORGIDOX (doxycycline/skin cleanser) kit NUZYRA (omadacycline) tablet SOLODYN ER (minocycline ER) tablet Tetracycline capsule XIMINO (minocycline ER) capsule	• Member has trialed and failed† therapy with a preferred doxycycline product and preferred minocycline OR clinical rationale is provided describing why these medications cannot be trialed (including resistance and sensitivity) AND • Member has diagnosis of either Community Acquired Bacterial Pneumonia (CABP) or Acute Bacterial Skin and Skin Structure Infection (ABSSSI) or clinical rationale and supporting literature describing/supporting intended use AND one of the following: o If member diagnosis is ABSSSI, member must have trial and failure† of sulfamethoxazole/trimethoprim product in addition to preferred tetracyclines OR o If member diagnosis is CABP, member must have trial and failure† of either a beta-lactam antibiotic (amoxicillin/clavulanic acid) or a macrolide (azithromycin) AND • Maximum duration of use is 14 days †Failure is defined as lack of efficacy with 7-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

III. Cardiovascular

Therapeutic Drug Class: **ALPHA-BLOCKERS** - *Effective 7/1/2024*

No PA Required	**PA Required**	Non-preferred products may be approved following trial and failure of one preferred product (failure is defined as lack of efficacy with 4-week trial, allergy or intolerable side effects).
Prazosin capsule	MINIPRESS (prazosin) capsule	

Therapeutic Drug Class: **BETA-BLOCKERS** - *Effective 7/1/2024*

Beta-Blockers, Single Agent

No PA Required **(*Must meet eligibility criteria)**	**PA Required**	***HEMANGEOL (propranolol) oral solution** may be approved for members between 5 weeks and 1 year of age with proliferating infantile hemangioma requiring systemic therapy. Maximum dose: 1.7 mg/kg twice daily Non-preferred products may be approved following trial and failure with two preferred products (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). **INNOPRAN XL** (propranolol ER) capsule brand product formulation may be approved if meeting the following: • Request meets non-preferred criteria listed above AND • Member has trialed and failed therapy with a generic propranolol ER capsule formulation OR prescriber provides clinical rationale supporting why generic propranolol ER capsule product formulations cannot be trialed. Failure is
	Betaxolol tablet	
Acebutolol capsule	BYSTOLIC (nebivolol) tablet	
Atenolol tablet	CORGARD (nadolol) tablet	
Bisoprolol tablet	COREG (carvedilol) tablet	
Carvedilol IR tablet	COREG CR (carvedilol ER) capsule	
*HEMANGEOL (propranolol) solution	Carvedilol ER capsule	
	INDERAL LA/XL (propranolol ER) capsule	
Labetalol tablet	INNOPRAN XL (propranolol ER) capsule	

Metoprolol tartrate tablet Metoprolol succinate ER tablet Nadolol tablet Nebivolol tablet Propranolol IR tablet, solution Propranolol ER capsule	KASPARGO (metoprolol succinate) sprinkle capsule LOPRESSOR (metoprolol tartrate) tablet Pindolol tablet TENORMIN (atenolol) tablet Timolol tablet TOPROL XL (metoprolol succinate) tablet	defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions. **KAPSPARGO SPRINKLE (metoprolol succinate)** extended-release capsule may be approved for members ≥ 6 years of age that have difficulty swallowing or require medication administration via a feeding tube. Maximum dose: 200mg/day (adult); 50mg/day (pediatric) Members currently stabilized on timolol oral tablet non-preferred products may receive approval to continue on that product. Members currently stabilized on the non-preferred Bystolic (nebivolol) tablets may receive approval to continue on that product. Members currently stabilized on the non-preferred carvedilol ER capsules may receive approval to continue on that product.

Table 1: Receptor Selectivity and Other Properties of Preferred Beta Blockers

	ß$_1$	ß$_2$	Alpha-1 receptor antagonist	Intrinsic sympathomimetic activity (ISA)
Acebutolol	X			X
Atenolol	X			
Betaxolol	X			
Bisoprolol	X			
Carvedilol	X	X	X	
Labetalol	X	X	X	
Metoprolol succinate	X			
Metoprolol tartrate	X			
Nadolol	X	X		
Nebivolol	X			
Pindolol	X	X		X
Propranolol	X	X		

Beta-Blockers, Anti-Arrhythmics		
No PA Required	**PA Required**	
Sotalol tablet	BETAPACE/AF (sotalol) tablet	**SOTYLIZE (sotalol)** oral solution may be approved for members 3 days to < 5 years of age. For members ≥ 5 years of age, SOTYLIZE (sotalol) oral solution may be approved for members who are unable to take a solid oral dosage form OR members that have

	SOTYLIZE (sotalol) solution	trialed and failed therapy with one preferred product. (Failure is defined as allergy or intolerable side effects.) Maximum dose: 320 mg/day
Beta-Blockers, Combinations		
No PA Required Atenolol/Chlorthalidone tablet Bisoprolol/HCTZ tablet Metoprolol/HCTZ tablet	**PA Required** TENORETIC (atenolol/chlorthalidone) tablet ZIAC (bisoprolol/HCTZ) tablet	Non-preferred products may be approved following trial and failure with two preferred products (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).
Therapeutic Drug Class: **CALCIUM CHANNEL-BLOCKERS -** *Effective 7/1/2024*		
Dihydropyridines (DHPs)		
No PA Required Amlodipine tablet Felodipine ER tablet Nifedipine ER tablet Nifedipine IR capsule	**PA Required** ADALAT CC (nifedipine ER) tablet NORLIQVA (amlodipine) suspension KATERZIA (amlodipine) suspension Isradipine capsule Levamlodipine tablet Nicardipine capsule Nimodipine capsule Nisoldipine ER tablet NORVASC (amlodipine) tablet NYMALIZE (nimodipine) solution, oral syringe PROCARDIA XL (nifedipine ER) tablet SULAR (nisoldipine ER) tablet	Non-preferred products may be approved following trial and failure of two preferred agents. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions. **Nimodipine oral capsule** oral capsule may be approved for adult members (≥ 18 years of age) with subarachnoid hemorrhage **NYMALIZE (nimodipine)** oral syringe may be approved for adult members (≥ 18 years of age) with subarachnoid hemorrhage who also have a feeding tube or have difficulty swallowing solid dosage forms. Maximum dose: 360 mg/day for 21 days (6 syringes/day or 126 syringes/21 days) **KATERZIA (amlodipine)** suspension may be approved if meeting the following: • The member has a feeding tube or confirmed difficulty swallowing solid oral dosage forms OR cannot obtain the required dose through crushed amlodipine tablets AND • For members < 6 years of age, the prescriber confirms that the member has already been receiving the medication following initiation in a hospital or other clinical setting
Non-Dihydropyridines (Non-DHPs)		
No PA Required	**PA Required**	

Diltiazem IR tablet Diltiazem CD/ER capsule Verapamil IR, ER tablet Verapamil ER 120 mg, 180 mg, 240 mg capsule	CALAN SR (verapamil ER) tablet CARDIZEM (diltiazem) tablet CARDIZEM CD/LA (diltiazem CD/ER) capsule, tablet Diltiazem ER/LA tablet TIAZAC ER (diltiazem ER) capsule Verapamil ER 360 mg capsule Verapamil PM ER 100 mg, 200 mg, 300 mg capsule VERELAN/PM (verapamil ER) pellet capsule	Non-preferred products may be approved following trial and failure of three preferred agents. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.
Therapeutic Drug Class: **ANGIOTENSIN MODIFIERS** - *Effective 7/1/2024*		
Angiotensin-converting enzyme inhibitors (ACE Inh)		
No PA Required Benazepril tablet Enalapril tablet Fosinopril tablet Lisinopril tablet Quinapril tablet Ramipril tablet	**PA Required** ACCUPRIL (quinapril) tablet ALTACE (ramipril) capsule Captopril tablet Enalapril solution EPANED (enalapril) solution LOTENSIN (benazepril) tablet Moexipril tablet Perindopril tablet PRINIVIL (lisinopril) tablet QBRELIS (lisinopril) solution Trandolapril tablet VASOTEC (enalapril) tablet	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction). ***Enalapril solution** may be approved without trial and failure of three preferred agents for members who are unable to take a solid oral dosage form. ***QBRELIS (lisinopril) solution** may be approved for members 6 years of age or older who are unable to take a solid oral dosage form and have trialed and failed Epaned (enalapril) solution. Failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

	ZESTRIL (lisinopril) tablet	
ACE Inhibitor Combinations		
No PA Required Amlodipine/Benazepril capsule Benazepril/HCTZ tablet Enalapril/HCTZ tablet Lisinopril/HCTZ tablet	**PA Required** ACCURETIC (quinapril/HCTZ) tablet Captopril/HCTZ tablet Fosinopril/HCTZ tablet LOTENSIN HCT (benazepril/HCTZ) tablet LOTREL (amlodipine/benazepril) capsule Quinapril/HCTZ tablet VASERETIC (enalapril/HCTZ) tablet ZESTORETIC (lisinopril/HCTZ) tablet	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction).
Angiotensin II receptor blockers (ARBs)		
No PA Required Irbesartan tablet Losartan tablet Olmesartan tablet Telmisartan tablet Valsartan tablet	**PA Required** ATACAND (candesartan) tablet AVAPRO (irbesartan) tablet BENICAR (olmesartan) tablet Candesartan tablet COZAAR (losartan) tablet DIOVAN (valsartan) tablet EDARBI (azilsartan) tablet Eprosartan tablet MICARDIS (telmisartan) tablet Valsartan solution	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction).
ARB Combinations		
Preferred	**Non-Preferred**	

No PA Required (Unless indicated*)	PA Required	
*ENTRESTO (sacubitril/valsartan) tablet[BNR] Irbesartan/HCTZ tablet Losartan/HCTZ tablet Olmesartan/Amlodipine tablet Olmesartan/HCTZ tablet Valsartan/Amlodipine tablet Valsartan/HCTZ tablet	ATACAND HCT (candesartan/HCTZ) tablet AVALIDE (irbesartan/HCTZ) tablet AZOR (olmesartan/amlodipine) tablet BENICAR HCT (olmesartan/HCTZ) tablet Candesartan/HCTZ tablet DIOVAN HCT (valsartan/HCTZ) tablet EDARBYCLOR (azilsartan/chlorthalidone) tablet ENTRESTO (sacubitril/valsartan) sprinkles EXFORGE (valsartan/amlodipine) tablet EXFORGE HCT (valsartan/amlodipine/HCTZ) tablet HYZAAR (losartan/HCTZ) tablet MICARDIS HCT (telmisartan/HCTZ) tablet Olmesartan/amlodipine/HCTZ tablet Telmisartan/amlodipine tablet Telmisartan/HCTZ tablet TRIBENZOR (olmesartan/amlodipine/HCTZ) tablet Valsartan/Amlodipine/HCTZ tablet	Non-preferred ACE inhibitors, ACE inhibitor combinations, ARBs, ARB combinations, renin inhibitors, and renin inhibitor combination products may be approved for members who have trialed and failed treatment with three preferred products (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction). ***ENTRESTO** (sacubitril/valsartan) may be approved for members if the following criteria are met: • Member is 1 to 17 years of age and has a diagnosis of symptomatic heart failure with systemic left ventricular systolic dysfunction (LVSD) and/or has chronic heart failure with a below-normal left ventricular ejection fraction (LVEF) OR • Member is ≥ 18 years of age and has a diagnosis of chronic heart failure. • Diagnosis will be verified through automated verification (AutoPA) of the appropriate corresponding ICD-10 diagnosis codes related to the indicated use of the medication.
Renin Inhibitors & Renin Inhibitor Combinations		
	PA Required Aliskiren tablet	Non-preferred renin inhibitors and renin inhibitor combination products may be approved for members who have failed treatment with three preferred products from the

	TEKTURNA (aliskiren) tablet TEKTURNA HCT (aliskiren/HCTZ) tablet	angiotensin modifier class (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction). Renin inhibitors and combinations will not be approved in patients with diabetes. Renin inhibitors are contraindicated when used in combination with an ACE-inhibitor, ACE-inhibitor combination, ARB, or ARB-combination.
Therapeutic Drug Class: **PULMONARY ARTERIAL HYPERTENSION THERAPIES -** *Effective 7/1/2024*		
Phosphodiesterase Inhibitors		
Preferred ***Must meet eligibility criteria**	**Non-Preferred** **PA Required**	***Eligibility criteria for preferred products:**
*Sildenafil tablet, oral suspension *Tadalafil 20mg tablet	ADCIRCA (tadalafil) tablet ALYQ (tadalafil) tablet LIQREV (sildenafil) suspension REVATIO (sildenafil) suspension, tablet TADLIQ suspension	Preferred sildenafil and tadalafil tablet formulations may be approved for a diagnosis of pulmonary hypertension or right-sided heart failure. **Sildenafil suspension** may be approved for a diagnosis of pulmonary hypertension for members < 5 years of age or members ≥ 5 years of age who are unable to take/swallow tablets. Non-preferred oral tablet products may be approved if meeting the following: • Member has a diagnosis of pulmonary hypertension **AND** • Member has trialed and failed treatment with preferred sildenafil tablet **AND** preferred tadalafil tablet. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction. Members who have been previously stabilized on a non-preferred product may receive approval to continue on the medication. Non-preferred oral liquid products may be approved if meeting the following: • Member has a diagnosis of pulmonary hypertension AND • Request meets one of the following: o Member has trialed and failed treatment with one preferred oral liquid formulation (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction) OR o Prescriber verifies that the member is unable to take a solid oral dosage form that there is clinical necessity for use of a regimen with a less frequent dosing interval.
Endothelin Receptor Antagonists		
Preferred ***Must meet eligibility criteria**	**Non-Preferred** **PA Required**	***Eligibility Criteria for all agents in the class**

*Ambrisentan tablet *Bosentan 62.5mg, 125mg tablet	LETAIRIS (ambrisentan) tablet OPSUMIT (macitentan) tablet TRACLEER (bosentan) 32mg tablet for suspension TRACLEER (bosentan) 62.5mg, 125mg tablet	Approval may be granted for a diagnosis of pulmonary hypertension. Member and prescriber should be enrolled in applicable REMS program for prescribed medication. Non-preferred agents may be approved for members who have trialed and failed two preferred agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Members who have been previously stabilized on a non-preferred product may receive approval to continue the medication.
Prostacyclin Analogues and Receptor Agonists		
Preferred **(*Must meet eligibility criteria)** *FLOLAN (epoprostenol) vial *ORENITRAM (treprostinil ER) tablet, titration kit *VENTAVIS (iloprost) inhalation solution	**Non-Preferred** **PA Required** Epoprostenol vial REMODULIN (treprostinil) vial Treprostinil vial TYVASO (treprostinil) inhaler, inhalation solution UPTRAVI (selexipag) tablet, dose pack, vial VELETRI (epoprostenol) vial	***Eligibility Criteria for all agents in the class** Approval will be granted for a diagnosis of pulmonary hypertension. Non-preferred products may be approved for members who have failed treatment with a Preferred Product. (Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication to IV therapy or significant drug-drug interaction). Members who have been previously stabilized on a non-preferred product may receive approval to continue on the medication.
Guanylate Cyclase (sGC) Stimulator		

	Non-Preferred
	PA Required
	
	ADEMPAS (riociguat) tablet
		ADEMPAS (riociguat) may be approved for members who meet the following criteria:
		• For members of childbearing potential:
		  ○ Member is not pregnant and is able to receive monthly pregnancy tests while taking ADEMPAS and one month after stopping therapy **AND**
		  ○ Member and their partners are utilizing one of the following contraceptive methods during treatment and for one month after stopping treatment (IUD, contraceptive implants, tubal sterilization, a hormone method with a barrier method, two barrier methods, vasectomy with a hormone method, or vasectomy with a barrier method)
		AND
		• Member has a CrCl ≥ 15 mL/min and is not on dialysis **AND**
		• Member does not have severe liver impairment (Child Pugh C) **AND**
		• Member has a diagnosis of persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment or has inoperable CTEPH **OR**
		• Member has a diagnosis of pulmonary hypertension and has failed treatment with a preferred product for pulmonary hypertension. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction).

Therapeutic Drug Class: **LIPOTROPICS** - *Effective 7/1/2024*		
Bile Acid Sequestrants		
No PA Required Colesevelam tablet Colestipol tablet Cholestyramine packet, light packet, powder	**PA Required** Colesevelam packet COLESTID (colestipol) tablet, granules Colestipol granules QUESTRAN (cholestyramine/sugar) packet, powder QUESTRAN LIGHT (cholestyramine/ aspartame) packet, powder WELCHOL (colesevelam) packet, tablet	Non-preferred bile acid sequestrants may be approved if the member has failed treatment with 2 preferred products in the last 12 months (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred lipotropic agents with a preferred product with same strength, dosage form, and active ingredient may be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ezetimibe and Zetia) and 2 additional agents. (Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).
Fibrates		
No PA Required Fenofibric acid DR (generic Trilipix) capsule Fenofibrate capsule, tablet (generic Lofibra/Tricor) Gemfibrozil tablet	**PA Required** ANTARA (fenofibrate) capsule Fenofibric acid tablet Fenofibrate capsule (generic Antara/Fenoglide/Lipofen) FENOGLIDE (fenofibrate) tablet LIPOFEN (fenofibrate) capsule LOPID (gemfibrozil) tablet TRICOR (fenofibrate nano) tablet TRILIPIX (fenofibric acid) capsule	Non-preferred fibrates may be approved if the member has failed treatment with generic gemfibrozil or generic fenofibrate and niacin ER in the last 12 months (failure is defined as lack of efficacy with 4-week trial of each drug, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred lipotropic agents with a preferred product with same strength, dosage form, and active ingredient may be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ezetimibe and Zetia) and 2 additional agents. (Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).
Other Lipotropics		
No PA Required **(*Must meet eligibility criteria)**	**PA Required**	Non-preferred lipotropic agents with a preferred product with same strength, dosage form, and active ingredient may be approved with adequate trial and/or failure of the preferred product with the same ingredient (such as preferred ezetimibe and Zetia) and 2

<table>
<tr>
<td>Ezetimibe tablet

Niacin ER tablet

*Omega-3 ethyl esters capsule (generic Lovaza)</td>
<td>Icosapent ethyl capsule

LOVAZA (omega-3 ethyl esters) capsule

NEXLETOL (bempedoic acid) tablet

NEXLIZET (bempedoic acid/ezetimibe) tablet

ZETIA (ezetimibe) tablet</td>
<td>additional agents. (Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

***Omega-3 ethyl esters** (generic Lovaza) may be approved for members who have a baseline triglyceride level ≥ 500 mg/dL

Lovaza (brand name) may be approved if meeting the following:
• Member has a baseline triglyceride level ≥ 500 mg/dl AND
• Member has failed an adequate trial of omega-3 Ethyl Esters AND an adequate trial of gemfibrozil or fenofibrate (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions)

Nexletol (bempedoic acid) or **Nexlizet** (bempedoic acid/ezetimibe) may be approved if meeting the following criteria:
• Member is ≥ 18 years of age **AND**
• Member is not pregnant **AND**
• Member is not receiving concurrent simvastatin > 20 mg daily or pravastatin > 40 mg daily **AND**
• Member has a diagnosis of either heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease (see definition below), **AND**
<table><tr><td>Conditions Which Define Clinical Atherosclerotic Cardiovascular Disease</td></tr><tr><td>• Acute Coronary Syndrome
• History of Myocardial Infarction
• Stable or Unstable Angina
• Coronary or other Arterial Revascularization
• Stroke
• Transient Ischemic Attack
• Peripheral Arterial Disease of Atherosclerotic Origin</td></tr></table>
• Member is concurrently adherent (> 80% of the past 180 days) on a maximally tolerated dose of a high intensity statin therapy (atorvastatin ≥ 40 mg daily **OR** rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product]) **AND** ezetimibe (as a single-entity or as a combination product) concomitantly for ≥ 8 continuous weeks), **AND**
• If intolerant to a statin due to side effects, member must have a one month documented trial with at least two other maximally dosed statins in addition to ezetimibe. For members with a past or current incidence of rhabdomyolysis, a one-month trial and failure of a statin is not required, **AND**
• Member has a treated LDL > 70 mg/dL for a clinical history of ASCVD **OR** LDL > 100 mg/dL if familial hypercholesterolemia
Initial Approval: 1 year

Reauthorization: Reauthorization may be approved for 1 year with provider attestation of medication safety and efficacy during the initial treatment period</td>
</tr>
</table>

Therapeutic Drug Class: **STATINS** -*Effective 7/1/2024*		
No PA Required	**PA Required**	
Atorvastatin tablet Lovastatin tablet Pravastatin tablet Rosuvastatin tablet Simvastatin tablet	ALTOPREV (lovastatin ER) tablet ATORVALIQ (atorvastatin) suspension CRESTOR (rosuvastatin) tablet EZALLOR (rosuvastatin) sprinkle capsule FLOLIPID (simvastatin) suspension Fluvastatin capsule, ER tablet LESCOL XL (fluvastatin ER) tablet LIPITOR (atorvastatin) tablet LIVALO (pitavastatin) tablet Pitavastatin tablet ZOCOR (simvastatin) tablet ZYPITAMAG (pitavastatin) tablet	Non-preferred Statins may be approved following trial and failure of treatment with two preferred products (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). Age Limitations: Altoprev will not be approved for members < 18 years of age. Fluvastatin will not be approved for members < 10 years of age. Livalo will not be approved for members < 8 years of age.
Therapeutic Drug Class: **STATIN COMBINATIONS** -*Effective 7/1/2024*		
No PA Required	**PA Required**	
Simvastatin/Ezetimibe tablet	Atorvastatin/Amlodipine tablet CADUET (atorvastatin/amlodipine) tablet VYTORIN (simvastatin/ezetimibe) tablet	Non-preferred Statin combinations may be approved following trial and failure of treatment with two preferred products (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). Age Limitations: Vytorin and generic ezetimibe/simvastatin will not be approved for members < 18 years of age. Caduet and generic amlodipine/atorvastatin will not be approved for members < 10 years of age.
Therapeutic Drug Class: **Movement Disorders** -*Effective 7/1/2024*		
No PA Required **(*Must meet eligibility criteria)**	**PA Required**	***Eligibility Criteria for all agents in the class** • Member is ≥18 years of age AND • Member has been diagnosed with tardive dyskinesia or chorea associated with Huntington's disease AND • If the member has hepatic impairment, FDA labeling for use has been evaluated AND
*Austedo (deutetrabenazine) tablet	Xenazine (tetrabenazine) tablet	

*Austedo (deutetrabenazine) XR tablet, titration pack *Ingrezza (valbenazine) capsule, initiation pack * Tetrabenazine tablet		• <u>For chorea associated with Huntington's disease:</u> o Member has been evaluated for untreated or inadequately treated depression and member has been counseled regarding the risks of depression and suicidality associated with agents in this therapeutic class. AND • <u>For tardive dyskinesia:</u> o If applicable, the need for ongoing treatment with 1st and 2nd generation antipsychotics, metoclopramide, or prochlorperazine has been evaluated AND o A baseline Abnormal Involuntary Movement Scale (AIMS) has been performed. Xenazine (tetrabenazine) Maximum dose 50 mg/day (PA available for extensive metabolizers of CYP2D6) Ingrezza (valbenazine) Quantity limits: • 40 mg: 1.767 capsules/day • 60 mg: 1 capsule/day • 80 mg: 1 capsule/day Austedo (deutetrabenazine) Maximum dose: 48 mg/day Non-preferred Movement Disorder Agents may be approved for members ≥18 years of age after trial and failure of two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.

IV. Central Nervous System

Therapeutic Drug Class: **ANTICONVULSANTS -Oral**-*Effective 4/1/2024*

No PA Required	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.***	Members currently stabilized (in outpatient or acute care settings) on any non-preferred medication in this class may receive prior authorization approval to continue on that medication. Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.
Barbiturates		
Phenobarbital elixir, solution, tablet	MYSOLINE (primidone) tablet	<u>Non-Preferred Products Newly Started for Treating Seizure Disorder or Convulsions:</u> Non-preferred medications newly started for members with a diagnosis of seizure disorder/convulsions may be approved if the following criteria are met:

Primidone tablet	
Hydantoins	
DILANTIN (phenytoin) 30 mg capsules, Infatab, suspension PHENYTEK (phenytoin ER) capsule Phenytoin suspension, chewable, ER capsule	DILANTIN (phenytoin ER), 100 mg capsules
Succinamides	
Ethosuximide capsule, solution	CELONTIN (methsuximide) Kapseal Methsuximide capsule ZARONTIN (ethosuximide) capsule, solution
Benzodiazepines	
Clobazam tablet, suspension Clonazepam tablet, ODT	KLONOPIN (clonazepam) tablet ONFI (clobazam) suspension, tablet SYMPAZAN (clobazam) SL film
Valproic Acid and Derivatives	
DEPAKOTE (divalproex DR) sprinkle capsule Divalproex sprinkle capsule, DR tablet, ER tablet Valproic acid capsule, solution	DEPAKOTE (divalproex DR) tablet DEPAKOTE ER (divalproex ER) tablet
Carbamazepine Derivatives	
Carbamazepine IR tablet, ER tablet, chewable, ER capsule, suspension	APTIOM (eslicarbazepine) tablet EQUETRO (carbamazepine) capsule

- The requested medication is being prescribed by a practitioner who has sufficient education and experience to safely manage treatment **AND**
- The request meets minimum age and maximum dose limits listed in Table 1 **AND**
- For medications indicated for use as adjunctive therapy, the medication is being used in conjunction with another medication indicated for treatment of seizure disorder/convulsions **AND**
- The request meets additional criteria listed for any of the following:

APTIOM (eslicarbazepine):
- Member has history of trial and failure‡ of any carbamazepine-containing product

BRIVIACT (brivaracetam):
- Member has history of trial and failure‡ of any levetiracetam-containing product

DIACOMIT (stiripentol):
- Member is concomitantly taking clobazam **AND**
- Member has diagnosis of seizures associated with Dravet syndrome

ELEPSIA XR (levetiracetam ER) tablet
- Member has history of trial and failure‡ of levetiracetam ER (KEPPRA XR)

EPIDIOLEX (cannabidiol):
- Member has diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet Syndrome **OR**
- Member has a diagnosis of seizures associated with tuberous sclerosis complex (TSC).

FINTEPLA (fenfluramine):
- Member has a diagnosis of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome

OXTELLAR XR (oxcarbazepine ER):
- Member is being treated for partial-onset seizures **AND**
- Member has history of trial and failure‡ of any carbamazepine or oxcarbazepine-containing product

SPRITAM (levetiracetam) tablet for suspension
- Member has history of trial and failure‡ of levetiracetam solution

SYMPAZAN (clobazam) film:
- Member has history of trial and failure‡ of clobazam tablet or solution **OR**
- Provider attests that member cannot take clobazam tablet or solution

CARBATROL ER (carbamazepine) capsule Oxcarbazepine tablet TEGRETOL (carbamazepine) suspension, tablet TEGRETOL XR (carbamazepine ER) tablet TRILEPTAL[BNR] (oxcarbazepine) suspension	Oxcarbazepine suspension OXTELLAR XR (oxcarbazepine) tablet TRILEPTAL (oxcarbazepine) tablet
Lamotrigines	
LAMICTAL (lamotrigine) chewable/dispersible dose pack[BNR], tablet Lamotrigine IR tablet, ER tablet, chewable/dispersible tablet, ODT	LAMICTAL (lamotrigine) ODT, ODT dose pack LAMICTAL XR (lamotrigine ER) tablet, dose pack Lamotrigine ER/IR/ODT dose packs
Topiramates	
Topiramate tablet, sprinkle capsule	EPRONTIA (topiramate) solution QUDEXY XR (topiramate) capsule TOPAMAX (topiramate) tablet, sprinkle capsule Topiramate ER capsule TROKENDI XR (topiramate ER) capsule
Brivaracetam/Levetiracetam	
Levetiracetam IR tablet, ER tablet, solution	BRIVIACT (brivaracetam) solution, tablet ELEPSIA XR (levetiracetam ER) tablet

Non-Preferred Products Newly Started for Non-Seizure Disorder Diagnoses:

Non-preferred medications newly started for non-seizure disorder diagnoses may be approved if meeting the following criteria:

- Member has history of trial and failure[‡] of two preferred agents AND
- The prescription meets minimum age and maximum dose limits listed in Table 1.

[‡]Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, documented contraindication to therapy, or inability to take preferred formulation. Members identified as HLA-B*15:02 positive, carbamazepine and oxcarbazepine should be avoided per Clinical Pharmacogenetics Implementation Consortium Guideline. This may be considered a trial for prior authorization approvals of a non-preferred agent.

Table 1: Non-preferred Product Minimum Age and Maximum Dose

	Minimum Age**	Maximum Dose**
Barbiturates		
primidone (MYSOLINE)		2,000 mg per day
Benzodiazepines		
clobazam (ONFI) suspension, tablet	2 years	40 mg per day
clobazam film (SYMPAZAN)	2 years	40 mg per day
clonazepam (KLONOPIN)		20 mg per day
Brivaracetam/Levetiracetam		
brivaracetam (BRIVIACT)	1 month	200 mg per day
levetiracetam (KEPPRA)	1 month	3,000 mg per day
levetiracetam (SPRITAM)	4 years	3,000 mg per day
levetiracetam ER (ELEPSIA XR)	12 years	3,000 mg per day
levetiracetam ER (KEPPRA XR)	12 years	3,000 mg per day
Carbamazepine Derivatives		
carbamazepine (EPITOL)		1,600 mg per day
carbamazepine ER (EQUETRO)		1,600 mg per day
eslicarbazepine (APTIOM)	4 years	1,600 mg per day
oxcarbazepine ER (OXTELLAR XR)	6 years	2,400 mg per day
Hydantoins		
phenytoin ER (DILANTIN) 100mg capsules, suspension, Infatab		1,000 mg loading dose 600 mg/day maintenance dose
Lamotrigines		
lamotrigine IR (LAMICTAL)	2 years	500 mg per day
lamotrigine (LAMICTAL ODT)	2 years	500 mg per day
lamotrigine ER (LAMICTAL XR)	13 years	600 mg per day

	KEPPRA (levetiracetam) tablet, solution KEPRA XR (levetiracetam ER) tablet SPRITAM (levetiracetam) tablet
Other	
*Felbamate suspension FELBATOL (felbamate) suspension FELBATOL (felbamate) [BNR] tablet Lacosamide solution, tablet Rufinamide tablet Zonisamide capsule	BANZEL (rufinamide) suspension, tablet DIACOMIT (stiripentol) capsule, powder packet EPIDIOLEX (cannabidiol) solution Felbamate tablet FINTEPLA (fenfluramine) solution FYCOMPA (perampanel) suspension, tablet GABITRIL (tiagabine) tablet Lacosamide UD solution MOTPOLY XR (lacosamide) capsule Rufinamide suspension SABRIL (vigabatrin) powder packet, tablet Tiagabine tablet Vigabatrin tablet, powder packet VIGAFYDE (vigabatrin) solution VIMPAT (lacosamide) solution, kit, tablet XCOPRI (cenobamate) tablet, pack ZONISADE (zonisamide) suspension ZTALMY (ganaxolone) suspension

Succinamides		
ethosuximide (ZARONTIN)		25 mg/kg/day
methsuximide (CELONTIN)		Not listed
Valproic Acid and Derivatives		
divalproex ER (DEPAKOTE ER)	10 years	60 mg/kg/day
Topiramates		
topiramate (TOPAMAX)	2 years	400 mg per day
topiramate ER (QUDEXY XR)	2 years	400 mg per day
topiramate ER (TROKENDI XR)	6 years	400 mg per day
Other		
cannabidiol (EPIDIOLEX)	1 year	25 mg/kg/day
cenobamate (XCOPRI)	18 years	400 mg per day
felbamate tablet, suspension	2 years	3,600 mg per day
fenfluramine (FINTEPLA)	2 years	26 mg per day
lacosamide (VIMPAT)	1 month	400 mg per day
perampanel (FYCOMPA)	4 years	12 mg per day
rufinamide (BANZEL) tablet and suspension	1 year	3,200 mg per day
stiripentol (DIACOMIT)	6 months (weighing ≥ 7 kg)	3,000 mg per day
tiagabine	12 years	56 mg per day
tiagabine (GABITRIL)	12 years	56 mg per day
vigabatrin	1 month	3,000 mg per day
vigabatrin (SABRIL)	1 month	3,000 mg per day
vigabatrin (VIGADRONE) powder packet	1 month	3,000 mg per day
zonisamide (ZONEGRAN)	16 years	600 mg per day
**Limits based on data from FDA package insert. Approval for age/dosing that falls outside of the indicated range may be evaluated on a case-by-case basis.		

No PA Required	PA Required	
Bupropion IR, SR, XL tablet Citalopram tablet, solution Desvenlafaxine succinate ER (generic Pristiq) tablet Duloxetine (generic Cymbalta) capsule Escitalopram tablet Fluoxetine capsule, solution, 60 mg tablet Fluvoxamine tablet Mirtazapine tablet, ODT Paroxetine IR tablet Sertraline tablet, solution Trazodone tablet Venlafaxine IR tablet Venlafaxine ER capsules	***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** APLENZIN (bupropion ER) tablet AUVELITY ER (dextromethorphan/bupropion) tablet Bupropion XL (generic Forfivo XL) tablet CELEXA (citalopram) tablet Citalopram hydrobromide capsule CYMBALTA (duloxetine) capsule Desvenlafaxine fumarate ER tablet DRIZALMA (duloxetine) sprinkle capsule EFFEXOR XR (venlafaxine ER) capsule Escitalopram solution FETZIMA (levomilnacipran ER) capsule, titration pack Fluoxetine IR tablet, DR capsule Fluvoxamine ER capsule FORFIVO XL (bupropion ER) tablet LEXAPRO (escitalopram) tablet Nefazodone tablet Paroxetine CR/ER tablet, suspension Paroxetine mesylate capsule PAXIL (paroxetine) tablet, suspension PAXIL CR (paroxetine ER) tablet PEXEVA (paroxetine mesylate) tablet PRISTIQ (desvenlafaxine succinate ER) tablet PROZAC (fluoxetine) Pulvule REMERON (mirtazapine) Soltab (ODT), tablet	Non-preferred products may be approved for members who have failed adequate trial with two preferred newer generation anti-depressant products. If two preferred newer generation anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred products FDA approved for that indication (failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction). **Zurzuvae** (zuranolone) may be approved if meeting the following criteria: • Member is ≥ 18 years of age **AND** • Member has a diagnosis of postpartum depression based on Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria for a major depressive episode **AND** • Member is not currently pregnant **AND** • Prescriber attests that the member has been counseled and has been engaged in shared decision making with regard to: o The importance of effective contraception during zuranolone treatment, as zuranolone may cause fetal harm **AND** o The potential risks for the breastfed child and the lack of data supporting safe use of zuranolone during lactation **AND** o Consideration for the favorable long-term safety data associated with use of SSRIs as first-line, recommended therapies for perinatal depressive disorders by the American College of Obstetricians and Gynecologists (ACOG) or SNRIs as reasonable ACOG-recommended alternatives **AND** • Prescriber attests that the member has been counseled to refrain from engaging in potentially hazardous activities requiring mental alertness, including driving, for ≥ 12 hours after each zuranolone dose **AND** • The member has been counseled to take the medication with 400 to 1,000 calories of food containing 25% to 50% fat **AND** • If patient is taking another oral antidepressant medication, the dose has been stable for ≥ 30 days **AND** • Prescriber verifies that concomitant medications have been assessed for potential drug interactions (CNS depressants, CYP3A4 inhibitors, CYP3A4 inducers) and any needed dosage adjustments for zuranolone have been made in accordance with package labeling **AND** • Baseline renal and hepatic function have been assessed and prescriber verifies that dosing is appropriate in accordance with package labeling. Quantity Limit:

	Sertraline capsule TRINTELLIX (vortioxetine) tablet Venlafaxine ER tablet Venlafaxine besylate ER tablet VIIBRYD (vilazodone) tablet, dose pack Vilazodone tablet WELLBUTRIN SR, XL (bupropion) tablet ZOLOFT (sertraline) tablet, oral concentrate ZURZUVAE (zuranolone) capsule	• Zurzuvae 20 mg and 25 mg: 28 capsules/14 days • Zurzuvae 30 mg: 14 capsules/14 days Maximum dose: 50 mg once daily Duration of Approval: Approval will allow 30 days to fill for one 14-day course of treatment per postpartum period **Citalopram** doses higher than 40mg/day for ≤60 years of age and 20mg/day for >60 years of age will require prior authorization. Please see the FDA guidance at: https://www.fda.gov/drugs/drugsafety/ucm297391.htm for important safety information. Members currently stabilized on a non-preferred newer generation antidepressant may receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**
Therapeutic Drug Class: **MONOAMINE OXIDASE INHIBITORS (MAOIs)** -*Effective 4/1/2024*		
	PA Required EMSAM (selegiline) patch MARPLAN (isocarboxazid) tablet NARDIL (phenelzine) tablet Phenelzine tablet Tranylcypromine tablet	Non-preferred products may be approved for members who have failed adequate trial (8 weeks) with three preferred anti-depressant products. If three preferred anti-depressant products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all preferred anti-depressant products FDA approved for that indication. (Failure is defined as: lack of efficacy after 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction) Members currently stabilized on a Non-preferred MAOi antidepressant may receive approval to continue that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**
Therapeutic Drug Class: **TRICYCLIC ANTI-DEPRESSANTS (TCAs)** -*Effective 4/1/2024*		
No PA Required Amitriptyline tablet Clomipramine capsule Desipramine tablet Doxepin 10mg, 25mg, 50mg, 75mg, 100mg, 150mg capsule, oral concentrate Imipramine HCl tablet Nortriptyline capsule	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** Amoxapine tablet ANAFRANIL (clomipramine) capsule Imipramine pamoate capsule NORPRAMIN (desipramine) tablet Nortriptyline solution	Non-preferred products may be approved for members who have failed adequate trial (8 weeks) with three preferred tricyclic products. If three preferred products are not available for indication being treated, approval of prior authorization for non-preferred products will require adequate trial of all tricyclic preferred products FDA approved for that indication. (Failure is defined as: lack of efficacy after 8-week trial, allergy, intolerable side effects, or significant drug-drug interaction) Members currently stabilized on a non-preferred tricyclic antidepressant may receive approval to continue on that agent for one year if medically necessary. **Verification may be provided from the prescriber or the pharmacy.**

	PAMELOR (nortriptyline) capsule Protriptyline tablet Trimipramine capsule	
Therapeutic Drug Class: **ANTI-PARKINSON'S AGENTS** -*Effective 4/1/2024*		
Dopa decarboxylase inhibitors, dopamine precursors and combinations		
No PA Required Carbidopa/Levodopa IR, ER tablet Carbidopa/Levodopa/Entacapone tablet	**PA Required** Carbidopa tablet Carbidopa/Levodopa ODT DHIVY (carbidopa/levodopa) tablet DUOPA (carbidopa/levodopa) suspension INBRIJA (levodopa) capsule for inhalation LODOSYN (carbidopa) tablet RYTARY ER (carbidopa/levodopa) capsule SINEMET (carbidopa/levodopa) IR tablet STALEVO (carbidopa/levodopa/ entacapone) tablet	Non-preferred agents may be approved with adequate trial and failure of carbidopa-levodopa IR and ER formulations (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). Carbidopa or levodopa single agent products may be approved for members with diagnosis of Parkinson's Disease as add-on therapy to carbidopa-levodopa. Non-preferred medications that <u>are not</u> prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval for other FDA-labeled indications without meeting trial and failure step therapy criteria. Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred. Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.
MAO-B inhibitors		
No PA Required Rasagiline tablet Selegiline capsule, tablet	**PA Required** AZILECT (rasagiline) tablet XADAGO (safinamide) tablet ZELAPAR (selegiline) ODT	Non-preferred agents may be approved with adequate trial and failure of selegiline capsule or tablet (failure is defined as lack of efficacy with a 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred medications that are not prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval for other FDA-labeled indications without meeting trial and failure step therapy criteria. Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred. Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.

Dopamine Agonists		
No PA Required Pramipexole IR tablet Ropinirole IR tablet	**PA Required** APOKYN (apomorphine) SC cartridge Apomorphine SC cartridge Bromocriptine capsule, tablet KYNMOBI (apomorphine) SL film MIRAPEX (pramipexole) ER tablet NEUPRO (rotigotine) patch PARLODEL (bromocriptine) capsule, tablet Pramipexole ER tablet Ropinirole ER tablet	Non-preferred agents may be approved with adequate trial and failure of ropinirole IR AND pramipexole IR (failure is defined as lack of efficacy with 4-week trial, documented contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions). **APOKYN (apomorphine subcutaneous cartridge)** may be approved if meeting the following: • APOKYN (apomorphine) is being used as an adjunct to other medications for acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) in patients with advanced Parkinson's disease AND • Due to the risk of profound hypotension and loss of consciousness, member is not concomitantly using a 5HT3 antagonist such as ondansetron, granisetron, dolasetron, palonosetron or alosetron. Maximum dose: 6mg (0.6mL) three times per day **KYNMOBI (apomorphine sublingual film)** may be approved if meeting the following: • KYNMOBI (apomorphine) is being used for the acute, intermittent treatment of "off" episodes in patients with Parkinson's disease AND • Due to the risk of profound hypotension and loss of consciousness, member must not be concomitantly using a 5HT3 antagonist such as ondansetron, granisetron, dolasetron, palonosetron or alosetron. Maximum dose: 30mg five times per day Non-preferred medications that <u>are not</u> prescribed for Parkinson's Disease (or an indication related to Parkinson's Disease) may receive approval for other FDA-labeled indications without meeting trial and failure step therapy criteria. Members with history of trial and failure of a non-preferred Parkinson's Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred. Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.
Other Parkinson's agents		
No PA Required Amantadine capsule, solution/syrup Benztropine tablet	**PA Required** Amantadine tablet COMTAN (entacapone) tablet	Non-preferred agents may be approved with adequate trial and failure of two preferred agents (failure is defined as lack of efficacy with 4-week trial, documented contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions).

<table>
<tr>
<td>Trihexyphenidyl tablet, elixir</td>
<td>Entacapone tablet

GOCOVRI ER (amantadine ER) capsule

NOURIANZ (istradefylline) tablet

ONGENTYS (opicapone) capsule

OSMOLEX ER (amantadine) tablet

TASMAR (tolcapone) tablet

Tolcapone tablet</td>
<td>Non-preferred medications that <u>are not</u> prescribed for Parkinson’s Disease (or an indication related to Parkinson’s Disease) may receive approval for other FDA-labeled indications without meeting trial and failure step therapy criteria.

Members with history of trial and failure of a non-preferred Parkinson’s Disease agent that is the brand/generic equivalent of a preferred product (same strength, dosage form and active ingredient) may be considered as having met a trial and failure of the equivalent preferred.

Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.</td>
</tr>
<tr>
<td colspan="3">Therapeutic Drug Class: BENZODIAZEPINES (NON-SEDATIVE HYPNOTIC) Effective 4/1/2024</td>
</tr>
<tr>
<td>No PA Required
(*may be subject to age limitations)

Alprazolam IR, ER tablet*

Chlordiazepoxide capsule*

Clonazepam tablet, ODT

Clorazepate tablet*

Diazepam tablet*, solution

Lorazepam tablet*, oral concentrate

Oxazepam capsule*</td>
<td>PA Required

Alprazolam ODT, oral concentrate

ATIVAN (lorazepam) tablet

Diazepam Intensol

KLONOPIN (clonazepam) tablet

LOREEV (lorazepam ER) capsule

XANAX (alprazolam) tablet

XANAX XR (alprazolam ER) tablet</td>
<td>Non-preferred products may be approved following trial and failure of three preferred agents. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.

<u>Children</u>: Prior authorization will be required for all agents when prescribed for children <18 years of age (with the exception of oral solution products) and may be approved with prescriber verification of necessity of use for member age.

Diazepam Intensol may be approved following trial and failure of the preferred 5 mg/5 mL oral solution. Failure is defined as intolerable side effects, drug-drug interaction, or lack of efficacy.

All benzodiazepine anxiolytics will require prior authorization for members ≥ 65 years of age when exceeding 90 days of therapy.

Continuation of Therapy:
• Members < 65 years of age who are currently stabilized on a non-preferred benzodiazepine medication may receive approval to continue that medication.
• Members < 18 years of age who are currently stabilized on a non-preferred oral solution product may receive authorization to continue that medication.

Prior authorization will be required for prescribed doses that exceed the maximum (Table 1).
<table>
<tr><th colspan="3">Table 1 Maximum Doses</th></tr>
<tr><th>Product</th><th>Maximum Daily Dose</th><th>Maximum Monthly Dose</th></tr>
<tr><td>Alprazolam tablet</td><td><u>Adults ≥ 18 years:</u></td><td></td></tr>
</table>
</td>
</tr>
</table>

		Alprazolam ER tablet Alprazolam ODT XANAX (alprazolam) tablet XANAX XR (alprazolam ER) tablet Alprazolam Intensol oral concentrate 1 mg/mL	10 mg/day	Total of 300 mg from all dosage forms per 30 days
		Clorazepate tablet TRANXENE (clorazepate) T-Tab	>12 years: 90 mg/day Children 9-12 years: up to 60 mg/day	Total of 2,700 mg (adults) and 1,800 mg (children) from all tablet strengths per 30 days
		Chlordiazepoxide capsule	Adults ≥ 18 years: 300 mg/day Children 6-17 years: up to 40 mg/day (pre-operative apprehension and anxiety)	Total of 9,000 mg (adults) and 120 mg (children, pre-op therapy) from all tablet strengths per 30 days
		Diazepam Intensol oral concentrate 5 mg/mL Diazepam solution 5 mg/5 mL Diazepam tablet	Adults ≥ 18 years: 40 mg/day Members age 6 months to 17 years: up to 10 mg/day	Total of 1200 mg (adults) and 300 mg (pediatrics) from all dosage forms per 30 days
		ATIVAN (lorazepam) Intensol concentrate 2 mg/mL ATIVAN (lorazepam) tablet Lorazepam oral concentrated soln 2 mg/mL Lorazepam tablet	Adults ≥ 18 years: 10 mg/day Children: N/A	Total of 300 mg from all dosage forms per 30 days
		Oxazepam capsule	Adults ≥ 18 years: 120 mg/day Children 6-18 years: absolute dosage not established	Total of 3600 mg from all dosage forms per 30 days
Therapeutic Drug Class: **ANXIOLYTIC, NON- BENZODIAZEPINES -** *Effective 4/1/2024*				
No PA Required Buspirone tablet		Non-preferred products may be approved following trial and failure of buspirone. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions.		

Therapeutic Drug Class: **ATYPICAL ANTI-PSYCHOTICS - Oral and Topical**- *Effective 4/1/2024*		
No PA Required (unless indicated by criteria) * *Brand/generic changes effective 08/08/2024* Aripiprazole tablet Asenapine SL tablet Clozapine tablet Lurasidone tablet Olanzapine tablet, ODT Paliperidone ER tablet Quetiapine IR tablet*** Quetiapine ER tablet Risperidone ODT, oral solution, tablet VRAYLAR (cariprazine) capsule* Ziprasidone capsule	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** ABILIFY (aripiprazole) tablet, MyCite Aripiprazole oral solution, ODT CAPLYTA (lumateperone) capsule Clozapine ODT CLOZARIL (clozapine) tablet, ODT GEODON (ziprasidone) capsule INVEGA ER (paliperidone) tablet LATUDA (lurasidone) tablet LYBALVI (olanzapine/samidorphan) tablet NUPLAZID (pimavanserin) capsule, tablet Olanzapine/Fluoxetine capsule REXULTI (brexpiprazole) dose pack, tablet RISPERDAL (risperidone) tablet, oral solution SAPHRIS (asenapine) SL tablet SECUADO (asenapine) patch SEROQUEL IR (quetiapine IR) tablet*** SEROQUEL XR (quetiapine ER) tablet SYMBYAX (olanzapine/fluoxetine) capsule	***Vraylar (cariprazine)** may be approved for members after trial and failure of one preferred agent. Failure is defined as contraindication, lack of efficacy with 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or known interacting genetic polymorphism that prevents safe preferred product dosing. Non-preferred products may be approved for members meeting all of the following: • Medication is being prescribed for an FDA-Approved indication AND • Prescription meets dose and age limitations (Table 1) AND • Request meets one of the following: o Member has history of trial and failure of two preferred products with FDA approval for use for the prescribed indication (failure defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, contraindication, significant drug-drug interactions, or known interacting genetic polymorphism that prevents safe preferred product dosing) **OR** o Prescriber attests that within the last year (365 days) the member has trialed and failed (been unsuccessfully treated with) a preferred antipsychotic medication that was used to treat the member's diagnosis (failure defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or known interacting genetic polymorphism that prevents safe preferred product dosing). Treatment must be under an FDA approved indication for a mental health condition or disorder. **Age Limits: All products including preferred products will require a PA for members younger than the FDA approved age for the agent (Table 1). Members younger than the FDA approved age for the agent who are currently stabilized on an atypical antipsychotic will be eligible for approval. **Atypical Antipsychotic prescriptions for members under 5 years of age may require a provider-provider telephone consult with a child and adolescent psychiatrist (provided at no cost to provider or member).** ***Quetiapine IR** when given at subtherapeutic doses may be restricted for therapy. Low-dose quetiapine (<150mg/day) is only FDA approved as part of a drug titration schedule to aid patients in getting to the target quetiapine dose. PA will be required for quetiapine < 150mg per day except for utilization (when appropriate) in members 65 years or older. PA will be approved for members 10-17 years of age with approved diagnosis (Table 1) stabilized on <150mg quetiapine IR per day. **Aripiprazole solution**: Aripiprazole tablet quantity limit is 2 tablets/day for pediatric members to allow for incremental dose titration and use of the preferred tablet formulation should be considered for dose titrations when possible and clinically appropriate. If incremental dose cannot be achieved with titration of the aripiprazole tablet for members < 18 years of age OR for members unable to swallow solid tablet

	VERSACLOZ (clozapine) suspension ZYPREXA (olanzapine) tablet ZYPREXA ZYDIS (olanzapine) ODT	dosage form, aripiprazole solution may be approved. For all other cases, aripiprazole solution is subject to meeting non-preferred product approval criteria listed above. **Nuplazid (pimavanserin tartrate)** may be approved for the treatment of hallucinations and delusions associated with Parkinson's Disease psychosis **AND** following trial and failure of therapy with quetiapine or clozapine, or clinical rationale is provided supporting why these medications cannot be trialed. Failure will be defined as contraindication, intolerable side effects, drug-drug interaction, or lack of efficacy. **Abilify MyCite** may be approved if meeting all of the following: • Member has history of adequate trial and failure of 5 preferred agents (one trial must include aripiprazole tablet). Failure is defined as lack of efficacy with 6-week trial on maximally tolerated dose, allergy, intolerable side effects, significant drug-drug interactions AND • Information is provided regarding adherence measures being recommended by provider and followed by member (such as medication organizer or digital medication reminders) AND • Member has history of adequate trial and failure of 3 long-acting injectable formulations of atypical antipsychotics, one of which must contain aripiprazole (failure is defined as lack of efficacy with 8-week trial, contraindication, allergy, intolerable side effects, significant drug-drug interactions) AND • Abilify MyCite is being used with a MyCite patch and member is using a compatible mobile application. AND • Medication adherence information is being shared with their provider via a web portal or dashboard. Quantity Limits: Quantity limits will be applied to all products (Table 1). In order to receive approval for off-label dosing, the member must have an FDA approved indication and must have tried and failed on the FDA approved dosing regimen. Members currently stabilized on a non-preferred atypical antipsychotic may receive approval to continue therapy with that agent for one year.
Therapeutic Drug Class: **ATYPICAL ANTI-PSYCHOTICS – Long Acting Injectables**- *Effective 10/1/2024*		

No PA Required

ABILIFY ASIMTUFII (aripiprazole) syringe, vial

ABILIFY MAINTENA (aripiprazole) syringe, vial

ARISTADA ER (aripiprazole lauroxil) syringe

ARISTADA INITIO (aripiprazole lauroxil) syringe

Chlorpromazine ampule, vial

Fluphenazine vial

Fluphenazine decanoate vial

HALDOL (haloperidol decanoate) ampule

Haloperidol decanoate ampule, vial

Haloperidol lactate syringe, vial

INVEGA HAFYERA (paliperidone palmitate) syringe

INVEGA SUSTENNA (paliperidone palmitate) syringe

INVEGA TRINZA (paliperidone palmitate) syringe

Olanzapine vial

PERSERIS ER (risperidone) syringe, syringe kit

PA Required

Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.

GEODON (ziprasidone) vial

Risperidone microspheres ER vial

RYKINDO (risperidone microspheres) vial, vial kit

ZYPREXA (olanzapine) vial

Preferred products do not require prior authorization. All products are subject to meeting FDA-labeled dosing quantity limits listed in Table 1.

Non-preferred products may be approved for members meeting the following:

- Medication is being prescribed for an FDA-Approved indication AND
- Prescription meets dose limitations (Table 1) AND
- Member has history of trial and failure of one preferred product with FDA approval for use for the prescribed indication (failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, contraindication, significant drug-drug interactions, or known interacting genetic polymorphism that prevents safe preferred product dosing).

Table 1: FDA-Labeled Dosing Quantity Limits*

Long-Acting injectable	Route	Quantity Limit
ABILIFY ASIMTUFII (aripiprazole)	IM	1 pack/2 months (56 days)
ABILIFY MAINTENA (aripiprazole)	IM	1 pack/28 days
ARISTADA ER (aripiprazole)	IM	1,064 mg: 1 pack/2 months (56 days) All other strengths: 1 pack/28 days
ARISTADA INITIO (aripiprazole)	IM	1 pack/7 weeks (49 days)
INVEGA HAFYERA (paliperidone)	IM	1 pack/6 months (168 days)
INVEGA SUSTENNA (paliperidone)	IM	156 mg: 2 packs/5 weeks (35 days) All other strengths: 1 pack/28 days
INVEGA TRINZA (paliperidone)	IM	1 pack/3 months (84 days)
PERSERIS ER (risperidone)	Subcutaneous	1 pack/28 days
RISPERDAL CONSTA (risperidone)	IM	2 packs/28 days
UZEDY (risperidone)	Subcutaneous	150 mg, 200 mg and 250 mg: 1 pack/2 months (56 days) All other strengths: 1 pack/28 days

RISPERDAL CONSTA[BNR] (risperidone microspheres) syringe, vial UZEDY (risperidone) syringe Ziprasidone ZYPREXA RELPREVV (olanzapine pamoate) Vial kit		<table><tr><td>ZYPREXA RELPREVV (olanzapine)</td><td>IM</td><td>405 mg: 1 pack/28 days All other strengths: 1 pack/14 days</td></tr><tr><td colspan="3">*Requests for dosing regimens exceeding maximum may be approved for one year with prescriber attestation that the member is stabilized on the requested dose and schedule.</td></tr></table> *Note: Effective January 14, 2022, no place of service prior authorization is required for extended-release injectable medications (LAIs) used for the treatment of mental health or substance use disorders (SUD), when administered by a healthcare professional and billed under the pharmacy benefit. In addition, LAIs may be administered in any setting (pharmacy, clinic, medical office or member home) and billed to the pharmacy or medical benefit as most appropriate and in accordance with all Health First Colorado billing policies.*

Table 1 Atypical Antipsychotics – FDA Approved Indication, Age Range, Quantity and Maximum Dose

Brand	Generic	Approved Indications	Age Range	Maximum Daily Dose by Age/Indication	Quantity and Maximum Dose Limitations
ABILIFY	aripiprazole	Schizophrenia Bipolar I Disorder Bipolar I Disorder Irritability w/autistic disorder Tourette's disorder Adjunctive treatment of MDD	≥ 13 years ≥ 18 years 10-17 years 6-17 years 6-18 years ≥ 18 years	30 mg 30 mg 30 mg 15 mg 20 mg (weight-based) 15 mg	Maximum one tablet per day (maximum of two tablets per day allowable for members < 18 years of age to accommodate for incremental dose changes)
CLOZARIL	clozapine	Treatment-resistant schizophrenia Recurrent suicidal behavior in schizophrenia or schizoaffective disorder	≥ 18 years	900 mg	Maximum dosage of 900mg per day
CAPLYTA	lumateperone	Schizophrenia Bipolar I Disorder Bipolar II Disorder	≥ 18 years	42 mg	Maximum dosage of 42mg per day

	clozapine	Treatment-resistant schizophrenia Recurrent suicidal behavior in schizophrenia or schizoaffective disorder	≥ 18 years	900 mg	Maximum dosage of 900mg per day
FANAPT	iloperidone	Schizophrenia Bipolar I Disorder	≥ 18 years	24 mg	Maximum two tablets per day
GEODON	ziprasidone	Schizophrenia Bipolar I Disorder	≥ 18 years ≥ 18 years	200 mg 160 mg	Maximum two capsules per day
INVEGA	paliperidone	Schizophrenia & schizoaffective disorder	≥ 12 years and weight ≥ 51 kg ≥ 12 years and weight < 51 kg	12 mg 6 mg	Maximum one capsule per day
LATUDA	lurasidone	Schizophrenia Schizophrenia Bipolar I disorder Bipolar I disorder	≥ 18 years 13-17 years ≥ 18 years 10–17 years	160 mg 80 mg 120 mg 80 mg	Maximum one tablet per day (If dosing 160mg for schizophrenia, then max of two tablets per day)
NUPLAZID	pimavanserin	Parkinson's disease psychosis	≥ 18 years	34 mg	Maximum dosage of 34mg per day
RISPERDAL	risperidone	Schizophrenia Schizophrenia Bipolar mania Irritability w/autistic disorder	≥ 18 years 13-17 years ≥ 10 years 5–17 years	16 mg 6 mg 6 mg 3 mg	Maximum dosage of 16mg/day (4 tablet/day limitation applied in claims system to allow for dose escalation and tapering)
REXULTI	brexpiprazole	Schizophrenia Adjunctive treatment of MDD Agitation associated with Alzheimer's disease (AD)	≥ 13 years ≥ 18 years	4 mg 3 mg	Maximum of 3mg/day for MDD adjunctive therapy, and agitation due to AD, Maximum of 4mg/day for schizophrenia
SAPHRIS	asenapine	Schizophrenia Bipolar mania or mixed episodes	≥ 18 years ≥ 10 years	20 mg 20 mg	Maximum two tablets per day
SECUADO	asenapine patch	Schizophrenia	≥ 18 years	7.6 mg/ 24 hours	Maximum 1 patch per day
SEROQUEL	quetiapine	Schizophrenia Schizophrenia Bipolar I mania or mixed Bipolar I mania or mixed Bipolar I depression Bipolar I Disorder Maintenance	≥ 18 years 13-17 years ≥ 18 years 10-17 years ≥ 18 years ≥ 18 years	750 mg 800 mg 800 mg 600 mg 300 mg 800 mg	Maximum three tablets per day
SEROQUEL XR	quetiapine ER	Schizophrenia Bipolar I mania Bipolar I mania Bipolar I depression Adjunctive treatment of MDD	≥ 13 years ≥ 18 years 10-17 years ≥ 18 years ≥ 18 years	800 mg 800 mg 600 mg 300 mg 300 mg	Maximum one tablet per day (for 300mg & 400mg tablets max 2 tablets per day)
SYMBYAX	olanzapine/ fluoxetine	Acute depression in Bipolar I Disorder Treatment resistant depression (MDD)	≥ 10 years	12 mg olanzapine/ 50 mg fluoxetine	Maximum three capsules per day (18mg olanzapine/75mg fluoxetine)

VRAYLAR	cariprazine	Schizophrenia Acute manic or mixed episodes with Bipolar I disorder Depressive episodes with Bipolar I disorder Adjunctive treatment of MDD	≥ 18 years ≥ 18 years ≥ 18 years ≥ 18 years	6 mg 6 mg 3 mg 3 mg	Maximum dosage of 6mg/day
ZYPREXA ZYPREXA ZYDIS	olanzapine	Schizophrenia Acute manic or mixed episodes with Bipolar I disorder	≥ 13 years	20 mg	Maximum one tablet per day

Therapeutic Drug Class: **CALCITONIN GENE – RELATED PEPTIDE INHIBITORS (CGRPis)** -*Effective 4/1/2024*

PA Required for all agents

Preferred	**Non-Preferred**
* AIMOVIG (erenumab-aooe) auto-injector * AJOVY (fremanezumab-vfrm) auto-injector, syringe * EMGALITY (galcanezumab-gnlm) pen, 120 mg syringe * NURTEC (rimegepant) ODT * UBRELVY (ubrogepant) tablet	EMGALITY (galcanezumab-gnlm) 100 mg syringe QULIPTA (atogepant) tablet ZAVZPRET (zavegepant) nasal

*Preferred agents may be approved if meeting the following criteria:

Preferred Medications for Migraine Prevention (must meet all of the following):

- The requested medication is being used as preventive therapy for episodic or chronic migraine AND
- Member has diagnosis of migraine with or without aura AND
- Member has tried and failed 2 oral preventive pharmacological agents listed as Level A per the most current American Headache Society/American Academy of Neurology guidelines (such as divalproex, topiramate, metoprolol, propranolol). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction OR
- If the prescribed medication is Nurtec, the member has tried and failed two preferred injectable product formulations. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.

Preferred Medications for Acute Migraine Treatment (must meet all of the following):

- The requested medication is being used as acute treatment for migraine headache AND
- Member has history of trial and failure of two triptans (failure is defined as lack of efficacy with 4-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

Non-Preferred Medications for Migraine Prevention (must meet all of the following):

- The requested medication is being used as preventive therapy for episodic or chronic migraine AND
- Member has diagnosis of migraine with or without aura AND
- Member has tried and failed two oral preventive pharmacological agents listed as Level A per the most current American Headache Society/American Academy of Neurology guidelines (such as divalproex, topiramate, metoprolol, propranolol). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND

- The requested medication is not being used in combination with another CGRP medication AND
- The member has history of adequate trial and failure of all preferred products indicated for preventive therapy (failure is defined as lack of efficacy with 4-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).

Non-Preferred Medications for Acute Migraine Treatment (must meet all of the following):

- Member is 18 years of age or older AND
- Medication is being prescribed to treat migraine headache with moderate to severe pain AND
- The requested medication is not being used in combination with another CGRP medication AND
- Member has history of trial and failure with all of the following (failure is defined as lack of efficacy with 4-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction):
    - Two triptans AND
    - One NSAID agent AND
    - One preferred agent indicated for acute migraine treatment

Non-Preferred Medications for Treatment of Episodic Cluster Headache (must meet all of the following):

- Member is 19-65 years of age AND
- Member meets diagnostic criteria for episodic cluster headache (has had no more than 8 attacks per day, a minimum of one attack every other day, and at least 4 attacks during the week prior to this medication being prescribed) AND
- Member is not taking other preventive medications to reduce the frequency of cluster headache attacks AND
- Member has history of trial and failure of all of the following (failure is defined as lack of efficacy with 4-week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction):
    - Oxygen therapy AND
    - Sumatriptan subcutaneous or intranasal OR zolmitriptan intranasal
- Initial authorization will be limited to 8 weeks. Continuation (12-month authorization) will require documentation of clinically relevant improvement with no less than 30% reduction in headache frequency in a 4-week period.

Age Limitations:

All products: ≥ 18 years

Table 1. Calcitonin Gene-Related Peptide Inhibitor Quantity Limits

Drug Name	Maximum Dosing
Aimovig (erenumab)	one 140 mg autoinjector per 30 days
Ajovy (fremanezumab)	one 225 mg autoinjector or syringe per 30 days or three 225

			mg autoinjectors or syringes every 90 days
		Emgality 100mg (galcanezumab)	three 100 mg prefilled syringes per 30 days
		Emgality 120 mg (galcanezumab)	two 120 mg pens or prefilled syringes once as first loading dose then one 120 mg pen or prefilled syringe per 30 days
		Nurtec (rimegepant)	Prevention: 16 tablets/30 days; Acute Treatment: 8 tablets/30 days
		Qulipta (atogepant)	30 tablets/30 days
		Ubrelvy 50 mg (ubrogepant)	16 tablets/30 days
		Ubrelvy 100 mg (ubrogepant)	16 tablets/30 days
		ZAVZPRET (zavegepant)	6 unit-dose nasal spray devices per 30 days
		Members with current prior authorization approval on file for a preferred agent may receive approval for continuation of therapy with the preferred agent.	

Therapeutic Drug Class: **LITHIUM AGENTS** -*Effective 4/1/2024*		
No PA Required Lithium carbonate capsule, tablet Lithium citrate solution Lithium ER tablet	**PA Required** ***Non-preferred brand name medications do not require a prior authorization when the equivalent generic is preferred and "dispense as written" is indicated on the prescription.*** LITHOBID ER (lithium ER) tablet	Non-preferred products may be approved with trial and failure of one preferred agent (failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, intolerance to dosage form). Members currently stabilized on a non-preferred product may receive approval to continue therapy with that product.

Therapeutic Drug Class: **NEUROCOGNITIVE DISORDER AGENTS** -*Effective 4/1/2024*		
Preferred ***Must meet eligibility criteria** *Donepezil 5mg, 10mg tablet *Donepezil ODT *Galantamine IR tablet *Memantine IR tablet, dose pack *Memantine ER capsule *Rivastigmine capsule, patch	**Non-Preferred** **PA Required** ADLARITY (donepezil) patch ARICEPT (donepezil) tablet Donepezil 23mg tablet EXELON (rivastigmine) patch Galantamine solution, ER capsule Memantine IR solution MESTINON (pyridostigmine) IR/ER tablet, syrup	***Eligibility criteria for Preferred Agents –** Preferred products may be approved for a diagnosis of neurocognitive disorder (eligible for AutoPA automated approval). Non-preferred products may be approved if the member has failed treatment with one of the preferred products in the last 12 months. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) Members currently stabilized on a non-preferred product may receive approval to continue on that agent for one year if medically necessary and if there is a diagnosis of neurocognitive disorder.

	NAMENDA (memantine) tablet, dose pack NAMENDA XR (memantine ER) capsule NAMZARIC (memantine/donepezil ER) capsule, dose pack Pyridostigmine syrup, IR/ER tablet	

Therapeutic Drug Class: **SEDATIVE HYPNOTICS** -*Effective 4/1/2024*		
Non-Benzodiazepines		
Preferred **No PA Required*** **(Unless age, dose, or duplication criteria apply)**	**Non-Preferred** **PA Required**	Non-preferred non-benzodiazepine sedative hypnotics may be approved for members who have failed treatment with two preferred non-benzodiazepine agents (failure is defined as lack of efficacy with a 2-week trial, allergy, intolerable side effects, or significant drug-drug interaction). <u>Children:</u> Prior authorization will be required for all agents for members < 18 years of age. <u>Duplications:</u> Only one agent in the sedative hypnotic drug class will be approved at a time (concomitant use of agents in the same sedative hypnotic class or differing classes will not be approved). All sedative hypnotics will require prior authorization for members ≥ 65 years of age when exceeding 90 days of therapy. **Belsomra** (suvorexant) may be approved for adult members that meet the following: • Member has trialed and failed therapy with two preferred agents (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) AND • Member is not receiving strong CYP3A4 inhibitors (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or strong CYP3A4 inducers (such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St John's Wort) AND • Member does not have a diagnosis of narcolepsy **Dayvigo** (lemborexant) may be approved for adult member that meet the following: • Member has trialed and failed therapy with two preferred agents AND Belsomra (surovexant). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
Eszopiclone tablet Ramelteon tablet Zaleplon capsule Zolpidem IR, ER tablet	AMBIEN (zolpidem) tablet AMBIEN CR (zolpidem ER) tablet BELSOMRA (suvorexant) tablet DAYVIGO (lemoborexant) tablet Doxepin tablet EDLUAR (zolpidem) SL tablet HETLIOZ (tasimelteon) capsule HETLIOZ LQ (tasimelteon) suspension LUNESTA (eszopiclone) tablet QUVIVIQ (daridorexant) tablet ROZEREM (ramelteon) tablet SILENOR (doxepin) tablet Tasimelteon capsule Zolpidem capsule, SL tablet	

		• Member is not receiving strong CYP3A4 inhibitors (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, delavirdine, and milk thistle) or strong CYP3A4 inducers (such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, and St John's Wort) AND • Member does not have a diagnosis of narcolepsy **Hetlioz (tasimelteon) capsules** may be approved for members meeting the following criteria: • Member is ≥18 years of age and has a documented diagnosis of Non-24-hour sleep wake disorder (Non-24) OR • Member is ≥16 years of age and has a documented diagnosis of nighttime sleep disturbances in Smith-Magenis syndrome (SMS) AND • The requested medication is being prescribed by a sleep specialist or a practitioner who has sufficient education and experience to safely prescribe tasimelteon **Hetlioz LQ (tasimelteon) oral suspension** may be approved for members meeting the following criteria: • Member is 3 to 15 years of age and has a documented diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) • AND the requested medication is being prescribed by a sleep specialist or a practitioner who has sufficient education and experience to safely prescribe tasimelteon. **Silenor** (**doxepin)** may be approved for adult members that meet ONE of the following criteria: • Member has tried and failed two preferred oral sedative hypnotics (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) OR • Provider attests to the medical necessity of prescribing individual doxepin doses of less than 10 mg, OR • Member's age is ≥ 65 years Prior authorization will be required for prescribed doses exceeding maximum (Table 1) below.
Benzodiazepines		
Preferred **No PA Required*** **(Unless age, dose, or duplication criteria apply)** Temazepam 15mg, 30mg capsule Triazolam tablet	**Non-Preferred** **PA Required** DORAL (quazepam) tablet Estazolam tablet Flurazepam capsule HALCION (triazolam) tablet	Non-preferred benzodiazepine sedative hypnotics may be approved for members who have trialed and failed therapy with two preferred benzodiazepine agents (failure is defined as lack of efficacy with a 2-week trial, allergy, intolerable side effects, or significant drug-drug interaction). Temazepam 22.5 mg may be approved if the member has trialed and failed temazepam 15mg or 30mg AND one other preferred product (failure is defined as lack of efficacy with a 2-week trial, allergy, intolerable side effects, or significant drug-drug interaction). Temazepam 7.5 mg may be approved if provider attests to the medical necessity of prescribing individual temazepam doses of less than 15 mg.

	Quazepam tablet RESTORIL (temazepam) capsule Temazepam 7.5mg, 22.5mg capsule	Children: Prior authorization will be required for all sedative hypnotic agents when prescribed for members < 18 years of age. Duplications: Only one agent in the sedative hypnotic drug class will be approved at a time (concomitant use of agents in the same sedative hypnotic class or differing classes will not be approved). All sedative hypnotics will require prior authorization for member's ≥ 65 years of age when exceeding 90 days of therapy. Members currently stabilized on a non-preferred benzodiazepine medication may receive authorization to continue that medication. Prior authorization will be required for prescribed doses exceeding maximum (Table 1).

Table 1: Sedative Hypnotic Maximum Dosing

Brand	Generic	Maximum Dose
Non-Benzodiazepine		
Ambien CR	Zolpidem CR	12.5 mg/day
Ambien IR	Zolpidem IR	10 mg/day
Belsomra	Suvorexant	20 mg/day
Dayvigo	Lemborexant	10 mg/day
Edluar	Zolpidem sublingual	10 mg/day
-	Zolpidem sublingual	Men: 3.5mg/day Women: 1.75 mg/day
Hetlioz	Tasimelteon capsule	20 mg/day
Hetlioz LQ	Tasimelteon liquid	≤ 28 kg: 0.7 mg/kg/day > 28 kg : 20 mg/day
Lunesta	Eszopiclone	3 mg/day
Quviviq	Daridorexant	50 mg/day
-	Zaleplon	20 mg/day
Rozerem	Ramelteon	8 mg/day
Benzodiazepine		
Halcion	Triazolam	0.5 mg/day
Restoril	Temazepam	30 mg/day
Silenor	Doxepin	6mg/day
-	Estazolam	2 mg/day
-	Flurazepam	30 mg/day
Doral	Quazepam	15 mg/day

Therapeutic Drug Class: **SKELETAL MUSCLE RELAXANTS** -*Effective 4/1/2024*

No PA Required (*if under 65 years of age)	PA Required	
Baclofen tablet Cyclobenzaprine tablet Methocarbamol tablet Tizanidine tablet	AMRIX ER (cyclobenzaprine ER) capsule Baclofen solution, suspension Carisoprodol tablet Carisoprodol/Aspirin tablet Chlorzoxazone tablet Cyclobenzaprine ER capsule DANTRIUM (dantrolene) capsule *Dantrolene capsule FEXMID (cyclobenzaprine) tablet FLEQSUVY (baclofen) solution LORZONE (chlorzoxazone) tablet LYVISPAH (baclofen) granules Metaxalone tablet NORGESIC/NORGESIC FORTE (orphenadrine/aspirin/ caffeine) tablet Orphenadrine ER tablet Orphenadrine/Aspirin/Caffeine tablet SOMA (carisoprodol) tablet Tizanidine capsule ZANAFLEX (tizanidine) capsule, tablet	All agents in this class will require a PA for members 65 years of age and older. The maximum allowable approval will be for a 7-day supply. Authorization for any **CARISOPRODOL** product will be given for a maximum 3-week one-time authorization for members with acute, painful musculoskeletal conditions who have failed treatment with three preferred products within the last 6 months. ***Dantrolene** may be approved for members who have trialed and failed‡ one preferred agent and meet the following criteria: ● Documentation of age-appropriate liver function tests AND ● One of following diagnoses: Multiple Sclerosis, Cerebral Palsy, stroke, upper motor neuron disorder, or spinal cord injury ● Dantrolene will be approved for the period of one year ● If a member is stabilized on dantrolene, they may continue to receive approval All other non-preferred skeletal muscle relaxants may be approved for members who have trialed and failed‡ three preferred agents. ‡Failure is defined as: lack of efficacy with 14-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.
Therapeutic Drug Class: **STIMULANTS AND RELATED AGENTS** -*Effective 4/1/2024*		
Preferred ***No PA Required (if age, max daily dose, and diagnosis met)**	**Non-Preferred** **PA Required**	*Preferred medications may be approved through AutoPA for indications listed in Table 1 (preferred medications may also receive approval for off-label use for fatigue associated with multiple sclerosis).

Brand/generic changes effective 08/08/2024 Amphetamine salts, mixed ER (generic Adderall XR) capsule Amphetamine salts, mixed (generic Adderall) tablet Armodafinil tablet Atomoxetine capsule Clonidine ER tablet DAYTRANA[BNR] (methylphenidate) patch Dexmethylphenidate IR tablet Dexmethylphenidate ER capsule Guanfacine ER tablet Methylphenidate (generic Methylin/Ritalin) solution, tablet Methylphenidate ER tablet (generic Concerta) Modafinil tablet VYVANSE[BNR] (lisdexamfetamine) capsule	ADDERALL XR (amphetamine salts, mixed ER) capsule ADZENYS XR-ODT (amphetamine) Amphetamine tablet (generic Evekeo) APTENSIO XR (methylphenidate ER) capsule AZSTARYS (serdexmethylphenidate/ dexmethylphenidate) capsule CONCERTA (methylphenidate ER) tablet COTEMPLA XR-ODT (methylphenidate ER) DESOXYN (methamphetamine) tablet DEXEDRINE (dextroamphetamine) Spansule Dextroamphetamine ER capsule, solution, tablet DYANAVEL XR (amphetamine) suspension, tablet EVEKEO (amphetamine) ODT, tablet FOCALIN (dexmethylphenidate) tablet, XR capsule INTUNIV (guanfacine ER) tablet JORNAY PM (methylphenidate) capsule Lisdexamfetamine capsule, chewable tablet Methamphetamine tablet METHYLIN (methylphenidate) solution Methylphenidate CD/ER/LA capsule, chewable tablet, ER tablet (generic Relexxi/Ritalin), patch MYDAYIS ER (dextroamphetamine/ amphetamine) capsule	Non-preferred medications may be approved for members meeting the following criteria (for Sunosi (solriamfetol) and Wakix (pitolisant), refer to specific criteria listed below): • Prescription meets indication/age limitation criteria (Table 1) **AND** • <u>If member is ≥ 6 years of age:</u> o Has documented trial and failure‡ with three preferred products in the last 24 months **AND** o If the member is unable to swallow solid oral dosage forms, two of the trials must be methylphenidate solution, dexmethylphenidate ER, Vyvanse, Adderall XR, or any other preferred product that can be taken without the need to swallow a whole capsule. **OR** • <u>If member is 3–5 years of age</u>: o Has documented trial and failure‡ with one preferred product in the last 24 months **AND** o **If the member is unable to** swallow solid oral dosage forms, the trial must be methylphenidate solution, dexmethylphenidate ER, Vyvanse, Adderall XR, or any other preferred product that can be taken without the need to swallow a whole capsule. **SUNOSI** (solriamfetol) prior authorization may be approved if member meets the following criteria: ● Member is 18 years of age or older AND ● Member has diagnosis of either narcolepsy or obstructive sleep apnea (OSA) and is experiencing excessive daytime sleepiness AND ● Member does not have end stage renal disease AND ● If Sunosi is being prescribed for OSA, member has 1 month trial of CPAP AND ● Member has trial and failure‡ of modafinil AND armodafinil AND one other agent in stimulant PDL class. **WAKIX** (pitolisant) prior authorization may be approved if member meets the following criteria: ● Member is 18 years of age or older **AND** ● Member has diagnosis of narcolepsy and is experiencing excessive daytime sleepiness **AND** ● Member does not have end stage renal disease (eGFR <15 mL/minute) **AND** ● Member does not have severe hepatic impairment **AND** ● Member has trial and failure‡ of modafinil **AND** armodafinil **AND** one other agent in the stimulant PDL class **AND** ● Member has been counseled that Wakix may reduce the efficacy of hormonal contraceptives and regarding use an alternative non-hormonal method of contraception during Wakix therapy and for at least 21 days after discontinuing treatment.

	NUVIGIL (armodafinil) tablet PROCENTRA (dextroamphetamine) solution PROVIGIL (modafinil) tablet QELBREE (viloxazine ER) capsule QUILLICHEW ER (methylphenidate) chewable tablet, XR suspension RELEXXII (methylphenidate ER) tablet RITALIN (methylphenidate) IR/ER tablet, ER capsule STRATTERA (atomoxetine) capsule SUNOSI (solriamfetol) tablet VYVANSE (lisdexamfetamine) chewable tablet WAKIX (pitolisant) tablet XELSTRYM (dextroamphetamine) patch ZENZEDI (dextroamphetamine) tablet	Maximum Dose (all products): See Table 2 **Exceeding Max Dose:** Prior authorization may be approved for doses that are higher than the listed maximum dose (Table 2) for members meeting the following criteria: • Member is taking medication for indicated use listed in Table 1 **AND** • Member has 30-day trial and failure‡ of three different preferred or non-preferred agents at maximum doses listed in Table 2 **AND** • Documentation of member's symptom response to maximum doses of three other agents is provided **AND** • Member is not taking a sedative hypnotic medication (such as temazepam, triazolam, or zolpidem from the Sedative Hypnotic PDL class). ‡Failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Table 1: Diagnosis and Age Limitations

- Approval for medically accepted indications <u>not</u> listed in Table 1 may be given with prior authorization review and may require submission of peer-reviewed literature or medical compendia showing safety and efficacy of the medication used for the prescribed indication.
- Preferred medications may also receive approval for off-label use for fatigue associated with multiple sclerosis if meeting all other criteria for approval.
- **Bolded drug names are preferred** (subject to preferential coverage changes for brand/generic equivalents)

Drug	Diagnosis and Age Limitations
Stimulants–Immediate Release	
Amphetamine sulfate (EVEKEO)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years)
Dexmethylphenidate IR (FOCALIN)	ADHD (Age ≥ 6 years)
Dextroamphetamine IR tablet (ZENZEDI)	ADHD (Age 3 to16 years), Narcolepsy (Age ≥ 6 years)
Dextroamphetamine solution (PROCENTRA)	ADHD (Age 3 to 16 years), Narcolepsy (Age ≥ 6 years)
Methamphetamine (DESOXYN)	ADHD (Age ≥ 6 years)
methylphenidate IR (generic METHYLIN, RITALIN)	ADHD (Age ≥ 6 years†), Narcolepsy (Age ≥ 6 years), OSA.

	†Prior Authorization for members 3-6 years of age with a diagnosis of ADHD may be approved with prescriber attestation to the following: • Member's symptoms have not significantly improved despite adequate behavior interventions AND • Member experiences moderate-to-severe continued disturbance in functioning AND • Prescriber has determined that the potential benefits of starting methylphenidate before the age of 6 years outweigh the potential harm of delaying treatment.
Mixed amphetamine salts IR (generic ADDERALL)	ADHD (Age ≥ 3 years), Narcolepsy (Age ≥ 6 years)
Stimulants –Extended-Release	
Amphetamine ER (ADZENYS XR-ODT and ADZENYS ER suspension)	ADHD (Age ≥ 6 years)
Amphetamine ER (DYANAVEL XR)	ADHD (Age ≥ 6 years)
Mixedamphetamine salts ER (**ADDERALL XR**)	ADHD (Age ≥ 6 years)
Dexmethylphenidate ER (generic Focalin XR)	ADHD (Age ≥ 6 years)
Dextroamphetamine ER (DEXEDRINE)	ADHD (Age 6 to 16 years), Narcolepsy (Age ≥ 6 years)
Dextroamphetamine ER/amphetamine ER (MYDAYIS ER)	ADHD (Age ≥ 13 years)
Dextroamphetamine ER patch (XELSTRYM)	ADHD (Age ≥ 6 years)
Lisdexamfetamine dimesylate (**VYVANSE capsule**, Vyvanse chewable)	ADHD (Age ≥ 6 years), Moderate to severe binge eating disorder in adults (Age ≥ 18 years)
Methylphenidate ER OROS **(CONCERTA)**	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years), OSA
Methylphenidate patch (DAYTRANA)	ADHD (Age ≥ 6 years)
Methylphenidate SR (METADATE ER)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)
Methylphenidate ER (METADATE CD)	ADHD (Age ≥ 6 years)
Methylphenidate ER (QUILLICHEW ER)	ADHD (Age 6 years to ≤ 65 years), Narcolepsy (Age ≥ 6 years)
Methylphenidate ER (QUILLIVANT XR)	ADHD (Age ≥ 6 years), Narcolepsy (Age ≥ 6 years)
Methylphenidate ER (RELEXXI ER)	ADHD (Age 6 to 65 years)
Methylphenidate ER (RITALIN LA)	ADHD (Age ≥ 6 years)
Methylphenidate ER (ADHANSIA XR)	ADHD (Age ≥ 6 years)
Methylphenidate ER (JORNAY PM)	ADHD (Age ≥ 6 years)
Methylphenidate XR (APTENSIO XR)	ADHD (Age ≥ 6 years)
Methylphenidate XR ODT (COTEMPLA XR-ODT)	ADHD (Age 6 to 17 years)
Serdexmethylphenidate/dexmethylphenidate (AZSTARYS)	ADHD (Age ≥ 6 years)
Non-Stimulants	
Atomoxetine (generic STRATTERA)	ADHD (Age ≥ 6 years)
Clonidine ER	ADHD as monotherapy or adjunctive therapy to stimulants (Age ≥ 6 years)
Guanfacine ER (generic INTUNIV)	ADHD as monotherapy or adjunctive therapy to stimulants (Age ≥ 6 years)

Viloxazine ER (QELBREE)	ADHD (Age ≥ 6 years)
Wakefulness-promoting Agents	
Armodafinil (generic NUVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, SWD, and adjunct therapy to treat fatigue and sleepiness in patients with major depressive disorder (MDD) (Age ≥ 18 years)
Modafinil (PROVIGIL)	Excessive sleepiness associated with narcolepsy, OSA, SWD, and adjunct therapy to treat fatigue and sleepiness in patients with major depressive disorder (MDD), antipsychotic medication-related fatigue (Age ≥ 18 years)
Pitolisant (WAKIX)	Excessive sleepiness associated with narcolepsy (Age ≥ 18 years)
Solriamfetol (SUNOSI)	Excessive sleepiness associated with narcolepsy, OSA (Age ≥ 18 years)
KEY: **ADHD**–attention-deficit/hyperactivity disorder, **OSA**–obstructive sleep apnea, **SWD**–shift work disorder	

Table 2: Maximum Dose

Drug	Maximum Daily Dose
ADDERALL	60 mg
ADDERALL XR	60 mg
ADHANSIA XR	85 mg
ADZENYS XR ODT ADZENYS ER SUSPENSION	18.8 mg (age 6-12) 12.5 mg (age ≥ 13)
AMPHETAMINE SALTS	40 mg
APTENSIO XR	60 mg
CONCERTA	54 mg (age 6-12) or 72 mg (≥ age 13)
AZSTARYS	52.3 mg serdexmethylphenidate and 10.4 mg dexmethylphenidate
CLONIDINE ER	0.4 mg
COTEMPLA XR-ODT	51.8 mg
DEXTROAMPHETAMINE ER	60 mg
DAYTRANA	30 mg/9 hour patch (3.3 mg/hr)
DESOXYN	25 mg
DEXEDRINE	60 mg
DYANAVEL XR	20 mg
EVEKEO	60 mg
FOCALIN	20 mg
FOCALIN XR	40 mg
GUANFACINE ER	4 mg (age 6-12) or 7 mg (age ≥ 13)
INTUNIV ER	4 mg (age 6-12) or 7 mg (age ≥ 13)
JORNAY PM	100 mg
METADATE CD	60 mg
METADATE ER	60 mg
METHYLIN	60 mg
METHYLIN ER	60 mg
METHYLIN SUSPENSION	60 mg

METHYLPHENIDATE	60 mg
METHYLPHENIDATE ER	60 mg
MYDAYIS ER	25 mg (age 13-17) or 50 mg (age ≥ 18)
NUVIGIL	250 mg
PROCENTRA	60 mg
PROVIGIL	400 mg
QELBREE	400 mg (age 6-17) or 600 mg (age ≥ 18)
QUILLICHEW ER	60 mg
QUILLIVANT XR	60 mg
RELEXXII	54 mg (ages 6-12) or 72 mg (≥ age 13)
RITALIN IR	60 mg
RITALIN SR	60 mg
RITALIN LA	60 mg
STRATTERA	100mg
SUNOSI	150 mg
VYVANSE CAPSULES AND CHEWABLE TABLETS	70 mg
WAKIX	35.6 mg
XELSTRYM ER PATCH	18 mg/9 hours
ZENZEDI	60 mg

Therapeutic Drug Class: **TRIPTANS, DITANS AND OTHER MIGRAINE TREATMENTS - Oral** -*Effective 4/1/2024*

No PA Required (Quantity limits may apply)	**PA Required**	
Eletriptan tablet (generic Relpax) Naratriptan tablet (generic Amerge) Rizatriptan tablet, ODT (generic Maxalt) Sumatriptan tablet (generic Imitrex) Zolmitriptan tablet (generic Zomig)	Almotriptan tablet FROVA (frovatriptan) tablet Frovatriptan tablet IMITREX (sumatriptan) tablet MAXALT/MAXALT MLT (rizatriptan) tablet, ODT RELPAX (eletriptan) tablet REYVOW (lasmiditan) tablet Sumatriptan/Naproxen tablet Zolmitriptan ODT ZOMIG (zolmitriptan) tablet	Non-preferred oral products may be approved for members who have trialed and failed three preferred oral products. Failure is defined as lack of efficacy with 4-week trial, allergy, documented contraindication to therapy, intolerable side effects, or significant drug-drug interaction. <u>Note</u>: There is limited information available regarding the safety, tolerability, and efficacy of coadministering lasmiditan with a triptan or a gepant. **Quantity Limits:**

Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan), Zomig (zolmitriptan)	9 tabs/30 days
Treximet (sumatriptan/naproxen)	9 tabs/30 days
Axert (almotriptan) and Relpax (eletriptan)	6 tabs/30 days
Maxalt (rizatriptan)	12 tabs/30 days
Reyvow (lasmiditan)	8 tabs/30 days

Therapeutic Drug Class: **TRIPTANS, DITANS, AND OTHER MIGRAINE TREATMENTS - Non-Oral** -*Effective 4/1/2024*

No PA Required (Quantity limits may apply)	PA Required	
IMITREX (sumatriptan) nasal spray Sumatriptan cartridge, pen injector MIGRANAL[BNR] (dihydroergotamine) nasal spray Sumatriptan nasal spray*, vial	Dihydroergotamine injection, nasal spray IMITREX (sumatriptan) cartridge, pen injector TOSYMRA (sumatriptan) nasal spray TRUDHESA (dihydroergotamine) nasal spray ZEMBRACE SYMTOUCH (sumatriptan) auto-injector Zolmitriptan nasal spray ZOMIG (zolmitriptan) nasal spray	**Zembrace Symtouch injection**, **Tosymra nasal spray**, or **Onzetra Xsail nasal powder** may be approved for members who have trialed and failed one preferred non-oral triptan products AND two oral triptan agents with different active ingredients. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, significant drug-drug interaction, or documented inability to take alternative dosage form. All other non-preferred products may be approved for members who have trialed and failed one preferred non-oral triptan product AND one preferred oral triptan product. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions, documented inability to tolerate dosage form. **Quantity Limits:** Dihydroergotamine mesylate vial 1mg/mL: 24 vials/ 28 days Imitrex (sumatriptan) injection: 4 injectors / 30 days Imitrex (sumatriptan) nasal spray: 6 inhalers / 30 days Migranal (dihydroergotamine mesylate) nasal spray: 8 nasal spray devices/ 30 days Onzetra Xsail (sumatriptan) nasal powder: 16 nosepieces / 30 days Tosymra (sumatriptan) nasal spray: 12 nasal spray devices / 30 days Zembrace Symtouch (sumatriptan) injection: 36mg / 30 days Zomig (zolmitriptan) nasal spray: 6 inhalers / 30 days Members currently utilizing a non-oral dihydroergotamine product formulation (based on recent claims history) may receive one year approval to continue therapy with that medication.

V. Dermatological

Therapeutic Drug Class: **ACNE AGENTS– Topical** -*Effective 7/1/2024*

Preferred No PA Required (if age and diagnosis criteria are met*)	Non-Preferred PA Required	
*Adapalene gel *Adapalene/benzoyl peroxide gel (generic Epiduo), gel pump (generic Epiduo Forte) *Clindamycin phosphate gel, lotion, solution, medicated swab/pledget	ACANYA (clindamycin/benzoyl peroxide) gel, pump Adapalene cream, gel pump, solution ALTRENO (tretinoin) lotion ARAZLO (tazarotene) lotion ATRALIN (tretinoin) gel	Authorization for all acne agents prescribed solely for cosmetic purposes will not be approved. Preferred topical clindamycin and erythromycin products may be approved by AutoPA verification of ICD-10 diagnosis code for acne vulgaris, psoriasis, cystic acne, comedonal acne, disorders of keratinization, neoplasms, folliculitis, hidradenitis suppurativa, or perioral dermatitis (erythromycin only). Approval of preferred topical clindamycin and erythromycin products for other medically accepted indications may be considered following clinical prior authorization review by a call center pharmacist. All other preferred topical acne agents may be approved if meeting the following criteria: • For members > 25 years of age, may be approved following prescriber verification that the medication is not being utilized for cosmetic purposes AND prescriber verification that the indicated use is for acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne. These

*Clindamycin/benzoyl peroxide gel jar (generic Benzaclin) *Clindamycin/benzoyl peroxide gel tube (generic Duac) *Dapsone gel *Erythromycin solution *Erythromycin/Benzoyl peroxide gel (generic Benzamycin) *Sulfacetamide sodium suspension *Sulfacetamide sodium/sulfur cleanser, *RETIN-A[BNR] (tretinoin) cream, gel	BENZAMYCIN (erythromycin/benzoyl peroxide) gel BP (sulfacetamide sodium/sulfur/urea) cleansing wash CABTREO (adapalene/benzoyl peroxide/clindamycin) gel CLEOCIN-T (clindamycin) lotion CLINDACIN ETZ/PAC (clindamycin phosphate) kit CLINDAGEL gel Clindamycin phosphate foam Clindamycin/Benzoyl peroxide gel pump Clindamycin/tretinoin gel Dapsone gel pump ERY/ERYGEL (erythromycin/ethanol) gel, medicated swabs/pads Erythromycin gel EVOCLIN (clindamycin) foam FABIOR (tazarotene) foam KLARON (sulfacetamide) suspension NEUAC (clindamycin/benzoyl peroxide/emollient) kit ONEXTON (clindamycin/benzoyl peroxide) gel, gel pump RETIN-A MICRO (tretinoin) (all products) ROSULA (sulfacetamide sodium/sulfur) cloths, wash	medications are only eligible for prior authorization approval for the aforementioned diagnoses. • For members ≤ 25 years of age, may be approved for a diagnosis of acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne. Diagnosis will be verified through automated verification (AutoPA) of the appropriate corresponding ICD-10 diagnosis code related to the indicated use of the medication. Non-preferred topical products may be approved for members meeting all of the following criteria: • Member has trialed/failed three preferred topical products with different mechanisms (such as tretinoin, antibiotic). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND • Prescriber verification that the medication is being prescribed for one of the following diagnoses: acne vulgaris, psoriasis, cystic acne, disorders of keratinization, neoplasms, or comedonal acne.

	SSS 10-5 (sulfacetamide sodium/sulfur) foam Sulfacetamide sodium cleanser, cleansing gel, lotion, shampoo, wash Sulfacetamide sodium/sulfur cream, pad, suspension, wash SUMADAN/XLT (sulfacetamide sodium/sulfur) kit, wash SUMAXIN/ CP/TS (sulfacetamide sodium/sulfur) kit, pads, suspension, wash Tazarotene cream, foam, gel Tretinoin (all products) Tretinoin microspheres (all products) WINLEVI (clascoterone) cream ZIANA (clindamycin/tretinoin) gel	

Therapeutic Drug Class: **ACNE AGENTS– ORAL ISOTRETINOIN** -*Effective 7/1/2024*

PA Required for all agents		
Preferred	**Non-Preferred**	Preferred products may be approved for adults and children ≥ 12 years of age for treating severe acne vulgaris or for treating moderate acne vulgaris in members unresponsive to conventional therapy. Non-preferred products may be approved for members meeting the following: ● Member has trialed/failed one preferred agent (failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) AND ● Member is an adult or child ≥ 12 years of age with severe, recalcitrant nodulocystic acne and has been unresponsive to conventional therapy.
AMNESTEEM capsule CLARAVIS capsule Isotretinoin 10 mg, 20 mg, 30 mg, 40 mg capsule (*Mayne-Pharma, Upsher-Smith, Zydus only)* ZENATANE capsule	ABSORICA capsule ABSORICA LD capsule Isotretinoin 10 mg, 20 mg, 30 mg, 40 mg capsule (*All manufacturers except Mayne-Pharma, Upsher-Smith, Zydus)* Isotretinoin 25 mg, 35 mg capsule MYORISAN capsule	

Therapeutic Drug Class: **ANTI-PSORIATICS - Oral** -*Effective 7/1/2024*

<table>
<tr><th>No PA Required</th><th>PA Required</th><td rowspan="2">Prior authorization for non-preferred oral agents may be approved with failure of two preferred anti-psoriatic agents, one of which must be a preferred oral agent. Failure is defined as lack of efficacy of a 4-week trial, allergy, intolerable side effects or significant drug-drug interaction.</td></tr>
<tr><td>Acitretin capsule</td><td>Methoxsalen capsule</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: ANTI-PSORIATICS -Topical -Effective 7/1/2024</td></tr>
<tr><th>No PA Required</th><th>PA Required</th><td rowspan="2">ZORYVE (roflumilast) may receive approval if meeting the following based on prescribed indication:

<u>Seborrheic dermatitis</u> (0.3% foam formulation)
• Member is ≥ 9 years of age AND
• Member has a diagnosis of seborrheic dermatitis AND
• Member does not have moderate or severe hepatic impairment (Child-Pugh B or C) AND
• Medication is being prescribed by or in consultation with a dermatologist AND
• <u>If the affected area is limited to the scalp</u>:
o Prescriber attests that member has been counseled regarding alternative treatment options, including over-the-counter (OTC) antifungal shampoo (such as selenium sulfide, zinc pyrithione) and OTC coal tar shampoo, when appropriate)

AND
o Member has documented trial and failure (with a minimum 2-week treatment period) of at least one prescription product for seborrheic dermatitis, such as ketoconazole 2% antifungal shampoo or a topical corticosteroid. Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.
• <u>If the affected area includes the face or body</u>:

Member has documented trial and failure (with a minimum 2-week treatment period) with at least one product from ALL of the following categories (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction):
▪ Topical antifungal (such as ketoconazole, ciclopirox)
▪ Topical corticosteroid
▪ Topical calcineurin inhibitor (such as pimecrolimus, tacrolimus)</td></tr>
<tr><td>Calcipotriene cream, solution

TACLONEX SCALP BNR (calcipotriene/betamethasone) suspension

TACLONEX (calcipotriene/betamethasone) ointment</td><td>Calcipotriene foam, ointment

Calcipotriene/betamethasone dipropionate ointment, suspension

Calcitriol ointment

DUOBRII (halobetasol/tazarotene) lotion

ENSTILAR (calcipotriene/betamethasone) foam

SORILUX (calcipotriene) foam

VTAMA (tapinarof) cream

ZORYVE 0.3% (roflumilast) cream</td></tr>
</table>

		AND • Member has been counseled that Zoryve foam is flammable. Fire, flame, or smoking during and immediately following application must be avoided. <u>Plaque psoriasis</u> (0.3% cream formulation) • Member is ≥ 6 years of age AND • Member has a diagnosis of plaque psoriasis AND • Member has body surface area (BSA) involvement of ≤20% AND • Member does not have moderate or severe hepatic impairment (Child-Pugh B or C) AND • Medication is being prescribed by or in consultation with a dermatologist AND • <u>If the affected area is limited to the scalp</u>: o Prescriber attests that member has been counseled regarding alternative treatment options, including over-the-counter (OTC) emollients, vitamin D analogs, and coal tar shampoo when appropriate **AND** o Member has documented trial and failure (with a minimum 2-week treatment period) of a topical corticosteroid. Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction. • <u>If the affected area includes the face or body</u>: o Member has documented trial and failure (with a minimum 2-week treatment period) of at least one product from ALL of the following categories. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction): ▪ Topical corticosteroid ▪ Topical calcineurin inhibitor (such as pimecrolimus, tacrolimus) <u>Quantity limit</u>: Foam or cream - 60 grams/30 days <u>Initial approval:</u> Foam or cream: 8 weeks

		Reauthorization: Reauthorization for one year may be approved based on provider attestation that member's symptoms improved during the initial 8 weeks of treatment and continuation of therapy is justified. Prior authorization for all other non-preferred topical agents may be approved with failure of two preferred topical agents. If non-preferred topical agent being requested is a combination product, trial of two preferred agents must include a preferred combination agent. Failure is defined as lack of efficacy of a 4-week trial, allergy, intolerable side effects or significant drug-drug interaction. Preferred and non-preferred products that contain a corticosteroid ingredient (such as betamethasone) will be limited to 4 weeks of therapy. Continued use will require one week of steroid-free time in between treatment periods. Members with >30% of their body surface area affected may not use Enstilar (calcipotriene/betamethasone DP) foam or Taclonex (calcipotriene/betamethasone DP) ointment products as safety and efficacy have not been established. Members may not apply Zoryve (roflumilast) cream to >20% of affected body surface area, as safety and efficacy have not been established.
Therapeutic Drug Class: **IMMUNOMODULATORS, TOPICAL** – *Effective 7/1/2024*		
Atopic Dermatitis		
No PA Required ELIDEL (pimecrolimus) cream[BNR] Tacrolimus ointment	**PA Required** EUCRISA (crisaborole) ointment OPZELURA (ruxolitinib) cream Pimecrolimus cream ZORYVE (tapinarof) 0.15% cream, foam	**EUCRISA** (crisaborole) may be approved if the following criteria are met: • Member is at least 3 months of age and older AND • Member has a diagnosis of mild to moderate atopic dermatitis AND • Member has a history of failure, contraindication, or intolerance to at least two medium-to high-potency topical corticosteroids for a minimum of 2 weeks OR is not a candidate for topical corticosteroids AND • Member must have tried and failed pimecrolimus and tacrolimus. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions. AND • Eucrisa (crisaborole) must be prescribed by or in consultation with a dermatologist or allergist/immunologist.

OPZELURA (ruxolitinib) cream may be approved if the following criteria are met based on prescribed indication:

Atopic Dermatitis

- Member is ≥ 12 years of age AND
- Member is immunocompetent AND
- Member has a diagnosis of mild to moderate atopic dermatitis AND
- Member has body surface area (BSA) involvement of ≤20% AND
- Medication is being prescribed by or in consultation with a dermatologist or allergist/immunologist AND
- Member has a history of failure, contraindication, or intolerance to at least two medium-to high potency topical corticosteroids for a minimum of 2 weeks OR is not a candidate for topical corticosteroids AND
- Member must have trialed and failed twice-daily pimecrolimus and tacrolimus. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction AND
- Member is not using Opzelura (ruxolitinib) cream along with a strong inhibitor of CYP3A4 (such as fluconazole ≥ 200 mg/day, ketoconazole, itraconazole, voriconazole, ritonavir) due to the potential for increased systemic exposure to ruxolitinib.

Nonsegmental Vitiligo

- Member is ≥ 12 years of age AND
- Member is immunocompetent AND
- Member has a diagnosis of stable nonsegmental vitiligo, defined as no increase in the size of existing lesions and the absence of new lesions in the previous 3 to 6 months, AND
- Medication is being prescribed by or in consultation with a dermatologist AND
- Member will be applying Opzelura (ruxolitinib) to ≤10% of body surface area (BSA) per application AND
- Member has a history of failure, contraindication, or intolerance to at least two medium-to high-potency topical corticosteroids for a minimum of 2 weeks OR is not a candidate for topical corticosteroids AND
- Member must have trialed and failed twice-daily pimecrolimus OR tacrolimus. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction AND
- Member is not using Opzelura (ruxolitinib) cream along with a strong inhibitor of CYP3A4 (such as fluconazole ≥ 200 mg/day,

		ketoconazole, itraconazole, voriconazole, ritonavir) due to the potential for increased systemic exposure to ruxolitinib. Quantity limit: 60 grams/week All other non-preferred topical immunomodulator products may be approved for atopic dermatitis following adequate trial and failure‡ of one prescription topical corticosteroid AND two preferred agents. ‡Failure is defined as a lack of efficacy with one month trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.
Antineoplastic Agents		
Preferred **No PA Required** **(Unless indicated*)** *Diclofenac 3% gel (generic Solaraze) Fluorouracil 5% cream (generic Efudex) Fluorouracil 2%, 5% solution	**Non-Preferred** **PA Required** Bexarotene gel CARAC (fluorouracil) cream EFUDEX (fluorouracil) cream Fluorouracil 0.5% (generic Carac) cream PANRETIN (alitretinoin) gel TARGRETIN (bexarotene) gel VALCHLOR (mechlorethamine) gel	*__Diclofenac 3% gel__ (generic Solaraze) may be approved if the member has a diagnosis of actinic keratosis (AK). **TARGRETIN** (bexarotene) gel or **VALCHLOR** (mechlorethamine) gel may be approved for members who meet the following criteria: • Member is ≥ 18 years of age **AND** • Member has been diagnosed with Stage IA or IB cutaneous T-cell lymphoma (CTCL) **AND** • Member has refractory or persistent CTCL disease after other therapies OR has not tolerated other therapies **AND** • Member and partners have been counseled on appropriate use of contraception Non-preferred agents may be approved for members who have failed an adequate trial of all preferred products FDA-approved for that indication. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.
Other Agents		
No PA Required Imiquimod (generic Aldara) cream Podofilox gel, solution	**PA Required** CONDYLOX (podofilox) gel HYFTOR (sirolimus) gel Imiquimod (generic Zyclara) cream, cream pump VEREGEN (sinecatechins) ointment ZYCLARA (imiquimod) cream, cream pump	**Hyftor** (sirolimus) gel • Member has a diagnosis of facial angiofibroma associated with tuberous sclerosis AND • Member is ≥ 6 years of age AND • Provider has evaluated, and member has received, all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment with HYFTOR Initial approval: 6 months Reauthorization: An additional 6 months may be approved based on provider attestation that symptoms improved during the initial 6 months of treatment and the provider has assessed use of all vaccinations recommended by current immunization guidelines.

		Maximum dose: one 10-gram tube/28 days **Veregen** (sinecatechins) may be approved if the following criteria are met: • Member has a diagnosis of external genital and/or perianal warts (Condylomata acuminata) AND • Member is ≥ 18 years of age AND Member is immunocompetent AND • Member has tried and failed two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **Zyclara** (imiquimod) **2.5% cream** may be approved if the following criteria are met: • Member has a diagnosis of clinically typical visible or palpable actinic keratoses (AK) of the full face or balding scalp AND • Member is ≥ 18 years of age AND • Member is immunocompetent AND • Member has tried and failed one preferred product in the Antineoplastic Agents class (such as diclofenac gel or fluorouracil) AND the preferred imiquimod (generic Aldara) product. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **Zyclara** (imiquimod) **3.75% cream** may be approved for: • Treatment of clinically typical visible or palpable, actinic keratoses (AK) of the full face or balding scalp if the following criteria are met: • Member is ≥ 18 years of age AND • Member is immunocompetent AND • Member has tried and failed one preferred product from the Antineoplastic Agents class (such as diclofenac gel or fluorouracil) AND the preferred imiquimod (generic Aldara) product. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **OR** • Treatment of external genital and/or perianal warts (Condylomata acuminata) if the following criteria are met: • Member is ≥ 12 years of age AND • Member has tried and failed two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. All other non-preferred products may be approved for members who have trialed and failed all preferred products that are FDA-approved for use for the prescribed indication. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

		Quantity Limits: Aldara (imiquimod) cream has a quantity limit of 12 packets/28 days.
Therapeutic Drug Class: **ROSACEA AGENTS** -*Effective 7/1/2024*		
No PA Required Azelaic acid gel (*Sandoz only)* FINACEA (azelaic acid) gel FINACEA (azelaic acid) foam Metronidazole cream, lotion Metronidazole 0.75% gel	**PA Required** Azelaic acid gel *(All other manufacturers)* Brimonidine gel pump *Doxycycline monohydrate DR capsule (generic Oracea) Ivermectin cream Metronidazole 1% gel, gel pump NORITATE (metronidazole) cream RHOFADE (oxymetazoline) cream ROSADAN (metronidazole/skin cleanser) cream kit, gel kit	Prior authorization for non-preferred products in this class may be approved if meeting the following criteria for the prescribed diagnosis: Rosacea: ● Member has a diagnosis of persistent (non-transient) facial erythema with inflammatory papules and pustules due to rosacea AND ● Prescriber attests that medication is not being used solely for cosmetic purposes AND ● Member has tried and failed two preferred agents of different mechanisms of action (Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects) Demodex Blepharitis: • Requests for non-preferred topical ivermectin cream may be approved for treatment of moderate to severe Demodex blepharitis *Doxycycline monohydrate DR (generic Oracea) may be approved if the following criteria are met: ● Member has taken generic doxycycline for a minimum of three months and failed therapy in the last 6 months. Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions AND ● Member has history of an adequate trial/failure (8 weeks) of 2 other preferred agents (oral or topical). Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions AND ● Member is ≥ 18 years of age and has been diagnosed with rosacea with inflammatory lesions (papules and pustules)
Therapeutic Drug Class: **TOPICAL STEROIDS** – *Effective 7/1/2024*		
Low potency		
No PA Required DERMA-SMOOTHE-FS (fluocinolone) 0.01% body oil/scalp oil[BNR] Desonide 0.05% cream, ointment	**PA Required** Alclometasone 0.05% cream, ointment CAPEX (fluocinolone) 0.01% shampoo Desonide 0.05% lotion	Non-preferred Low Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the Low Potency class (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

Fluocinolone 0.01% cream Hydrocortisone (Rx) cream, lotion, ointment	Fluocinolone 0.01% body oil, 0.01% scalp oil, 0.01% solution PROCTOCORT (hydrocortisone) (Rx) 1% cream SYNALAR (fluocinolone) 0.01% solution SYNALAR TS (fluocinolone/skin cleanser) Kit TEXACORT (hydrocortisone) 2.5% solution	
Medium potency		
No PA Required Betamethasone dipropionate 0.05% cream, lotion, ointment Betamethasone valerate 0.1% cream, ointment Fluocinolone 0.025% cream, 0.05% cream, 0.005% ointment Fluticasone cream, ointment Hydrocortisone valerate 0.2% cream Mometasone 0.1% cream, 0.1% ointment, 0.1% solution Triamcinolone acetonide 0.025% cream, 0.1% cream, 0.025% ointment, 0.05% ointment, 0.1% ointment, 0.025% lotion, 0.1% lotion Triamcinolone 0.1% dental paste	**PA Required** BESER (fluticasone) lotion, emollient kit Betamethasone valerate 0.1% lotion, 0.12% foam Clocortolone 0.1% cream, cream pump CLODERM (clocortolone) 0.1% cream, cream pump CUTIVATE (fluticasone) 0.05% cream, lotion Diflorasone 0.05% cream Fluocinolone 0.025% ointment Fluocinonide-E 0.05% cream Flurandrenolide 0.05% cream, lotion, ointment Fluticasone 0.05% lotion Hydrocortisone butyrate 0.1% cream, lotion, solution, ointment, lipid/lipocream Hydrocortisone valerate 0.2% ointment KENALOG (triamcinolone) spray LOCOID (hydrocortisone butyrate) 0.1% lotion LOCOID LIPOCREAM (hydrocortisone butyrate-emollient) 0.1% cream	Non-preferred Medium Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the Medium Potency class (failure is defined as: lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

	LUXIQ (betamethasone valerate) 0.12% foam PANDEL (hydrocortisone probutate) 0.1% cream Prednicarbate 0.1% cream, ointment PSORCON (diflorasone) 0.05% cream SYNALAR (fluocinolone) 0.025% cream/kit, ointment/kit Triamcinolone 0.147 mg/gm spray	
High potency		
No PA Required (*unless exceeds duration of therapy) * Betamethasone dipropionate 0.05% ointment *Betamethasone dipropionate/propylene glycol (augmented) 0.05% cream *Fluocinonide 0.05% cream, 0.05% gel, 0.05% solution, 0.05% ointment *Triamcinolone acetonide 0.5% cream, 0.5% ointment	**PA Required** Amcinonide 0.1% cream, lotion APEXICON-E (diflorasone/emollient) 0.05% cream Desoximetasone 0.05%, 0.25% cream, 0.05% gel, 0.05%, 0.25% ointment Diflorasone 0.05% ointment Halcinonide 0.1% cream HALOG (halcinonide) 0.1% cream, ointment, solution TOPICORT (desoximetasone) 0.05%, 0.25% cream, 0.05% gel, 0.05%, 0.25% ointment	Non-preferred High Potency topical corticosteroids may be approved following adequate trial and failure of two preferred agents in the High Potency class (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions). *All High Potency topical corticosteroids will require prior authorization beyond 4 weeks of therapy. The provider will be encouraged to transition to a medium or low potency topical steroid after this time has elapsed. Claims for compounded products containing high-potency topical steroids will be limited to a maximum of 60 grams or 60 mL of a high-potency ingredient per 4-week treatment period. Claims exceeding this quantity limit will require prior authorization with prescriber's justification for use of the product at the prescribed dose.
Very high potency		
No PA Required (Unless exceeds duration of therapy*) *Betamethasone dipropionate/propylene glycol (augmented) ,0.05% lotion 0.05% ointment	**PA Required** Betamethasone dipropionate/propylene glycol (augmented) 0.05% gel BRYHALI (halobetasol) 0.01% lotion Clobetasol emollient/emulsion 0.05% cream, foam	Non-preferred Very High Potency topical corticosteroids may be approved following adequate trial and failure of clobetasol propionate in the same formulation as the product being requested (if the formulation of the requested non-preferred product is not available in preferred clobetasol product options, then trial and failure of any preferred clobetasol product formulation will be required). Failure is defined as lack of efficacy with 2-week trial, allergy, intolerable side effects or significant drug-drug interactions.

*Clobetasol 0.05% cream, 0.05% gel, 0.05% ointment, 0.05% solution *Fluocinonide 0.1% cream	Clobetasol 0.05% lotion, foam, spray, shampoo CLODAN (clobetasol) 0.05% cleanser kit Desoximetasone 0.25% spray DIPROLENE (betamethasone dipropionate/propylene glycol, augmented) 0.05% ointment Halobetasol 0.05% cream, foam, ointment IMPEKLO (clobetasol) 0.05% lotion LEXETTE (halobetasol) 0.05% foam OLUX (clobetasol) 0.05% foam TOPICORT (desoximetasone) 0.25% spray TOVET EMOLLIENT (clobetasol) 0.05% foam ULTRAVATE (halobetasol) 0.05% lotion VANOS (fluocinonide) 0.1% cream	*All Very High Potency topical corticosteroids will require prior authorization beyond 2 weeks of therapy. If clobetasol propionate shampoo is being used to treat plaque psoriasis, then prior authorization will be required beyond 4 weeks of therapy. The provider will be encouraged to transition to a medium or low potency topical steroid after this time has elapsed.

VI. Endocrine

Therapeutic Drug Class: **ANDROGENIC AGENTS, Topical, Injectable, Oral -***Effective 10/1/2024*

PA Required for all agents in this class		
Preferred	**Non-Preferred**	
Testosterone cypionate IM injection Testosterone gel packet	ANDROGEL (testosterone) gel packet ANDROGEL (testosterone) gel 1.62% pump	<u>Hypogonadotropic or Primary Hypogonadism (may be secondary to Klinefelter Syndrome):</u> Preferred products may be approved for members meeting the following: • Member is a male patient <u>≥</u> 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism OR ≥ 12 years of age with a

Testosterone 1.62% gel pump ***Injectable testosterone cypionate is a pharmacy benefit when self-administered. Administration in an office setting is a medical benefit.***	DEPO-TESTOSTERONE (testosterone cypionate) IM injection JATENZO (testosterone undecanoate) capsule KYZATREX (testosterone undecanoate) capsule METHITEST (methyltestosterone) tablet Methyltestosterone capsule NATESTO (testosterone) nasal spray TESTIM (testosterone) gel Testosterone 1% gel tube, 30 mg/1.5 ml pump Testosterone enanthate IM injection TLANDO (testosterone undecanoate) capsule UNDECATREX (testosterone undecanoate) capsule XYOSTED (testosterone enanthate) SC injection	diagnosis of hypogonadotropic or hypogonadism secondary to Klinefelter Syndrome (all other diagnoses will require manual review) AND • Member has two documented low serum testosterone levels below the lower limit of normal range for testing laboratory prior to initiation of therapy AND • Member does not have a diagnosis of breast or prostate cancer AND • If the member is > 40 years of age, has prostate-specific antigen (PSA) < 4 ng/mL or has no palpable prostate nodule AND • Member has baseline hematocrit < 50% Reauthorization Criteria (requests for renewal of a currently expiring prior authorization for a preferred product may be approved for members meeting the following criteria): • Member is a male patient ≥ 16 years of age with a documented diagnosis of hypogonadotropic or primary hypogonadism OR ≥ 12 years of age with a diagnosis of hypogonadotropic or hypogonadism secondary to Klinefelter Syndrome AND • Serum testosterone is being regularly monitored (at least annually) to achieve total testosterone level in the middle tertile of the normal reference range AND • Member does not have a diagnosis of breast or prostate cancer AND • Member has a hematocrit < 54% <u>Gender Transition/Affirming Hormone Therapy:</u> Preferred androgenic drugs may be approved for members meeting the following: 1. Female sex assigned at birth and has reached Tanner stage 2 of puberty AND 2. Is undergoing female to male transition AND 3. Has a negative pregnancy test prior to initiation AND 4. Hematocrit (or hemoglobin) is being monitored. **Non-Preferred Products:** Non-preferred **topical** androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with two preferred topical androgen formulations. Non-preferred **injectable** androgenic agents may be approved for patients meeting the above criteria with trial and failed‡ therapy with a preferred injectable androgenic drug. Prior authorization for **oral** androgen agents (tablet, capsule, buccal) may be approved if member has trialed and failed‡ therapy with a preferred topical agent AND testosterone cypionate injection. ‡Failure is defined as lack of efficacy with 8 week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction. For all agents and diagnoses, members < 16 years of age will require a manual prior authorization review by a pharmacist (with exception of members ≥ 12 years of age with a diagnosis of hypogonadotropic or hypogonadism secondary to Klinefelter Syndrome).

<table>
<tr><th colspan="3">Bisphosphonates</th></tr>
<tr><td>No PA Required

Alendronate tablet, solution

Ibandronate tablet

Risedronate tablet</td><td>PA Required

ACTONEL (risedronate) tablet

ATELVIA (risedronate) tablet

BINOSTO (alendronate) effervescent tablet

FOSAMAX (alendronate) tablet

FOSAMAX plus D (alendronate/vit D) tablet</td><td>Non-preferred bisphosphonates may be approved for members who have failed treatment with one preferred product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, intolerable side effects, or significant drug-drug interaction.

For members who have a low risk of fracture, discontinuation of bisphosphonate therapy and drug holiday should be considered following 5 years of treatment. Low risk is defined as having a bone mineral density, based on the most recent T-score, of greater than (better than) -2.5 AND no history of low trauma or fragility fracture.</td></tr>
<tr><th colspan="3">Non-Bisphosphonates</th></tr>
<tr><td>No PA Required

Raloxifene tablet</td><td>PA Required

Calcitonin salmon nasal spray

EVISTA (raloxifene) tablet

FORTEO (teriparatide) SC pen

Teriparatide SC pen

TYMLOS (abaloparatide) SC pen</td><td>CALCITONIN SALMON (nasal) may be approved if the member meets the following criteria:
● Member has a diagnosis of post-menopausal osteoporosis (BMD T-scores of -2.5 or less) AND
● Has trial and failure of one preferred bisphosphonate or non-bisphosphonate product for 12 months (failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) OR
● Member is unable to use a solid oral dosage form.
Quantity limit: One spray daily

FORTEO (teriparatide) or generic teriparatide may be approved if the member meets the following criteria:
● Member has one of the following diagnoses:
○ Male primary or hypogonadal osteoporosis (BMD T-scores of -2.5 or less).
○ Osteoporosis due to corticosteroid use
○ Postmenopausal osteoporosis
AND
● Member is at very high risk for fracture* OR member has history of trial and failure of one preferred bisphosphonate or non-bisphosphonate product for 12 months. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND
● Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (Forteo and Tymlos) shall not exceed two years
Maximum dose: 20mcg daily

TYMLOS (abaloparatide) may be approved if the member meets the following criteria:
● Member has a diagnosis of postmenopausal osteoporosis (BMD T-scores of -2.5 or less) AND
● Member is post-menopausal with very high risk for fracture* OR member has history of trial and failure of one preferred bisphosphonate or non-bisphosphonate product for 12 months</td></tr>
</table>

		(Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND** Prior authorization will be given for one year and total exposure of parathyroid hormone analogs (Forteo and Tymlos) shall not exceed two yearsMaximum dose: 80 mcg daily All other non-preferred non-bisphosphonates may be approved for members who have failed treatment with one preferred bisphosphonate or non-bisphosphonate product at treatment dose. Failure is defined as lack of efficacy with a 12-month trial, allergy, unable to use oral therapy, intolerable side effects, or significant drug-drug interaction. *Members at very high risk for fracture: Members will be considered at very high risk for fracture if they meet <u>one</u> of the following: • A history of fracture within the past 12 months **OR** • Fractures experienced while receiving guideline-supported osteoporosis therapy **OR** • A history of multiple fractures **OR** • A history of fractures experienced while receiving medications that cause skeletal harm (such as long-term glucocorticoids) **OR** • A very low T-score (less than -3.0) **OR** • A high risk for falls or a history of injurious falls **OR** • A very high fracture probability by FRAX (> 30% for a major osteoporosis fracture or > 4.5% for hip fracture) Raloxifene maximum dose: 60mg daily *Note: Prior authorization criteria for Prolia (denosumab) and other injectable bone resorption and related agents are listed on Appendix P.*

Therapeutic Drug Class: **CONTRACEPTIVES - Topical** *Effective 10/1/2024*

Effective 01/14/22, topical contraceptive patch products are eligible for coverage with a written prescription by an enrolled pharmacist. Additional information regarding pharmacist enrollment can be found at https://hcpf.colorado.gov/pharm-serv.

No PA Required	PA Required	
ANNOVERA (segesterone acetate/EE) vaginal ring Norelgestromin/EE TD patch	Etonorgestrel/EE vaginal ring XULANE (norelgestromin/EE) TD patch ZAFEMY (norelgestromin/EE) TD patch	Non-preferred topical contraceptive products may be approved following a trial and failure of one preferred topical contraceptive product. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. ***PHEXXI** (lactic acid/citric/potassium) vaginal gel quantity limit: 120 grams per 30 days

NUVARING[BNR] (etonorgestrel/EE) vaginal ring *PHEXXI (lactic acid/citric/potassium) vaginal gel TWIRLA (levonorgestrel/EE) TD patch		Continuation of therapy: Members who are currently using Annovera (segesterone/ethinyl estradiol) vaginal ring may receive approval to continue use of the product. Effective 7/1/2022: Prescriptions are eligible to be filled for up to a twelve-month supply. *Note: IUD and select depot product formulations are billed through the medical benefit*
Therapeutic Drug Class: **DIABETES MANAGEMENT CLASSES, INSULINS**- *Effective 10/1/2024*		
Rapid-Acting		
No PA Required HUMALOG[BNR] 100U/mL KwikPen, vial HUMALOG (insulin lispro) cartridge HUMALOG Jr.[BNR] (insulin lispro) KwikPen Insulin aspart cartridge, pen, vial NOVOLOG (insulin aspart) cartridge, FlexTouch pen, vial	**PA Required** ADMELOG (insulin lispro) Solostar pen, vial AFREZZA (regular insulin) cartridge, unit APIDRA (insulin glulisine) Solostar pen, vial FIASP (insulin aspart) FlexTouch pen, PenFill, pump cartridge, vial HUMALOG (insulin lispro) 200 U/mL pen, Tempo pen Insulin lispro Kwikpen, Jr. Kwikpen, vial LYUMJEV (insulin lispro-aabc) Kwikpen, vial, Tempo pen	All non-preferred products may be approved following trial and failure of treatment with two preferred products, one of which is the same rapid-acting insulin analog (lispro or aspart) as the non-preferred product being requested. (Failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, and angioedema] or intolerable side effects). **Afrezza** (human insulin) may be approved if meeting the following criteria: • Member is 18 years or older AND • Member has trialed and failed treatment with two preferred products (failure is defined as allergy [hives, maculopapular rash, erythema multiforme, pustular rash, severe hypotension, bronchospasm, or angioedema] or intolerable side effects) AND • Member must not have chronic lung disease such as COPD or asthma AND • If member has type 1 diabetes, must use in conjunction with long-acting insulin AND • Prescriber acknowledges that Afrezza is not recommended in patients who smoke or have recently stopped smoking.
Short-Acting		
No PA Required HUMULIN R U-100 (insulin regular) vial (OTC) NOVOLIN R U-100 (insulin regular) FlexPen (OTC)	**PA Required** NOVOLIN R U-100 (insulin regular) vial (OTC)	Non-preferred products may be approved following trial and failure of treatment with one preferred product (failure is defined as allergy or intolerable side effects).
Intermediate-Acting		
No PA Required HUMULIN N U-100 (insulin NPH) vial (OTC)	**PA Required** HUMULIN N U-100 (insulin NPH) KwikPen (OTC)	Non-preferred products may be approved following trial and failure of treatment with one preferred product (failure is defined as allergy or intolerable side effects).

NOVOLIN N U-100 (insulin NPH) FlexPen (OTC)	NOVOLIN N U-100 (insulin NPH) vial (OTC)	
Long-Acting		
No PA Required LANTUS[BNR] (insulin glargine) Solostar, vial Insulin degludec vial* TRESIBA [BNR] (insulin degludec) FlexTouch*	**PA Required** BASAGLAR (insulin glargine) Kwikpen, Tempo pen Insulin degludec FlexTouch Insulin glargine solostar, vial Insulin glargine MAX solostar Insulin glargine-yfgn pen, vial LEVEMIR (insulin detemir) FlexTouch, vial REZVOGLAR (insulin glargine-aglr) Kwikpen SEMGLEE (insulin glargine-yfgn) pen, vial TOUJEO (insulin glargine) Solostar TOUJEO MAX (insulin glargine) Solostar TRESIBA (insulin degludec) vial	*Preferred Tresiba pen and insulin degludec vial formulations may be approved for members who have trialed and failed‡ Lantus. Non-preferred products may be approved if the member has tried and failed‡ treatment with Lantus **AND** a preferred insulin degludec product. ‡Failure is defined as lack of efficacy, allergy, or intolerable side effects.
Concentrated		
No PA Required HUMULIN R U-500 (insulin regular) concentrated vial, Kwikpen	**PA Required**	Non-preferred products may be approved following trial and failure of treatment with one preferred product (failure is defined as allergy or intolerable side effects).
Mixtures		
No PA Required HUMALOG MIX 50/50 Kwikpen, vial	**PA Required** NOVOLIN 70/30 FlexPen, vial (OTC)	Non-preferred products may be approved if the member has failed treatment with two of the preferred products (failure is defined as: allergy or intolerable side effects).

HUMALOG MIX 75/25 Kwikpen[BNR], vial HUMULIN 70/30 (OTC) Kwikpen, vial Insulin aspart protamine/insulin aspart 70/30 FlexPen, vial (generic Novolog Mix) NOVOLOG MIX 70/30 FlexPen, vial	Insulin lispro protamine/insulin lispro 75/25 Kwikpen (generic Humalog Mix)	
Therapeutic Drug Class: **DIABETES MANAGEMENT CLASSES, NON- INSULINS**- *10/1/2024*		
Amylin		
	PA Required SYMLIN (pramlintide) pen	**SYMLIN** (pramlintide) may be approved following trial and failure of metformin AND trial and failure of a DPP4-inhibitor or GLP-1 analogue. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen) following 3-month trial, allergy, intolerable side effects, or a significant drug-drug interaction. Prior authorization may be approved for Symlin (pramlintide) products for members with a diagnosis of Type 1 diabetes without requiring trial and failure of other products. Maximum Dose: Prior authorization will be required for doses exceeding FDA-approved dosing listed in product package labeling.
Biguanides		
No PA Required Metformin IR tablets Metformin ER 500mg, 750mg tablets (generic Glucophage XR)	**PA Required** GLUMETZA ER (metformin) tablet Metformin 625 mg tablets Metformin ER (generic Fortamet, Glumetza) Metformin solution (generic Riomet) RIOMET (metformin) solution RIOMET ER (metformin) suspension	Non-preferred products may be approved for members who have failed treatment with two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Liquid metformin may be approved for members that are unable to use a solid oral dosage form.
Dipeptidyl Peptidase-4 Enzyme inhibitors (DPP-4is)		
Preferred JANUVIA (sitagliptin) tablet TRADJENTA (linagliptin) tablet	**Non-Preferred** **PA Required** Alogliptin tablet NESINA (alogliptin) tablet	Non-preferred DPP-4 inhibitors may be approved after a member has failed a 3-month trial of two preferred products. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction. <u>Maximum Dose:</u>

	ONGLYZA (saxagliptin) tablet Saxagliptin tablet Sitagliptin (generic Zituvio) ZITUVIO (sitagliptin tablet)	Prior authorization will be required for doses exceeding the FDA-approved maximum dosing listed in the following table: **DPP-4 Inhibitor** / **FDA-Approved Maximum Daily Dose** Alogliptin (generic Nesina) — 25 mg/day Januvia (sitagliptin) — 100 mg/day Nesina (alogliptin) — 25 mg/day Onglyza (saxagliptin) — 5 mg/day Tradjenta (linagliptin) — 5 mg/day Zituvio (sitagliptin) — 100 mg/day

DPP-4 Inhibitors – Combination with Metformin

Preferred	Non-Preferred PA Required	
JANUMET (sitagliptin/metformin) tablet JANUMET XR (sitagliptin/metformin) tablet JENTADUETO (linagliptin/metformin) tablet JENTADUETO XR (linagliptin/metformin) tablet	Alogliptin/metformin tablet KAZANO (alogliptin/metformin) tablet KOMBIGLYZE XR (saxagliptin/metformin) Saxagliptin/metformin tablet Sitagliptin/metformin (generic Zituvimet)	Non-preferred combination products may be approved for members who have been stable on the two individual ingredients of the requested combination for three months AND have had adequate three-month trial and failure of a preferred combination agent. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction. Maximum Dose: Prior authorization will be required for doses exceeding the FDA-approved maximum dosing listed in the following table: **DPP-4 Inhibitor Combination** / **FDA Approved Maximum Daily Dose** Alogliptin/metformin tablet — 25 mg alogliptin/2,000 mg metformin Janumet and Janumet XR (sitagliptin/metformin) — 100 mg sitagliptin/ 2,000 mg of metformin Jentadueto and Jentadueto XR (linagliptin/metformin) — 5 mg linagliptin/ 2,000 mg metformin

Kazano (alogliptin/metformin)	25 mg alogliptin/ 2,000 mg metformin
Kombiglyze XR (saxagliptin ER/metformin ER) tablet	5 mg saxagliptin/ 2,000 mg metformin

Glucagon-like Peptide-1 Receptor Agonists (GLP-1 Analogues)

Preferred *Must meet eligibility criteria	Non-Preferred PA Required	
*BYETTA (exenatide) pen *TRULICITY (dulaglutide) pen *VICTOZA [BNR] (liraglutide) pen **BYDUREON BCISE (exenatide ER) autoinjector *(changes effective 08/08/2024)*	Liraglutide pen MOUNJARO (tirzepatide) pen OZEMPIC (semaglutide) pen RYBELSUS (semaglutide) oral tablet WEGOVY (Semaglutide) pen	*Preferred products may be approved for members with a diagnosis of type 2 diabetes. ****BYDUREON BCISE (**exenatide ER): may be approved for members with a diagnosis of Type 2 diabetes following a 3-month trial and failure‡ of ONE other preferred product. **WEGOVY (semaglutide)** may be approved if meeting the following criteria: • Member is 18 years of age or older AND • Member has established cardiovascular disease (history of myocardial infarction, stroke, or symptomatic peripheral arterial disease) and either obesity or overweight (defined as a BMI ≥25 kg/m^2) AND • Member does not have a diagnosis of Type 1 or Type 2 diabetes AND • Wegovy (semaglutide) is being prescribed to decrease the risk of adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) AND • Member has been counseled regarding implementation of lifestyle interventions (diet modification and exercise) to promote weight loss. **Note: Prior authorization requests for Wegovy (semaglutide) prescribed solely for weight loss will not be approved.** All other non-preferred products may be approved for members with a diagnosis of type 2 diabetes following a 3-month trial and failure‡ of two preferred products . Maximum Dose: Prior authorization is required for all products exceeding maximum dose listed in product package labeling.

Table 1: GLP-1 Analogue Maximum Dose	
Bydureon Bcise (exenatide)	2 mg weekly
Byetta (exenatide)	20 mcg daily
Mounjaro (tirzepatide)	15 mg weekly
Ozempic (semaglutide)	2 mg weekly
Rybelsus (semaglutide)	14 mg daily
Trulicity (dulaglutide)	4.5 mg weekly
Victoza (liraglutide)	1.8 mg daily
Wegovy (semaglutide)	2.4 mg weekly

		‡Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, limited dexterity resulting in the inability to administer doses of a preferred product, or a significant drug-drug interaction. ***Note: Prior Authorization for GLP-1 analogues prescribed solely for weight loss will not be approved.***
Other Hypoglycemic Combinations		
	PA Required Alogliptin/pioglitazone tablet Glipizide/metformin tablet Glyburide/metformin tablet GLYXAMBI (empagliflozin/linagliptin) tablet OSENI (alogliptin/pioglitazone) tablet Pioglitazone/glimepiride tablet QTERN (dapagliflozin/saxagliptin) tablet SOLIQUA (insulin glargine/lixisenatide) pen STEGLUJAN (ertugliflozin/sitagliptin) tablet TRIJARDY XR tablet(empagliflozin/linagliptin/metformin) XULTOPHY (insulin degludec/liraglutide) pen	Non-preferred products may be approved for members who have been stable on each of the individual ingredients in the requested combination for 3 months (including cases where the ingredients are taken as two separate 3-month trials or when taken in combination for at least 3 months).
Meglitinides		
	PA Required Nateglinide tablet Repaglinide tablet	Non-preferred products may be approved for members who have failed treatment with one sulfonylurea. Failure is defined as: lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or significant drug-drug interaction.
Meglitinides Combination with Metformin		
	PA Required Repaglinide/metformin	Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.
Sodium-Glucose Cotransporter Inhibitors (SGLT inhibitors)		

No PA Required	PA Required	Non-preferred products may receive approval following trial and failure with two preferred products. Failure is defined as lack of efficacy with 3-month trial (such as not meeting hemoglobin A1C goal despite adherence to regimen), allergy, intolerable side effects, or a significant drug-drug interaction.
FARXIGA[BNR] (dapagliflozin) tablet JARDIANCE (empagliflozin) tablet	Dapagliflozin tablet INPEFA (sotagliflozin) tablet INVOKANA (canagliflozin) tablet STEGLATRO (ertugliflozin) tablet	

SGLT Inhibitor	Clinical Setting	Renal Dosing Recommendations (FDA labeling)
FARXIGA (dapagliflozin)	Glycemic control in patients without established CV disease or CV risk factors	Initiation of therapy not recommended when eGFR is less than 45 mL/min/1.73 m^2
	Reduce risk of CV death; Chronic kidney disease (CKD); Reduce risk of CV death, hospitalization or urgent visit for heart failure (HF)	Initiation of therapy not recommended when eGFR is less than 25 mL/min/1.73 m^2
INPEFA (sotagliflozin)	Reduce risk of CV death, HF hospitalization and urgent HF visit in adults with HF or Type 2 DM, chronic kidney disease and other CV risk factors	Safety and efficacy of initiating therapy when eGFR is less than 25 mL/min/1.73 m^2 or on dialysis has not been established
INVOKANA (canagliflozin)	Glycemic control in adults with Type 2 DM	Safety and efficacy of initiating therapy when eGFR is less than 30 mL/min/1.73 m^2 or on dialysis has not been established
	Reduce risk of major CV events in adults with Type 2 DM and established CVD; Reduce risk of ESKD, doubling of serum creatinine, CV death, and hospitalization for HF in adults with Type 2 DM and diabetic nephropathy (albuminuria > 300 mg/day)	Initiation of therapy not recommended when eGFR is less than 30 mL/min/1.73 m^2
JARDIANCE (empagliflozin)	Glycemic control in patients 10 years and older with Type 2 DM without established CV disease or CV risk factors	Not recommended when eGFR is less than 30 mL/min/1.73 m^2
	Reduce risk of CV death and hospitalization for HF; Chronic kidney disease (CKD); Reduce risk of CV death in adults with Type 2 DM and established CVD	Initiation of therapy not recommended when eGFR is less than 20 mL/min/1.73 m^2 or on dialysis

<table>
<tr><td></td><td></td><td>
<table>
<tr><td>STEGLATRO (ertugliflozin)</td><td>Adjunct to diet and exercise in patients with Type 2 DM</td><td>Not recommended when eGFR is less than 45 mL/min/1.73 m^2</td></tr>
</table>

Maximum Dose:
Prior authorization is required for all products exceeding maximum dose listed in product package labeling.</td></tr>
<tr><td colspan="3">SGLT Inhibitor Combinations with Metformin</td></tr>
<tr><td>No PA Required

SYNJARDY (empagliflozin/metformin) tablet

SYNJARDY XR (empagliflozin/metformin) tablet

XIGDUO XR[BNR] (dapagliflozin/metformin) tablet</td><td>PA Required

Dapagliflozin/Metformin XR tablet

INVOKAMET (canagliflozin/metformin) tablet

INVOKAMET XR (canagliflozin/metformin) tablet

SEGLUROMET (ertugliflozin/metformin) tablet</td><td>Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.

INVOKAMET, INVOKAMET XR, SEGLUROMET, SYNJARDY, SYNJARDY XR and XIGDUO XR are contraindicated in patients with an eGFR less than 30 mL/min/1.73 m^2 or on dialysis.</td></tr>
<tr><td colspan="3">Thiazolidinediones (TZDs)</td></tr>
<tr><td>No PA Required

Pioglitazone tablet</td><td>PA Required

ACTOS (pioglitazone) tablet</td><td>Non-preferred agents may be approved following trial and failure of one preferred product. Failure is defined as lack of efficacy (such as not meeting hemoglobin A1C goal despite adherence to regimen) with a 3-month trial, allergy, intolerable side effects, or a significant drug-drug interaction.</td></tr>
<tr><td colspan="3">Thiazolidinediones Combination with Metformin</td></tr>
<tr><td></td><td>PA Required

ACTOPLUS MET (pioglitazone/metformin) TABLET

Pioglitazone/metformin tablet</td><td>Non-preferred products may be approved for members who have been stable on the two individual ingredients of the requested combination for 3 months.</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: ESTROGEN AGENTS -Effective 10/1/2024</td></tr>
<tr><td>No PA Required</td><td>PA Required</td><td rowspan="3">Non-preferred parenteral estrogen agents may be approved with trial and failure of one preferred parenteral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.</td></tr>
<tr><td colspan="2">Parenteral</td></tr>
<tr><td></td><td>Estradiol valerate 10mg/mL vial, 20mg/mL vial</td></tr>
</table>

DELESTROGEN[BNR] (estradiol valerate) vial DEPO-ESTRODIOL (estradiol cypionate) vial Estradiol valerate 40mg/mL vial		Non-preferred oral estrogen agents may be approved with trial and failure of one preferred oral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Non-preferred transdermal estrogen agents may be approved with trial and failure of two preferred transdermal agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.
Oral/Transdermal		
Estradiol oral tablet Estradiol (generic Climara) weekly patch MINIVELLE[BNR] (estradiol) patch VIVELLE-DOT[BNR] (estradiol) patch	CLIMARA (estradiol) patch DOTTI (estradiol) patch ESTRACE (estradiol) oral tablet Estradiol bi-weekly patch LYLLANA (estradiol) patch MENOSTAR (estradiol) patch	

Table 1: Transdermal Estrogen FDA-Labeled Dosing	
ALORA (estradiol) patch	2/week
CLIMARA (estradiol) patch	1/week
DOTTI (estradiol) patch	2/week
Estradiol patch (once weekly)	1/week
Estradiol patch (twice weekly)	2/week
LYLLANA (estradiol) patch	2/week
MENOSTAR (estradiol) patch	1/week
MINIVELLE (estradiol) patch	2/week
VIVELLE-DOT (estradiol) patch	2/week

Note: Estrogen agents are a covered benefit for gender affirming hormone therapy and treating clinicians and mental health providers should be knowledgeable about the diagnostic criteria for gender-affirming hormone treatment and have sufficient training and experience in assessing related mental health conditions.

Therapeutic Drug Class: **GLUCAGON, SELF-ADMINISTERED** -*Effective 11/8/2024*		
Preferred **No PA Required**	**Non-Preferred** **PA Required**	
BAQSIMI (glucagon) nasal spray Glucagon Emergency Kit (*Eli Lilly, Fresenius, Amphastar)* ZEGALOGUE (dasiglucagon) autoinjector	GVOKE (glucagon) Hypopen, Syringe, vial ZEGALOGUE (dasiglucagon) syringe	Non-preferred products may be approved if the member has failed treatment with two preferred products (failure is defined as allergy to ingredients in product, intolerable side effects, contraindication, or inability to administer dosage form). Quantity limit for all products: 2 doses per year unless used/ damaged/ lost

Therapeutic Drug Class: **GROWTH HORMONES** -*Effective 10/1/2024*

Preferred
No PA Required
(If diagnosis and dose met)

GENOTROPIN (somatropin) cartridge, Miniquick pen

NORDITROPIN (somatropin) Flexpro pen

Non-Preferred
PA Required

HUMATROPE (somatropin) cartridge

NGENLA (somatrogon-ghla) pen

NUTROPIN AQ (somatropin) Nuspin injector

OMNITROPE (somatropin) cartridge, vial

SAIZEN (somatropin) cartridge, vial

SEROSTIM (somatropin) vial

SKYTROFA (lonapegsomatropin-tcgd) cartridge

SOGROYA (somapacitan-beco) pen

ZOMACTON (somatropin) vial

All preferred products may be approved if the member has one of the qualifying diagnoses listed below (diagnosis may be verified through AutoPA) AND if prescription does not exceed limitations for maximum dosing (Table 1).

Non-preferred Growth Hormone products may be approved if the following criteria are met:

- Member failed treatment with one preferred growth hormone product (failure is defined as lack of efficacy, allergy, intolerable side effects or signific
- ant drug-drug interactions) AND
- Member has a qualifying diagnosis that includes any of the following conditions:
  - Prader-Willi Syndrome (PWS)
  - Chronic renal insufficiency/failure requiring transplantation (defined as Creatinine Clearance < 30mL/min)
  - Turner's Syndrome
  - Hypopituitarism: as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy or trauma verified by one of the following:
    - Has failed at least one GH stimulation test (peak GH level < 10 ng/mL)
    - Has at least one documented low IGF-1 level (below normal range for patient's age – refer to range on submitted lab document)
    - Has deficiencies in ≥ 3 pituitary axes (such as TSH, LH, FSH, ACTH, ADH)
  - Cachexia associated with AIDS
  - Noonan Syndrome
  - Short bowel syndrome
  - Neonatal symptomatic growth hormone deficiency (limited to 3-month PA approval)

  AND
- Prescription does not exceed limitations for FDA-labeled maximum dosing for prescribed indication (Table 1) based on prescriber submission/verification of patient weight from most recent clinical documentation

Table 1: Growth Hormone Product Maximum Dosing*

Medication	Pediatric Maximum Dosing per week (age < 18 years)	Adult Maximum Dosing per week (age ≥ 18 years)
Genotropin	0.48 mg/kg/week	0.08 mg/kg/week
Humatrope	0.47 mg/kg/week	0.0875 mg/kg/week
Ngenla	0.66 mg/kg/week	Not Indicated
Norditropin Flexpro	0.47 mg/kg/week	0.112 mg/kg/week
Nutropin AQ Nuspin	0.7 mg/kg/week	0.175 mg/kg/week for ≤35 years of age

		0.0875 mg/kg/week for >35 years of age
Omnitrope	0.48 mg/kg/week	0.08 mg/kg/week
Saizen	0.18 mg/kg/week	0.07 mg/kg/week
Serostim	Not Indicated	42 mg/week for HIV wasting or cachexia (in combination with antiretroviral therapy)
Skytrofa	1.68 mg/kg/week	Not Indicated
Sogroya	Dose Individualized for each patient, based on growth response	8 mg/week
Zomacton	0.47 mg/kg/week	0.0875 mg/kg/week
Zorbtive	Not Indicated	56 mg/week for up to 4 weeks for short bowel syndrome only

*Based on FDA labeled indications and dosing

VII. Gastrointestinal

Therapeutic Drug Class: **BILE SALTS** -*Effective 7/1/2024*

No PA Required	**PA Required**	
Ursodiol capsule Ursodiol tablet	BYLVAY (odevixibat) capsule, pellet CHENODAL (chenodiol) tablet CHOLBAM (cholic acid) capsule LIVMARLI (maralixibat) solution OCALIVA (obeticholic acid) tablet RELTONE (ursodiol) capsule	**Chenodal** (chenodiol) and **Actigall** (ursodiol) may be approved for members who meet the following criteria: • Member is ≥ 18 years of age AND • Member has tried and failed therapy with a 12-month trial of a preferred ursodiol product (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions). **Cholbam** (cholic acid) may be approved for members who meet the following criteria: • Bile acid synthesis disorders: o Member age must be greater than 3 weeks old AND o Member has a diagnosis for bile acid synthesis disorder due to single enzyme defect (Single Enzyme-Defect Disorders: Defective sterol nucleus synthesis, 3β-hydroxy-Δ-c27-steroid oxidoreductase deficiency, AKR1D1 deficiency, CYP7A1 deficiency, Defective side-chain

	URSO (ursodiol) tablet URSO FORTE (ursodiol) tablet	synthesis, CYP27A1 deficiency (cerebrotendinous xanthomatosis), 2-methylacyl-CoA racemase deficiency (AMACR), 25-hydroxylation pathway (Smith–Lemli-Opitz). • Peroxisomal disorder including Zellweger spectrum disorders: o Member age must be greater than 3 weeks old AND o Member has diagnosis of peroxisomal disorders (PDs) including Zellweger spectrum disorders AND o Member has manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption. **Ocaliva** (obeticholic acid) may be approved for members meeting the following criteria: • Member is ≥ 18 years of age AND • Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND • Member has the diagnosis of primary biliary cholangitis without cirrhosis OR a diagnosis of primary biliary cholangitis with compensated cirrhosis with no evidence of portal hypertension AND • Member has failed treatment with a preferred ursodiol product for at least 6 months due to an inadequate response, intolerable side effects, drug-drug interaction, or allergy to preferred ursodiol formulations. **Reltone** (ursodiol) may be approved for members meeting the following criteria: • Member is ≥ 18 years of age AND • The requested medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND • The requested medication is being prescribed for one of the following: o Treatment of radiolucent, noncalcified gallbladder stones < 20 mm in greatest diameter AND elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for those patients who refuse surgery OR o Prevention of gallstone formation in obese patients experiencing rapid weight loss AND • No compelling reasons for the member to undergo cholecystectomy exist, including unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-gastrointestinal fistula, **AND** • Member has trialed and failed treatment with a preferred ursodiol product for at least 6 months due to an inadequate response, intolerable side effects, drug-drug interaction, or allergy to inactive ingredients contained in the preferred ursodiol formulations. Initial approval: 1 year

		Reauthorization: May be reauthorized for 1 additional year with provider attestation that partial or complete stone dissolution was observed after completion of the initial year of Reltone therapy. Maximum cumulative approval per member is 24 months. **Urso** (ursodiol) and **Urso Forte** (ursodiol) may be approved for members meeting the following criteria: • Member is ≥ 18 years of age AND • Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND • Member has the diagnosis of Primary Biliary Cholangitis as evidenced by two of the following at the time of diagnosis: o Evidence of cholestasis with an alkaline phosphatase elevation of at least 1.5 times the upper limit of normal o Presence of antimitochondrial antibody with titer of 1:40 or higher o Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts AND • Member has failed treatment with a preferred ursodiol product for at least 6 months due to an inadequate response, intolerable side effects, drug-drug interaction, or allergy to inactive ingredients contained in the preferred ursodiol formulations. **Requests for drug products that are FDA-indicated for the treatment of nonalcoholic steatohepatitis (NASH) may be approved if meeting the following:** • A diagnosis of NASH has been confirmed through liver biopsy AND • Member meets the FDA-labeled minimum age requirement for the prescribed product AND • Member does not have significant liver disease other than NASH, AND • The requested medication is being prescribed for use for the FDA-labeled indication and as outlined in product package labeling AND • Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider. Non-preferred products prescribed for FDA-labeled indications not identified above may receive approval for use as outlined in product package labeling.
Therapeutic Drug Class: **ANTI-EMETICS, Oral** -*Effective 7/1/2024*		
No PA Required DICLEGIS DR[BNR] tablet (doxylamine/pyridoxine) Meclizine (Rx) 12.5 mg, 25 mg tablet	**PA Required** AKYNZEO (netupitant/palonosetron) capsule ANTIVERT (meclizine) 50 mg tablet ANZEMET (dolasetron) tablet	**Emend (aprepitant) TriPack** or **Emend (aprepitant) powder kit** may be approved following trial and failure of two preferred products AND Emend (aprepitant) capsule. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction. **Doxylamine/pyridoxine tablet (generic)** or **Bonjesta (doxylamine/pyridoxine)** may be

Metoclopramide solution, tablet Ondansetron ODT; 4mg, 8mg tablet Ondansetron oral suspension/ solution Prochlorperazine tablet Promethazine syrup, tablet	Aprepitant capsule, tripack BONJESTA ER (doxylamine/pyridoxine) tablet Doxylamine/pyridoxine tablet (generic Diclegis) Dronabinol capsule EMEND (aprepitant) capsule, powder for suspension, dose/tri-pack Granisetron tablet MARINOL (dronabinol) capsule Ondansetron 16mg tablet REGLAN (metoclopramide) tablet Trimethobenzamide capsule ZOFRAN (ondansetron) tablet	approved for 9 months if meeting the following criteria: • Member has nausea and vomiting associated with pregnancy **AND** • Member has trialed and failed DICLEGIS DR tablet **AND** one of the following (failure is defined as lack of efficacy with a 7-day trial, allergy, intolerable side effects, or significant drug-drug interaction): o Antihistamine (such as diphenhydramine, dimenhydrinate, meclizine) **OR** o Dopamine antagonist (such as metoclopramide, prochlorperazine, promethazine) **OR** o Serotonin antagonist (ondansetron, granisetron) All other non-preferred products may be approved for members who have trialed and failed treatment with two preferred products. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction. **Dronabinol** prior authorization may be approved for members meeting above non-preferred criteria OR via AutoPA for members with documented HIV diagnosis. **Promethazine** product formulations require prior authorization for members < 2 years of age due to risk of fatal respiratory depression.
Therapeutic Drug Class: **ANTI-EMETICS, Non-Oral** -*Effective 7/1/2024*		
No PA Required Prochlorperazine 25 mg suppository Promethazine 12.5 mg, 25 mg suppository Scopolamine patch	**PA Required** PROMETHEGAN 50 mg (Promethazine) suppository SANCUSO (granisetron) patch TRANSDERM-SCOP (scopolamine) patch	Non-preferred products may be approved for members who have trialed and failed treatment with two preferred products. Failure is defined as lack of efficacy with 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.
Therapeutic Drug Class: **GI MOTILITY, CHRONIC** -*Effective 7/1/2024*		
PA Required for all agents in this class		All agents will only be approved for FDA labeled indications and up to FDA approved maximum doses listed below. Preferred agents may be approved if the member meets the following criteria: • Has diagnosis of Irritable Bowel Syndrome – Constipation (IBS-C), Chronic
Preferred	**Non-Preferred**	
	Alosetron tablet	

LINZESS (linaclotide) capsule Lubiprostone capsule MOVANTIK (naloxegol) tablet	AMITIZA (lubiprostone) capsule IBSRELA tablet LOTRONEX (alosetron) tablet MOTEGRITY (prucalopride) tablet RELISTOR (methylnaltrexone) syringe, tablet, vial SYMPROIC (naldemedine) tablet TRULANCE (plecanatide) tablet VIBERZI (eluxadoline) tablet	Idiopathic Constipation (CIC), or Opioid Induced Constipation (OIC) in patients with opioids prescribed for noncancer pain **AND** • Member does not have a diagnosis of GI obstruction **AND** • For indication of OIC, member opioid use must exceed 4 weeks of treatment • For indications of CIC, OIC, IBS-C; member must have documentation of adequate trial of two or more over-the-counter motility agents (polyethylene glycol, docusate or bisacodyl, for example). OR If the member cannot take oral medications, then the member must fail a 7-day trial with a nonphosphate enema (docusate or bisacodyl enema). Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction **AND** • For indication of IBS-D, must have documentation of adequate trial and failure with loperamide and trial and failure with dicyclomine or hyoscyamine. Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction. Non-preferred agents may be approved if the member meets the following criteria: • Member meets all listed criteria for preferred agents **AND** • Member has trialed and failed two preferred agents OR if the indication is OIC caused by methadone, then a non-preferred agent may be approved after an adequate trial of MOVANTIK (naloxegol). Failure is defined as a lack of efficacy for a 7-day trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction **AND** • If prescribed Viberzi (eluxadoline) or Lotronex (alosetron), member meets the additional criteria for those agents listed below. **VIBERZI (eluxadoline)** may be approved for members who meet the following additional criteria: • Diagnosis of Irritable Bowel Syndrome – Diarrhea (IBS-D) **AND** • Member has a gallbladder **AND** • Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation, known mechanical gastrointestinal obstruction, biliary duct obstruction, history of pancreatitis or structural disease of the pancreas **AND** • Member does not drink more than 3 alcoholic drinks per day **LOTRONEX (alosetron)** and generic alosetron may be approved for members who meet the following additional criteria: • Member is a female with Irritable Bowel Syndrome – Diarrhea (IBS-D) with symptoms lasting 6 months or longer **AND** • Member does not have severe hepatic impairment (Child-Pugh C), history of severe constipation or ischemic colitis, hypercoagulable state, Crohn's disease or ulcerative colitis, or known mechanical gastrointestinal obstruction.

Medication	FDA approved indication	FDA Max Dose
Amitiza (lubiprostone)	IBS-C (females only), CIC, OIC (not caused by methadone)	48mcg/day
Linzess (linaclotide)	IBS-C, CIC	290mcg/day
Movantik (naloxegol)	OIC	25mg/day
Viberzi (eluxadoline)	IBS-D	200mg/day
Relistor subcutaneous injection (methylnaltrexone)	OIC	12mg/day
Relistor oral (methylnaltrexone)	OIC	450mg/day
Lotronex (alosetron)	IBS-D (females only)	2mg/day (females only)
Symproic (Naldemedine)	OIC	0.2mg/day
Trulance (plecanatide)	CIC, IBS-C	3mg/day
Motegrity (prucalopride)	CIC	2mg/day

CIC – chronic idiopathic constipation, OIC – opioid induced constipation, IBS – irritable bowel syndrome, D – diarrhea predominant, C – constipation predominant

Therapeutic Drug Class: **H. PYLORI TREATMENTS -***Effective 7/1/2024*

No PA Required	PA Required	
PYLERA[BNR] capsule (bismuth subcitrate/metronidazole tetracycline)	Amoxicillin/lansoprazole/clarithromycin pack Bismuth subcitrate/metronidazole tetracycline capsule OMECLAMOX-PAK (amoxicillin/ omeprazole/clarithromycin) TALICIA (omeprazole/amoxicillin/ rifabutin) tablet VOQUEZNA DUAL (vonoprazan/amoxicillin) dose pack VOQUEZNA TRIPLE (vonoprazan/amoxicillin/ clarithromycin dose pack	Non-preferred *H. pylori* treatments should be used as individual product ingredients unless one of the individual products is not commercially available, then a PA for the combination product may be given.

Therapeutic Drug Class: **HEMORRHOIDAL, ANORECTAL, AND RELATED TOPICAL ANESTHETIC AGENTS -** *Effective 7/1/2024*

Hydrocortisone single agent

No PA Required	PA Required	
ANUSOL-HC (hydrocortisone) 2.5% cream with applicator	CORTENEMA (hydrocortisone) enema PROCORT cream	Non-preferred products may be approved following trial and failure of therapy with 3 preferred products (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions).

CORTIFOAM (hydrocortisone) 10% aerosol Hydrocortisone 1% cream with applicator Hydrocortisone 2.5% cream with applicator Hydrocortisone enema		
Lidocaine single agent		
No PA Required	**PA Required**	
Lidocaine 5% ointment	Lidocaine 3% cream	
Other and Combinations		
No PA Required	**PA Required**	
Hydrocortisone-Pramoxine 1%-1% cream Lidocaine-Hydrocortisone 3-0.5% cream with applicator Lidocaine-Prilocaine Cream *(all other manufacturers)* PROCTOFOAM-HC (hydrocortisone-pramoxine) 1%-1% foam	ANALPRAM HC (Hydrocortisone-Pramoxine) 1%-1% cream, 2.5%-1% cream EPIFOAM (Hydrocortisone-Pramoxine) 1%-1% foam Hydrocortisone-Pramoxine 2.5%-1% cream Lidocaine-Hydrocortisone in Coleus 2%-2% cream kit Lidocaine-Hydrocortisone 2.8%-0.55% gel Lidocaine-Hydrocortisone 3%-0.5% cream w/o applicator, cream kit Lidocaine-Hydrocortisone 3%-1% cream kit Lidocaine-Hydrocortisone 3%-2.5% gel kit Lidocaine-Prilocaine Cream *(Fougera only)* PLIAGIS (lidocaine-tetracaine) 7%-7% cream PROCORT (Hydrocortisone-Pramoxine) 1.85%-1.15% cream RECTIV (nitroglycerin) 0.4% ointment	**Rectiv** (nitroglycerin) ointment may be approved if meeting the following: • Member has a diagnosis of anal fissure **AND** • Prescriber attests that member has trialed and maximized use of appropriate supportive therapies including sitz bath, fiber, topical analgesics (such as lidocaine), and stool softeners/laxatives.

<table>
<tr><th colspan="3">Therapeutic Drug Class: PANCREATIC ENZYMES -Effective 7/1/2024</th></tr>
<tr><th>No PA Required</th><th>PA Required</th><td rowspan="2">Non-preferred products may be approved for members who have failed an adequate trial (4 weeks) with at least two preferred products. (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.)</td></tr>
<tr><td>CREON (pancrelipase) capsule

VIOKACE (pancrelipase) tablet

ZENPEP (pancrelipase) capsule</td><td>PERTZYE (pancrelipase) capsule</td></tr>
<tr><th colspan="3">Therapeutic Drug Class: PROTON PUMP INHIBITORS -Effective 7/1/2024</th></tr>
<tr><th>No PA Required</th><th>PA Required</th><td rowspan="2">For members treating GERD symptoms that are controlled on PPI therapy, it is recommended that the dose of the PPI be re-evaluated or step-down with an H2 blocker (such as famotidine) be trialed in order to reduce long-term PPI use.
Prior authorization for non-preferred proton pump inhibitors may be approved if all of the following criteria are met:
● Member has a qualifying diagnosis (below) AND
● Member has trialed and failed therapy with three preferred agents within the last 24 months. (Failure is defined as: lack of efficacy following 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction) AND
● Member has been diagnosed using one of the following diagnostic methods:
o Diagnosis made by GI specialist
o Endoscopy
o X-ray
o Biopsy
o Blood test
o Breath Test

Qualifying Diagnoses:
Barrett’s esophagus, duodenal ulcer, erosive esophagitis, gastric ulcer, GERD, GI Bleed, H. pylori infection, hypersecretory conditions (Zollinger-Ellison), NSAID-induced ulcer, pediatric esophagitis, requiring mechanical ventilation, requiring a feeding tube

Quantity Limits:
All agents will be limited to once daily dosing except when used for the following diagnoses: Barrett’s esophagus, GI Bleed, H. pylori infection, hypersecretory conditions (Zollinger-Ellison), or members who have spinal cord injury with associated acid reflux.

Adult members with GERD on once daily, high-dose PPI therapy who continue to experience symptoms may receive initial prior authorization approval for a 4-week trial of twice daily, high-dose PPI therapy. Continuation of the twice daily dosing regimen for GERD beyond 4 weeks will require additional prior authorization approval verifying adequate member response to the dosing regimen and approval may be placed for one year. If a member with symptomatic GERD does not respond to twice daily, high-dose PPI therapy, this should be considered a treatment failure.</td></tr>
<tr><td>Esomeprazole DR packet for oral suspension, capsule (RX)

Lansoprazole DR capsules (RX)

Lansoprazole ODT (lansoprazole) (for members under 2 years)

Omeprazole DR capsule (RX)

Pantoprazole tablet

PROTONIX (pantoprazole DR) packet for oral suspension[BNR]</td><td>ACIPHEX (rabeprazole) tablet, sprinkle capsule

DEXILANT (dexlansoprazole) capsule

Dexlansoprazole capsule

Esomeprazole DR 49.3 capsule (RX), (OTC) capsule

KONVOMEP (Omeprazole/Na bicarbonate) suspension

Lansoprazole DR capsule OTC

NEXIUM (esomeprazole) capsule (RX), oral suspension packet, 24HR (OTC)

Omeprazole/Na bicarbonate capsule, packet for oral suspension

Omeprazole DR tablet (OTC), ODT (OTC)

Pantoprazole packet for oral suspension

PREVACID (lansoprazole) capsule, Solutab, suspension

PRILOSEC (omeprazole) suspension

PROTONIX (pantoprazole DR) tablet

Rabeprazole tablet

VOQUEZNA (vonoprazan) tablet</td></tr>
</table>

	ZEGERID (omeprazole/Na bicarbonate) capsule, packet for oral suspension	**Pediatric members (< 18 years of age)** on once daily dosing of a PPI who continue to experience symptoms may receive one-year prior authorization approval for twice daily PPI therapy. **Age Limits:** **Nexium 24H** and **Zegerid** will not be approved for members less than 18 years of age. **Prevacid Solutab** may be approved for members < 2 years of age OR for members ≥ 2 years of age with a feeding tube. Continuation of Care: Members currently taking Dexilant (dexlansoprazole) capsules may continue to receive approval for that medication.
Therapeutic Drug Class: **NON-BIOLOGIC ULCERATIVE COLITIS AGENTS- Oral** -*Effective 7/1/2024*		
No PA Required *Brand/generic changes effective 08/08/2024* APRISO[BNR] (mesalamine ER) capsule Mesalamine DR tablet (generic Lialda) (*Takeda only)* PENTASA[BNR] (mesalamine) capsule Sulfasalazine IR and DR tablet	**PA Required** AZULFIDINE (sulfasalazine) Entab, tablet Balsalazide capsule Budesonide DR tablet COLAZAL (balsalazide) capsule DELZICOL (mesalamine DR) capsule DIPENTUM (olsalazine) capsule LIALDA (mesalamine DR) tablet Mesalamine DR tablet (generic Asacol HD, Lialda) Mesalamine DR/ER capsule (generic Apriso, Delzicol, Pentasa) UCERIS (budesonide) tablet	Prior authorization for non-preferred oral formulations will require trial and failure of two preferred oral products with different active ingredients AND one preferred rectal product. If inflammation is not within reach of topical therapy, trial of preferred rectal product is not required. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **Uceris (budesonide) tablet**: Prior authorization may be approved following trial and failure of one preferred oral product AND one preferred rectal product. If inflammation is not within reach of topical therapy, trial of preferred rectal product is not required. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Approval will be placed for 8 weeks. Further prior authorization may be approved if 7 days of steroid-free time has elapsed, and member continues to meet the above criteria.
Therapeutic Drug Class: **NON-BIOLOGIC ULCERATIVE COLITIS AGENTS- Rectal** -*Effective 7/1/2024*		
No PA Required Mesalamine suppository Mesalamine 4gm/60 ml enema (generic SF ROWASA)	**PA Required** Budesonide foam CANASA (mesalamine) suppository Mesalamine enema, kit	Prior authorization for non-preferred rectal formulations will require trial and failure of one preferred rectal formulation and one preferred oral formulation (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction). **Uceris (budesonide) foam**: If the above criteria are met, Uceris (budesonide) foam prior authorization may be approved for 6 weeks. Further prior authorization may be approved

	ROWASA/SF ROWASA enema, kit (mesalamine) UCERIS (budesonide) foam	if 7 days of steroid-free time has elapsed, and member continues to meet the above criteria.

VIII. Hematological

Therapeutic Drug Class: **ANTICOAGULANTS- Oral** -*Effective 7/1/2024*		
No PA Required Dabigatran capsule ELIQUIS (apixaban) tablet, tablet pack Warfarin tablet XARELTO (rivaroxaban) 10 mg, 15 mg, 20 mg tablet, dose pack	**PA Required** PRADAXA (dabigatran) capsule, pellet SAVAYSA (edoxaban) tablet XARELTO (rivaroxaban) 2.5 mg tablet XARELTO (rivaroxaban) oral suspension	**SAVAYSA** (edoxaban) may be approved if all the following criteria have been met: ● The member has failed therapy with two preferred agents. (Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) **AND** ● Member is not on dialysis **AND** ● Member does not have CrCl > 95 mL/min **AND** ● The member has a diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE) **OR** ● The member has a diagnosis of non-valvular atrial fibrillation **AND** ● The member does not have a mechanical prosthetic heart valve **XARELTO 2.5mg** (rivaroxaban) may be approved for members meeting all of the following criteria: ● Xarelto 2.5mg is being prescribed to reduce major CV events in members diagnosis of chronic coronary artery disease (CAD) or peripheral artery disease **AND** ● Xarelto 2.5mg is being taken twice daily and in combination with aspirin 75-100mg daily **AND** ● Member must not be receiving dual antiplatelet therapy, other non-aspirin antiplatelet therapy, or other oral anticoagulant **AND** ● Member must not have had an ischemic, non-lacunar stroke within the past month **AND** ● Member must not have had a hemorrhagic or lacunar stroke at any time **XARELTO** (rivaroxaban) oral suspension may be approved without prior authorization for members <18 years of age who require a rivaroxaban dose of less than 10 mg **OR** with prior authorization verifying the member is unable to use the solid oral dosage form. All other non-preferred oral agents require trial and failure of two preferred oral agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Continuation of Care: Members with current prior authorization approval on file for a non-preferred oral anticoagulant medication may continue to receive approval for that medication
Therapeutic Drug Class: **ANTICOAGULANTS- Parenteral** -*Effective 7/1/2024*		

<table>
<tr><td>No PA Required

Enoxaparin syringe

Enoxaparin vial</td><td>PA Required

ARIXTRA (fondaparinux) syringe

Fondaparinux syringe

FRAGMIN (dalteparin) vial, syringe

LOVENOX (enoxaparin) syringe, vial</td><td>Non-preferred parenteral anticoagulants may be approved if member has trial and failure of one preferred parenteral agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction

ARIXTRA (fondaparinux) may be approved if the following criteria have been met:
● Member is 18 years of age or older AND
● Member has a CrCl > 30 ml/min AND
● Member weighs > 50 kg AND
● Member has a documented history of heparin induced-thrombocytopenia OR
● Member has a contraindication to enoxaparin

Members currently stabilized on fondaparinux (Arixtra) or dalteparin (Fragmin) may receive prior authorization approval to continue receiving that medication.</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: ANTI-PLATELETS -Effective 7/1/2024</td></tr>
<tr><td>No PA Required

Aspirin/dipyridamole ER capsule

BRILINTA (tigacrelor) tablet

Cilostazol tablet

Clopidogrel tablet

Dipyridamole tablet

Pentoxifylline ER tablet

Prasugrel tablet</td><td>PA Required

EFFIENT (prasugrel) tablet

PLAVIX (clopidogrel) tablet</td><td>Zontivity (vorapaxar) may be approved for patients with a diagnosis of myocardial infarction or peripheral artery disease without a history of stroke, transient ischemic attack, intracranial bleeding, or active pathological bleeding. Patients must also be taking aspirin and/or clopidogrel concomitantly.

Non-preferred products without criteria will be reviewed on a case-by-case basis.</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: COLONY STIMULATING FACTORS -Effective 7/1/2024</td></tr>
<tr><td colspan="2">PA Required for all agents in this class*

Preferred

FULPHILA (pegfilgrastim-jmdb) syringe

NEUPOGEN (filgrastim) vial, syringe

Non-Preferred

FYLNETRA (pegfilgrastim-jmdb) syringe

GRANIX (tbo-filgrastim) syringe, vial

LEUKINE (sargramostim) vial

NEULASTA (pegfilgrastim) kit, syringe

NIVESTYM (filgrastim-aafi) syringe, vial</td><td>*Prior authorization for preferred agents may be approved if meeting the following criteria:
• Medication is being used for one of the following indications:
o Patient with cancer receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm3 or the risk of neutropenia for the member is calculated to be greater than 20%)
o Acute Myeloid Leukemia (AML) patients receiving chemotherapy
o Bone Marrow Transplant (BMT)
o Peripheral Blood Progenitor Cell Collection and Therapy
o Hematopoietic Syndrome of Acute Radiation Syndrome</td></tr>
</table>

	NYVEPRIA (pegfilgrastim-apgf) syringe RELEUKO (filgrastim-ayow) syringe, vial STIMUFEND (pegfilgrastim-fpgk) syringe UDENYCA (pegfilgrastim-cbqv) autoinjector, On-Body, syringe ZARXIO (filgrastim-sndz) syringe ZIEXTENZO (pegfilgrastim-bmez) syringe	○ Severe Chronic Neutropenia (Evidence of neutropenia infection exists or ANC is below 750 cells/mm3) ▪ Prior authorization for non-preferred agents may be approved if meeting the following criteria: • Medication is being used for one of the following indications: ○ Patient with cancer receiving myelosuppressive chemotherapy –to reduce incidence of infection (febrile neutropenia) (Either the post nadir ANC is less than 10,000 cells/mm3 or the risk of neutropenia for the member is calculated to be greater than 20%) ○ Acute Myeloid Leukemia (AML) patients receiving chemotherapy ○ Bone Marrow Transplant (BMT) ○ Peripheral Blood Progenitor Cell Collection and Therapy ○ Hematopoietic Syndrome of Acute Radiation Syndrome ○ Severe Chronic Neutropenia (Evidence of neutropenia infection exists or ANC is below 750 cells/mm3) **AND** • Member has history of trial and failure of Neupogen AND one other preferred agent. Failure is defined as a lack of efficacy with a 3-month trial, allergy, intolerable side effects, significant drug-drug interactions, or contraindication to therapy. Trial and failure of Neupogen will not be required if meeting one of the following: ○ Member has limited access to caregiver or support system for assistance with medication administration **OR** ○ Member has inadequate access to healthcare facility or home care interventions.
Therapeutic Drug Class: **ERYTHROPOIESIS STIMULATING AGENTS** *Effective 7/1/2024*		
PA Required for all agents in this class*		
Preferred	**Non-Preferred**	
EPOGEN (epoetin alfa) vial RETACRIT (epoetin alfa-epbx) (*Pfizer only)* vial	ARANESP (darbepoetin alfa) syringe, vial MIRCERA (methoxy peg-epoetin beta) syringe PROCRIT (epoetin alfa) vial RETACRIT (epoetin alfa-epbx) (*Vifor only)* vial	*Prior Authorization is required for all products and may be approved if meeting the following: ● Medication is being administered in the member's home or in a long-term care facility **AND** ● Member meets <u>one</u> of the following: ○ A diagnosis of cancer, currently receiving chemotherapy, with chemotherapy-induced anemia, and hemoglobin† of 10g/dL or lower **OR** ○ A diagnosis of chronic renal failure, and hemoglobin† below 10g/dL **OR** ○ A diagnosis of hepatitis C, currently taking ribavirin and failed response to a reduction of ribavirin dose, and hemoglobin† less than 10g/dL (or less than 11g/dL if symptomatic) **OR** ○ A diagnosis of HIV, currently taking zidovudine, hemoglobin† less than 10g/dL, and serum erythropoietin level of 500 mU/mL or less **OR**

		○ Member is undergoing elective, noncardiac, nonvascular surgery and medication is given to reduce receipt of allogenic red blood cell transfusions, hemoglobin† is greater than 10g/dL, but less than or equal to 13g/dL and high risk for perioperative blood loss. Member is not willing or unable to donate autologous blood pre-operatively **AND** • For any non-preferred product, member has trialed and failed treatment with one preferred product. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction. †Hemoglobin results must be from the last 30 days.

IX. Immunological

Therapeutic Drug Class: **IMMUNE GLOBULINS** -*Effective 1/1/2025*

PA Required for all agents in this class*

Preferred	Non-Preferred	
CUVITRU 20% SQ liquid GAMMAGARD 10% IV/SQ liquid GAMUNEX-C 10% IV/SQ liquid HIZENTRA 20% SQ syringe, vial PRIVIGEN 10% IV liquid *If immune globulin is being administered in a long-term care facility or in a member's home by a home healthcare provider, it should be billed as a pharmacy claim. All other claims must be submitted through the medical benefit.*	ALYGLO 10% IV liquid BIVIGAM 10% IV liquid CUTAQUIG 16.5% SQ liquid FLEBOGAMMA DIF 5%, 10% IV liquid GAMMAGARD S/D vial GAMMAKED 10% IV/SQ liquid GAMMAPLEX 5%, 10% IV liquid HYQVIA 10% SQ liquid OCTAGAM 5%, 10% IV liquid PANZYGA 10% IV liquid XEMBIFY 20% IV liquid	Preferred agents may be approved for members meeting at least one of the approved conditions listed below for prescribed doses not exceeding maximum (Table 1). Non-preferred agents may be approved for members meeting the following: • Member meets at least one of the approved conditions listed below AND • Member has history of trial and failure of two preferred agents (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions) AND • Prescribed dose does not exceed listed maximum (Table 1) Approved Conditions for Immune Globulin Use: • Primary Humoral Immunodeficiency disorders including: ○ Common Variable Immunodeficiency (CVID) ○ Severe Combined Immunodeficiency (SCID) ○ X-Linked Agammaglobulinemia ○ X-Linked with Hyperimmunoglobulin M (IgM) Immunodeficiency ○ Wiskott-Aldrich Syndrome ○ Members < 13 years of age with pediatric Human Immunodeficiency Virus (HIV) and CD-4 count > 200/mm3 • Neurological disorders including: ○ Guillain-Barré Syndrome ○ Relapsing-Remitting Multiple Sclerosis ○ Chronic Inflammatory Demyelinating Polyneuropathy ○ Myasthenia Gravis ○ Polymyositis and Dermatomyositis ○ Multifocal Motor Neuropathy • Kawasaki Syndrome • Chronic Lymphocytic Leukemia (CLL) • Autoimmune Neutropenia (AN) with absolute neutrophil count < 800 mm and history of recurrent bacterial infections • Autoimmune Hemolytic Anemia (AHA)

- Liver or Intestinal Transplant
- Immune Thrombocytopenia Purpura (ITP) including:
  - Requiring preoperative therapy for undergoing elective splenectomy with platelet count < 20,000/mcL
  - Members with active bleeding & platelet count <30,000/mcL
  - Pregnant members with platelet counts <10,000/mcL in the third trimester
  - Pregnant members with platelet count 10,000 to 30,000/mcL who are bleeding
- Multisystem Inflammatory Syndrome in Children (MIS-C)

Table 1: FDA-Approved Maximum Immune Globulin Dosing	
Asceniv – IV admin	800 mg/kg every 3 to 4 weeks
Bivigam – IV admin	800 mg/kg every 3 to 4 weeks
Cuvitru –subcutaneous admin	12 grams protein/site for up to four sites weekly (48grams/week)
Flebogamma DIF – IV admin	600 mg/kg every 3 weeks
Gammaplex 5% – IV admin	1 gram/kg for 2 consecutive days
Gammagard liquid subcutaneous or IV admin	2.4 grams/kg/month
Gammaked –subcutaneous or IV admin	600 mg/kg every 3 weeks
Gamunex-C –subcutaneous or IV admin	600 mg/kg every 3 weeks
Hizentra –subcutaneous admin	0.4 g/kg per week
Octagam – IV admin	2 grams/kg every 4 weeks
Panzyga – IV admin	2 g/kg every 3 weeks
Privigen – IV admin	2 g/kg over 2 to 5 consecutive days

Members currently receiving a preferred or non-preferred immunoglobulin product may receive approval to continue therapy with that product at prescribed doses not exceeding maximum (Table 1).

Therapeutic Drug Class: **NEWER GENERATION ANTIHISTAMINES -***Effective 1/1/2025*		
No PA Required	**PA Required**	
Cetirizine (OTC) syrup/solution (OTC/RX), tablet Desloratadine tablet (RX) Levocetirizine tablet (RX/OTC)	Cetirizine (OTC) chewable tablet, softgel, UD cups solution CLARINEX (desloratadine) tablet Desloratadine ODT (RX)	Non-preferred single agent antihistamine products may be approved for members who have failed treatment with two preferred products in the last 6 months. For members with respiratory allergies, an additional trial of an intranasal corticosteroid will be required in the last 6 months. Failure is defined as lack of efficacy with a 14-day trial, allergy, intolerable side effects, or significant drug-drug interaction.

Loratadine tablet (OTC), syrup/solution (OTC)	Fexofenadine tablet (OTC), suspension (OTC) Levocetirizine solution (RX) Loratadine chewable (OTC), ODT (OTC)	

Therapeutic Drug Class: **ANTIHISTAMINE/DECONGESTANT COMBINATIONS** - *Effective 1/1/2025*		
No PA Required	**PA Required**	Non-preferred antihistamine/decongestant combinations may be approved for members who have failed treatment with the preferred product in the last 6 months. For members with respiratory allergies, an additional trial of an intranasal corticosteroid will be required in the last 6 months. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.
Loratadine-D (OTC) tablet	Cetirizine-PSE (OTC) CLARINEX-D (desloratadine-D) Fexofenadine/PSE (OTC)	

Therapeutic Drug Class: **INTRANASAL RHINITIS AGENTS** -*Effective 1/1/2025*		
No PA Required	**PA Required**	Non-preferred products may be approved following trial and failure of treatment with three preferred products (failure is defined as lack of efficacy with a 2-week trial, allergy, intolerable side effects or significant drug-drug interactions). Non-preferred combination agents may be approved following trial of individual products with same active ingredients AND trial and failure of one additional preferred agent (failure is defined as lack of efficacy with 2-week trial, allergy, intolerable side effects or significant drug-drug interactions).
Azelastine 137 mcg Budesonide (OTC) DYMISTA (azelastine/ fluticasone) BNR Fluticasone (RX) Ipratropium Olopatadine Triamcinolone acetonide (OTC)	Azelastine (Astepro) 0.15% Azelastine/Fluticasone BECONASE AQ (beclomethasone dipropionate) Flunisolide 0.025% Fluticasone (OTC) Mometasone NASONEX (mometasone) OMNARIS (ciclesonide) PATANASE (olopatadine) QNASL (beclomethasone) RYALTRIS (olopatadine/mometasone) XHANCE (fluticasone) ZETONNA (ciclesonide)	

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<tr><td></td><td></td><td></td></tr>
<tr><td colspan="3">Therapeutic Drug Class: LEUKOTRIENE MODIFIERS -Effective 1/1/2025</td></tr>
<tr><td>No PA Required

Montelukast tablet, chewable</td><td>PA Required

ACCOLATE (zafirlukast) tablet

Montelukast granules

SINGULAIR (montelukast) tablet, chewable, granules

Zafirlukast tablet

Zileuton ER tablet

ZYFLO (zileuton) tablet</td><td>Non-preferred products may be approved if meeting the following criteria:
• Member has trialed and failed treatment with one preferred product (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) AND
• Member has a diagnosis of asthma.

Montelukast granules may be approved if a member has tried and failed montelukast chewable tablets AND has difficulty swallowing.</td></tr>
<tr><td colspan="3">Therapeutic Drug Class: METHOTREXATE PRODUCTS -Effective 1/1/2025</td></tr>
<tr><td>No PA Required

Methotrexate oral tablet, vial</td><td>PA Required

JYLAMVO (methotrexate) oral solution

OTREXUP (methotrexate) auto-injector

RASUVO (methotrexate) auto-injector

REDITREX (methotrexate) syringe

TREXALL (methotrexate) oral tablet

XATMEP (methotrexate) oral solution</td><td>OTREXUP, REDITREX or RASUVO may be approved if meeting the following criteria:
• Member has diagnosis of severe, active rheumatoid arthritis OR active polyarticular juvenile idiopathic arthritis (pJIA) OR inflammatory bowel disease (IBD) AND
• Member has trialed and failed preferred methotrexate tablet formulation (failure is defined as lack of efficacy, allergy, intolerable side effects, inability to take oral product formulation, or member has a diagnosis of pJIA and provider has determined that the subcutaneous formulation is necessary to optimize methotrexate therapy) AND
• Member (or parent/caregiver) is unable to administer preferred methotrexate vial formulation due to limited functional ability (such as vision impairment, limited manual dexterity and/or limited hand strength).

TREXALL may be approved if meeting the following criteria:
• Member has trialed and failed preferred methotrexate tablet formulation. Failure is defined as allergy or intolerable side effects.

XATMEP may be approved for members who meet the following criteria:
• Member is < 18 years of age
• Member has a diagnosis of acute lymphoblastic leukemia OR
• Member has a diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA) and has had an insufficient therapeutic response to, or is intolerant to, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs) AND
• Member has a documented swallowing difficulty due to young age and/or a medical condition and is unable to use the preferred methotrexate tablet formulation</td></tr>
</table>

		Methotrexate can cause serious embryo-fetal harm when administered during pregnancy and it is contraindicated for use during pregnancy for the treatment of non-malignant diseases. Advise members of reproductive potential to use effective contraception during and after treatment with methotrexate, according to FDA product labeling. Members currently stabilized on a non-preferred methotrexate product may receive approval to continue that agent.

Therapeutic Drug Class: **MULTIPLE SCLEROSIS AGENTS** -*Effective 4/1/2024*		
Disease Modifying Therapies		
Preferred **No PA Required** **(Unless indicated*)**	**Non-Preferred** **PA Required**	
AVONEX (interferon beta 1a) pen, syringe BETASERON (interferon beta 1b) injection COPAXONE[BNR] (glatiramer) injection Dimethyl fumarate tablet, starter pack Fingolimod capsule *KESIMPTA (ofatumumab) pen[**2nd Line**] Teriflunomide tablet	AUBAGIO (teriflunomide) tablet BAFIERTAM (monomethyl fumarate DR) capsule EXTAVIA (interferon beta 1b) kit, vial GILENYA (fingolimod) capsule Glatiramer 20mg, 40mg injection GLATOPA (glatiramer) injection MAVENCLAD (cladribine) tablet MAYZENT (siponimod) tablet, pack PLEGRIDY (peg-interferon beta 1a) pen, syringe PONVORY (ponesimod) tablet, pack REBIF (interferon beta 1a) syringe REBIF REDIDOSE (interferon beta 1a) pen TASCENSO ODT (fingolimod) tablet TECFIDERA (dimethyl fumarate) tablet, pack VUMERITY (diroximel DR) capsule ZEPOSIA (ozanimod) capsule, kit, starter pack	*Kesimpta (ofatumumab) may be approved if member has trialed and failed treatment with one preferred agent (failure is defined as intolerable side effects, contraindication to therapy, drug-drug interaction, or lack of efficacy). <u>Non-Preferred Products:</u> Non-preferred products may be approved if meeting the following: • Member has a diagnosis of a relapsing form of multiple sclerosis AND • Member has previous trial and failure with three preferred agents. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND • Prescribed dose does not exceed the maximum FDA-approved dose for the medication being ordered AND • If indicated in the product labeling, a negative pre-treatment pregnancy test has been documented, AND • If indicated in the product labeling, an ophthalmologic examination has been performed and documented prior to medication initiation, AND • The request meets additional criteria listed for any of the following: **Mayzent (siponimod):** • Member has previous trial and failure of three preferred agents, one of which must be Gilenya (fingolimod). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **Mavenclad (cladribine):** • Member has history of ≥ 1 relapse in the 12 months preceding initiation of therapy AND • Member has previous trial and failure of three other therapies for relapsing forms of multiple sclerosis (failure is defined as lack of efficacy with 3-month trial, allergy, intolerable side effects, or significant drug-drug interactions) **Vumerity (diroximel fumarate)** or **Bafiertam (monomethyl fumarate DR)**:

		• Member has previous trial and failure of three preferred agents, one of which must be Tecfidera (dimethyl fumarate). Failure is defined as lack of efficacy, allergy, significant drug-drug interactions, intolerable side effects (if GI adverse events, must meet additional criteria below) AND • If the requested medication is being prescribed due to GI adverse events with Tecfidera therapy (and no other reason for failure of Tecfidera is given), then the following additional criteria must be met: o Member has trialed a temporary dose reduction of Tecfidera (with maintenance dose being resumed within 4 weeks) AND o Member has trialed taking Tecfidera with food AND o GI adverse events remain significant despite maximized use of gastrointestinal symptomatic therapies (such as calcium carbonate, bismuth subsalicylate, PPIs, H2 blockers, anti-bloating/anti-constipation agents, anti-diarrheal, and centrally acting anti-emetics) AND o Initial authorization will be limited to 3 months. Continuation (12-month authorization) will require documentation of clinically significant reduction in GI adverse events. Members currently stabilized on a preferred second line (Kesimpta) or non-preferred product (may receive approval to continue therapy with that agent.
Symptom Management Therapies		
No PA Required Dalfampridine ER tablet	**PA Required** AMPYRA ER (dalfampridine) tablet	Non-preferred products may be approved with prescriber attestation that there is clinical rationale supporting why the preferred brand/generic equivalent product formulation is unable to be used. <u>Maximum Dose:</u> Ampyra (dalfampridine) 10mg twice daily
Therapeutic Drug Class: **TARGETED IMMUNE MODULATORS** -*Effective 1/1/2025* *Preferred agents:* ADBRY (tralokinumab-ldrm); DUPIXENT (dupilumab); ENBREL (etanercept); FASENRA (benralizumab) pen; HADLIMA (adalimumab- bwwd); HUMIRA (adalimumab); OTEZLA (apremilast) tablet; KEVZARA (sarilumab); TALTZ (ixekizumab); TEZSPIRE (tezepelumab-ekko) pen; XELJANZ IR (tofacitinib) tablet; XOLAIR (omalizumab) syringe		
Rheumatoid Arthritis, all other Arthritis (except psoriatic arthritis, see below), and Ankylosing Spondylitis		
Preferred No PA Required (If diagnosis met) (*Must meet eligibility criteria) Adalimumab-aaty pen, syringe Adalimumab-adbm pen, syringe	**Non-Preferred** PA Required ABRILADA (adalimumab-afzb) pen, syringe ACTEMRA (tocilizumab) syringe, Actpen Adalimumab-aacf pen, syringe	First line preferred agents (preferred adalimumab products, ENBREL, and XELJANZ IR) may receive approval for use for FDA-labeled indications. ***TALTZ (ixekizumab)** may receive approval for use for FDA-labeled indications following trial and failure‡ of a preferred adalimumab product or ENBREL. ***KEVZARA (sarilumab)** may receive approval for use for FDA-labeled indications following trial and failure‡ of:

CYLTEZO (adalimumab-adbm) pen, syringe ENBREL (etanercept) HADLIMA (adalimumab-bwwd) Pushtouch, syringe HUMIRA (adalimumab) *KEVZARA (sarilumab) pen, syringe *TALTZ (ixekizumab) 80 mg syringe, autoinjector *TYENNE (tocilizumab-aazg) pen, syringe XELJANZ IR (tofacitinib) tablet	Adalimumab-adaz pen, syringe Adalimumab-fkjp pen, syringe Adalimumab-ryvk auto-injector AMJEVITA (adalimumab-atto) auto-injector, syringe CIMZIA (certolizumab pegol) syringe, vial COSENTYX (secukinumab) syringe, pen-injector HULIO (adalimumab-fkjp) pen, syringe HYRIMOZ (adalimumab-adaz) pen, syringe IDACIO (adalimumab-aacf) pen, syringe ILARIS (canakinumab) vial KINERET (anakinra) syringe OLUMIANT (baricitinib) tablet ORENCIA (abatacept) clickject, syringe RINVOQ (upadacitinib), solution, tablet SIMLANDI (adalimumab-ryvk) auto-injector SIMPONI (golimumab) pen, syringe SKYRIZI (risankizumab-rzaa) OnBody, SC pen, syringe XELJANZ (tofacitinib) solution XELJANZ XR (tofacitinib ER) tablet YUFLYMA (adalimumab-aaty) auto-injector, syringe YUSIMRY (adalimumab-aqvh) pen	• A preferred adalimumab product or ENBREL **AND** • XELJANZ IR. ***TYENNE (tocilizumab-aazg)** may receive approval for use for FDA-labeled indications following trial and failure‡ of: • A preferred adalimumab product or ENBREL **AND** • XELJANZ IR. Quantity Limit: XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30-day supply **Non-Preferred Agents:** **COSENTYX (secukinumab)** may receive approval for: • FDA-labeled indications following trial and failure‡ of all indicated preferred agents OR • Treatment of enthesitis-related arthritis if meeting the following: o Member is ≥ 4 years of age and weighs ≥ 15 kg **AND** o Member has had trialed and failed‡ NSAID therapy and ENBREL and a preferred adalimumab product **KINERET (anakinra)** may receive approval for: • Treatment of systemic juvenile idiopathic arthritis (sJIA) or Adult-Onset Still's Disease (AOSD) **OR** • Treatment of rheumatoid arthritis following trial and failure‡ of o A preferred adalimumab product or ENBREL **AND** o XELJANZ IR **ILARIS (canakinumab)** may receive approval if meeting the following: • Medication is being prescribed for systemic juvenile idiopathic arthritis (sJIA) or Adult-Onset Still's Disease (AOSD), **AND** • Member has trialed and failed‡ a tocilizumab product. Quantity Limit: 300mg (2mL) every 4 weeks **XELJANZ (tofacitinib) XR** approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed below. **XELJANZ (tofacitinib) oral solution** may be approved when the following criteria are met:

	Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P	• Member has a diagnosis of polyarticular course juvenile idiopathic arthritis (pJIA) who require a weight-based dose for <40 kg following trial and failure‡ of a preferred adalimumab product or ENBREL **OR** • Member cannot swallow a tofacitinib tablet All other non-preferred agents may receive approval for FDA-labeled indications following trial and failure‡ of all preferred agents that are FDA-indicated or have strong evidence supporting use for the prescribed indication from clinically recognized guideline compendia (only one preferred adalimumab product trial required). Non-preferred agents that are being prescribed per FDA labeling to treat non-radiographic axial spondyloarthritis (nr-axSpA) will require trial and failure‡ of preferred agents that are FDA-labeled for treating an axial spondyloarthritis condition, including ankylosing spondylitis (AS) or nr-axSpA. Continuation of therapy: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent may receive approval for continuation of therapy with the prescribed agent. ‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Note that trial and failure of preferred TNF inhibitors will not be required when prescribed to treat polyarticular juvenile idiopathic arthritis (pJIA) in members with documented clinical features of lupus. *The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.*
Psoriatic Arthritis		
Preferred **No PA Required** **(If diagnosis met)** **(*Must meet eligibility criteria)** Adalimumab-aaty pen, syringe Adalimumab-adbm pen, syringe CYLTEZO (adalimumab-adbm) pen, syringe ENBREL (etanercept)	**Non-Preferred** **PA Required** ABRILADA (adalimumab-afzb) pen, syringe Adalimumab-aacf pen, syringe Adalimumab-adaz pen, syringe Adalimumab-fkjp pen, syringe Adalimumab-ryvk auto-injector AMJEVITA (adalimumab-atto) auto-injector, syringe	First line preferred agents (HADLIMA, HUMIRA, ENBREL, XELJANZ IR) may receive approval for psoriatic arthritis indication. ***OTEZLA (apremilast)** may receive approval for psoriatic arthritis indication following trial and failure‡ of: • A preferred adalimumab product or ENBREL **AND** • XELJANZ IR or TALTZ. ***TALTZ (ixekizumab)** may receive approval for psoriatic arthritis indication following trial and failure‡ of: • A preferred adalimumab product or ENBREL **AND** • XELJANZ IR or OTEZLA.

HADLIMA (adalimumab-bwwd) Pushtouch, syringe
 	
HUMIRA (adalimumab)
 	
*OTEZLA (apremilast) tablet
 	
*TALTZ (ixekizumab) 80 mg syringe
 	
XELJANZ IR (tofacitinib) tablet
	CIMZIA (certolizumab pegol) syringe, vial
	
	COSENTYX (secukinumab) syringe, pen-injector
	
	HULIO (adalimumab-fkjp) pen, syringe
	
	HYRIMOZ (adalimumab-adaz) pen, syringe
	
	IDACIO (adalimumab-aacf) pen, syringe
	
	ORENCIA (abatacept) syringe, clickject
	
	RINVOQ (upadacitinib) tablet
	
	RINVOQ LQ (upadacitinib) solution
	
	SIMLANDI (adalimumab-ryvk) auto-injector
	
	SIMPONI (golimumab) pen, syringe
	
	SKYRIZI (risankizumab-rzaa) OnBody, pen, syringe
	
	STELARA (ustekinumab) syringe
	
	TREMFYA (guselkumab) injector, syringe
	
	XELJANZ (tofacitinib) solution
	
	XELJANZ XR (tofacitinib ER) tablet
	
	YUFLYMA (adalimumab-aaty) auto-injector, syringe
	
	YUSIMRY (adalimumab-aqvh) pen
	
	Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P
		Quantity Limit: XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30-day supply
		
		Non-Preferred Agents:
		
		COSENTYX (secukinumab) may receive approval for psoriatic arthritis indication for members ≥ 2 years of age and weighing ≥ 15 kg following trial and failure‡ of:
		• A preferred adalimumab product or ENBREL **AND**
		• XELJANZ IR **AND**
		• TALTZ or OTEZLA.
		
		STELARA (ustekinumab) syringe for subcutaneous use may receive approval if meeting the following:
		• Member has trial and failure‡ of:
		  ○ A preferred adalimumab product or ENBREL **AND**
		  ○ XELJANZ IR **AND**
		  ○ TALTZ or OTEZLA
		AND
		• Prior authorization approval may be given for an initial 16-week supply and authorization approval for continuation may be provided based on clinical response.
		
		XELJANZ (tofacitinib) XR approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed below.
		
		All other non-preferred agents may receive approval for psoriatic arthritis following trial and failure‡ of:
		• A preferred adalimumab product or ENBREL **AND**
		• XELJANZ IR **AND**
		• TALTZ or OTEZLA.
		
		‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.
		
		Continuation of therapy: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent may receive approval for continuation of therapy with the prescribed agent.

		The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.
Plaque Psoriasis		
Preferred **No PA Required** **(If diagnosis met)** **(*Must meet eligibility criteria)** Adalimumab-aaty pen, syringe Adalimumab-adbm pen, syringe CYLTEZO (adalimumab-adbm) pen, syringe ENBREL (etanercept) HADLIMA (adalimumab-bwwd) Pushtouch, syringe HUMIRA (adalimumab) *OTEZLA (apremilast) tablet *TALTZ (ixekizumab) 80 mg syringe TYENNE (tocilizumab-aazg) pen, syringe	**Non-Preferred** **PA Required** ABRILADA (adalimumab-afzb) pen, syringe Adalimumab-aacf pen, syringe Adalimumab-adaz pen, syringe Adalimumab-fkjp pen, syringe Adalimumab-ryvk auto-injector AMJEVITA (adalimumab-atto) auto-injector, syringe CIMZIA (certolizumab pegol) syringe, vial COSENTYX (secukinumab) syringe, pen-injector HULIO (adalimumab-fkjp) pen, syringe HYRIMOZ (adalimumab-adaz) pen, syringe IDACIO (adalimumab-aacf) pen, syringe ORENCIA (abatacept) syringe, clickject SILIQ (brodalumab) syringe SIMLANDI (adalimumab-ryvk) auto-injector SKYRIZI (risankizumab-rzaa) OnBody, pen, syringe SOTYKTU (ducravacitinib) oral tablet STELARA (ustekinumab) syringe	First line preferred agents (preferred adalimumab products, ENBREL) may receive approval for plaque psoriasis indication. *Second line preferred agents (TALTZ, OTEZLA) may receive approval for plaque psoriasis indication following trial and failure‡ of a preferred adalimumab product OR ENBREL. **Non-Preferred Agents:** **STELARA (ustekinumab) syringe for subcutaneous use** may receive approval if meeting the following: • Member has trial and failure‡ of one indicated first line agent (preferred adalimumab products, ENBREL) **AND** two indicated second line agents (TALTZ, OTEZLA), **AND** • Prior authorization approval may be given for an initial 16-week supply and authorization approval for continuation may be provided based on clinical response. All other non-preferred agents may receive approval for plaque psoriasis indication following trial and failure‡ of one indicated first line agent (a preferred adalimumab product, ENBREL) AND two second line agents (TALTZ, OTEZLA). ‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Continuation of therapy: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent may receive approval for continuation of therapy with the prescribed agent. *The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.*

	TALTZ (ixekizumab) 20mg, 40mg syringe TREMFYA (guselkumab) injector, syringe YUFLYMA (adalimumab-aaty) auto-injector, syringe YUSIMRY (adalimumab-aqvh) pen ***Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P***	
Crohn's Disease and Ulcerative Colitis		
Preferred **No PA Required** **(If diagnosis met)** **(*Must meet eligibility criteria)** Adalimumab-aaty pen, syringe Adalimumab-adbm pen, syringe CYLTEZO (adalimumab-adbm) pen, syringe HADLIMA (adalimumab-bwwd) Pushtouch, syringe HUMIRA (adalimumab) *XELJANZ IR (tofacitinib) tablet	**Non-Preferred** **PA Required** ABRILADA (adalimumab-afzb) pen, syringe Adalimumab-aacf pen, syringe Adalimumab-adaz pen, syringe Adalimumab-fkjp pen, syringe Adalimumab-ryvk auto-injector AMJEVITA (adalimumab-atto) auto-injector, syringe CIMZIA (certolizumab pegol) syringe, vial COSENTYX (secukinumab) syringe, pen-injector ENTYVIO (vedolizumab) pen HULIO (adalimumab-fkjp) syringe HYRIMOZ (adalimumab-adaz) pen, syringe IDACIO (adalimumab-aacf) pen, syringe OLUMIANT (baricitinib) tablet OMVOH (mirikizumab-mrkz) pen	Preferred agents (preferred adalimumab products, XELJANZ IR) may receive approval for Crohn's disease and ulcerative colitis indications. Quantity Limit: XELJANZ IR is limited to 2 tablets per day or 60 tablets for a 30-day supply **Non-Preferred Agents:** **ENTYVIO (vedolizumab) pen for subcutaneous injection** may receive approval if the following criteria are met: • For treatment of moderately-to-severely active Crohn's disease, member has trial and failure‡ of one preferred adalimumab product **OR** for treatment of moderately-to-severely active ulcerative colitis, member has trial and failure‡ of one preferred adalimumab product and XELJANZ IR **AND** • Member is ≥ 18 years of age **AND** • Prescriber acknowledges that administration of IV induction therapy prior to approval of ENTYVIO (vedolizumab) pen for subcutaneous injection using the above criteria should be avoided and will not result in an automatic approval of requests for these formulations. **OMVOH (mirikizumab-mrkz) pen for subcutaneous injection** may receive approval if the following criteria are met: • The requested medication is being prescribed for treatment of moderately-to-severely active ulcerative colitis **AND** • Member is ≥ 18 years of age **AND** • Member has trial and failure‡ of one preferred adalimumab product AND XELJANZ IR AND ENTYVIO (vedolizumab) **AND** • Prescriber acknowledges that administration of IV induction therapy prior to approval of OMVOH (mirikizumab-mrkz) pen for subcutaneous injection using the above criteria should be avoided and will not result in an automatic approval of requests for these formulations.

	RINVOQ (upadacitinib) tablet
	
	RINVOQ LQ (upadacitinib) solution
	
	SIMLANDI (adalimumab-ryvk) auto-injector
	
	SIMPONI (golimumab) pen, syringe
	
	SKYRIZI (risankizumab-rzaa) OnBody, pen, syringe
	
	STELARA (ustekinumab) syringe
	
	VELSIPITY (etrasimod) tablet
	
	XELJANZ (tofacitinib) solution
	
	XELJANZ XR (tofacitinib ER) tablet
	
	YUFLYMA (adalimumab-aaty) auto-injector
	
	YUSIMRY (adalimumab-aqvh) pen
	
	ZYMFENTRA (infliximab-dyyb) pen kit, syringe kit
	
	Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P
		SKYRIZI (risankizumab) syringe for subcutaneous use and **on-body injector formulations** may receive approval if meeting the following:
		• The requested medication is being prescribed for use for treating moderately-to-severely active Crohn's disease or for treating moderate-to-severly ulcerative colitis **AND**
		• Member is ≥ 18 years of age **AND**
		• Request meets one of the following based on prescribed indication:
		  ○ For treatment of moderately-to-severely active Crohn's disease, member has trial and failure‡ of one preferred adalimumab product and ENTYVIO (vedolizumab) **OR**
		  ○ For treatment of moderately-to-severely active ulcerative colitis, member has trial and failure‡ of one preferred adalimumab product and XELJANZ IR and ENTYVIO (vedolizumab)
		AND
		• Prescriber acknowledges that administration of IV induction therapy prior to approval of SKYRIZI (risankizumab) prefilled syringe or on-body injector formulation using the above criteria should be avoided and will not result in an automatic approval of requests for these formulations.
		
		Dosing Limit: SKYRIZI on-body formulation maintenance dosing is limited to one 360 mg/2.4 mL single-dose prefilled cartridge or one 180 mg/1.2mL prefilled cartridge every 8 weeks.
		
		STELARA (ustekinumab) syringe for subcutaneous use may receive approval if meeting the following:
		• The requested medication is being prescribed for use for treating moderately-to-severely active Crohn's disease or for treating moderately-to-severely active ulcerative colitis **AND**
		• Request meets one of the following based on prescribed indication:
		  ○ For treatment of moderately-to-severely active Crohn's disease, member has trial and failure‡ of one preferred adalimumab product and ENTYVIO (vedolizumab) **OR**
		  ○ For treatment of moderately-to-severely active ulcerative colitis, member has trial and failure‡ of one preferred adalimumab product and XELJANZ IR and ENTYVIO (vedolizumab)
		AND
		• The member is ≥ 18 years of age **AND**
		• Prescriber acknowledges that loading dose administration prior to approval of STELARA for maintenance therapy using the above criteria should be avoided and will not result in an automatic approval of STELARA for maintenance therapy **AND**
		• Prior authorization approval may be given for an initial 16-week supply and authorization approval for continuation may be provided based on clinical response.

		TREMFYA (guselkumab) pen for subcutaneous injection may receive approval if the following criteria are met: • For treatment of moderately-to-severely active ulcerative colitis, member has trial and failure‡ of one preferred adalimumab product and XELJANZ IR **AND** • Member is ≥ 18 years of age **AND** • Prescriber acknowledges that administration of IV induction therapy prior to approval of TREMFYA (guselkumab) pen for subcutaneous injection using the above criteria should be avoided and will not result in an automatic approval of requests for these formulations. **XELJANZ (tofacitinib) XR** approval will require verification of the clinically relevant reason for use of the XELJANZ XR formulation versus the XELJANZ IR formulation, in addition to meeting non-preferred criteria listed below. All other non-preferred agents may receive approval for FDA-labeled indications if meeting the following: • The requested medication is being prescribed for treating moderately-to-severely active Crohn's disease or moderately-to-severely active Ulcerative Colitis in alignment with indicated use outlined in FDA-approved product labeling **AND** • The requested medication meets FDA-labeled indicated age for prescribed use **AND** • For treatment of moderately-to-severely active Crohn's disease, member has trial and failure‡ of one preferred adalimumab product **OR** for treatment of moderately-to-severely active ulcerative colitis, member has trial and failure‡ of one preferred adalimumab product and XELJANZ IR. <u>Continuation of therapy</u>: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent may receive approval for continuation of therapy with the prescribed agent. ‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Note that trial and failure of Xeljanz IR will not be required when prescribed for ulcerative colitis for members ≥ 50 years of age that have an additional CV risk factor. *The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.*
Asthma		
Preferred **PA Required** **(*Must meet eligibility criteria)**	**Non-Preferred** **PA Required**	*Preferred products (Dupixent, Fasenra, Tezspire, Xolair) may receive approval if meeting the following:

*DUPIXENT (dupilumab) pen, syringe
 	
*FASENRA (benralizumab) pen
 	
*TEZSPIRE (tezepelumab-ekko) pen
 	
*XOLAIR (omalizumab) syringe, autoinjector
	NUCALA (mepolizumab) auto-injector, syringe
	
	Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P
		DUPIXENT (dupilumab):
		• Member is 6 years of age or older **AND**
		• Member has an FDA-labeled indicated use for treating one of the following:
		  ○ Moderate to severe asthma (on medium to high dose inhaled corticosteroid and a long-acting beta agonist) with eosinophilic phenotype based on a blood eosinophil level of ≥ 150/mcL **OR**
		  ○ Oral corticosteroid dependent asthma
		AND
		• Member's asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies **AND**
		• Medication is being prescribed as add-on therapy to existing asthma regimen.
		
		Quantity Limit: 2 syringes every 28 days after initial 14 days of therapy (first dose is twice the regular scheduled dose)
		
		FASENRA (benralizumab):
		• Member is ≥ 6 years of age **AND**
		• Member has an FDA-labeled indicated use for treating severe asthma with an eosinophilic phenotype based on a blood eosinophil level of ≥ 150/mcL **AND**
		• Member's asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies **AND**
		• The requested medication is being prescribed as add-on therapy to existing asthma regimen.
		
		Quantity Limit: One 30 mg unit dose pack every 28 days for the first 3 doses and then every 8 weeks thereafter
		
		TEZSPIRE (tezepelumab-ekko):
		• Member is ≥ 12 years of age **AND**
		• Member has a diagnosis of severe asthma **AND**
		• Member's asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies **AND**
		• The requested medication is being prescribed as add-on therapy to existing asthma regimen.
		
		Quantity Limit: Four 210 mg unit dose packs every 28 days
		
		XOLAIR (omalizumab) may receive approval if meeting the following based on prescribed indication:
		• Member is ≥ 6 years of age **AND**
		• Member has an FDA-labeled indicated use for treating asthma **AND**
		• Member has a positive skin test or in vitro reactivity to a perennial inhaled allergen or has a pre-treatment IgE serum concentration ≥ 30 IU/mL **AND**

		• Member's asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies **AND** • The requested medication is being prescribed as add-on therapy to existing asthma regimen. **<u>Non-Preferred Agents:</u>** Non-preferred FDA-indicated biologic agents for asthma may receive approval if meeting the following: • The requested medication is being prescribed for treating asthma in alignment with indicated use outlined in FDA-approved product labeling (including asthma type and severity) **AND** • If prescribed for use for asthma with eosinophilic phenotype, member has a blood eosinophil count ≥ 150 cells/mcL **AND** • The requested medication meets FDA-labeled indicated age for prescribed use **AND** • Member's asthma has been refractory to recommended evidence-based, guideline-supported pharmacologic therapies **AND** • The requested medication is being prescribed as add-on therapy to existing asthma regimen **AND** • Member has trialed and failed‡ two preferred agents. <u>Quantity Limits</u>: Non-preferred medications will be subject to quantity limitations in alignment with FDA-approved dosing per product package labeling. **Nucala (mepolizumab)** is limited to 100mg every 4 weeks (members ≥ 12 years of age) or 40mg every 4 weeks (members 6-11 years of age). ‡Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions. <u>Continuation of therapy</u>: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent may receive approval for continuation of therapy with the prescribed agent.
Atopic Dermatitis		
Preferred **(*Must meet eligibility criteria)** *ADBRY (tralokinumab-ldrm) syringe, autoinjector	**Non-Preferred** **PA Required** CIBINQO (abrocitinib) tablet RINVOQ (upadacitinib) tablet	*Preferred products (Adbry and Dupixent) may receive approval if meeting the following: **ADBRY (tralokinumab-ldrm):** • The requested drug is being prescribed for moderate-to-severe atopic dermatitis **AND** • Member has trialed and failed‡ the following agents:

*DUPIXENT (dupilumab) pen, syringe	***Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P***	○ One medium potency to very-high potency topical corticosteroid (such as mometasone furoate, betamethasone dipropionate) **AND** ○ One topical calcineurin inhibitor (such as pimecrolimus or tacrolimus) Maximum Dose: 600 mg/2 weeks Quantity Limit: Four 150 mg/mL prefilled syringes/2 weeks **DUPIXENT (dupilumab):** • Member has a diagnosis of moderate to severe atopic dermatitis **AND** • Member has trialed and failed‡ the following agents: ○ One medium potency to very-high potency topical corticosteroid [such as mometasone furoate, betamethasone dipropionate, or fluocinonide (see PDL for list of preferred products) **AND** ○ One topical calcineurin inhibitor (such as pimecrolimus or tacrolimus) Quantity Limit: 2 syringes every 28 days after initial 14 days of therapy (first dose is twice the regular scheduled dose) **Non-Preferred Agents:** Non-preferred agents indicated for the treatment of atopic dermatitis may receive approval if meeting the following: • Member has a diagnosis of moderate to severe chronic atopic dermatitis **AND** • Member has trialed and failed‡ therapy with two preferred agents for the prescribed indication **AND** • Member has trialed and failed‡ the following agents: ○ One medium potency to very-high potency topical corticosteroid (such as mometasone furoate, betamethasone dipropionate, or fluocinonide) ○ One topical calcineurin inhibitor (such as pimecrolimus and tacrolimus) **AND** • The medication is being prescribed by or in consultation with a dermatologist, allergist, immunologist, or rheumatologist. Approval: One year ‡Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions. Continuation of therapy: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent may receive approval for continuation of therapy with the prescribed agent.

Other indications		
Preferred **(If diagnosis met, No PA required)** **(Must meet eligibility criteria*)** *DUPIXENT (dupilumab) pen, syringe ENBREL (etanercept) *FASENRA (benralizumab) pen HUMIRA (adalimumab) *KEVZARA (sarilumab) OTEZLA (apremilast) tablet XELJANZ IR (tofacitinib) tablet *XOLAIR (omalizumab) syringe, autoinjector	**Non-Preferred** **PA Required** ACTEMRA (tocilizumab) syringe, Actpen ARCALYST (rilonacept) injection CIMZIA (certolizumab pegol) syringe COSENTYX (secukinumab) syringe, pen-injector CYLTEZO (adalimumab-adbm) pen, syringe ILARIS (canakinumab) vial KINERET (anakinra) syringe NUCALA (mepolizumab) auto-injector, syringe OLUMIANT (baricitinib) tablet YUFLYMA (adalimumab-aaty) auto-injector ***Note: Product formulations in the physician administered drug (PAD) category are located on Appendix P***	***DUPIXENT (dupilumab)** may receive approval if meeting the following based on prescribed indication: <u>Chronic Obstructive Pulmonary Disease</u> • Member is ≥ 18 years of age **AND** • Medication is being prescribed by or in consultation with a pulmonologist or allergist **AND** • Requested medication is being prescribed as an add-on maintenance treatment for inadequately controlled chronic obstructive pulmonary disease (COPD) **AND** • Member's COPD is an eosinophilic phenotype based on a blood eosinophil level of ≥ 300 cells/mcL **AND** • Member is receiving, and will continue, standard maintenance triple therapy for COPD (inhaled corticosteroid, long-acting muscarinic agent, long-acting beta agonist) as recommended by the current Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines **AND** • Member has experienced at least 2 moderate-to-severe COPD exacerbations during the past 12 months <u>Chronic Rhinosinusitis with Nasal Polyposis</u> • Member is ≥ 18 years of age **AND** • Medication is being prescribed as an add-on maintenance treatment for inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP) **AND** • Member has trialed and failed‡ therapy with at least two intranasal corticosteroid regimens <u>Eosinophilic Esophagitis (EoE)</u>: • Member is ≥ 1 year of age **AND** • Member weighs at least 15 kg **AND** • Member has a diagnosis of eosinophilic esophagitis (EoE) with ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf), with or without a history of esophageal dilations **AND** • Member is following appropriate dietary therapy interventions **AND** • Medication is being prescribed by or in consultation with a gastroenterologist, allergist or immunologist **AND** • Member has trialed and failed‡ one of the following treatment options for EoE: ○ Proton pump inhibitor trial of at least eight weeks in duration if reflux is a contributing factor **OR**

		○ Minimum four-week trial of local therapy with a corticosteroid medication Prurigo Nodularis: • Member is ≥ 18 years of age AND • Medication is being prescribed as treatment for prurigo nodularis AND • Member has trialed and failed‡ therapy with at least two corticosteroid regimens (topical or intralesional injection). ***FASENRA (benralizumab)** may be approved for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). ***KEVZARA (sarilumab)** treatment of adult patients with polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper. **TYENNE (tocilizumab-aazg)** may receive approval for use for FDA-label indications following trial and failure‡ of a preferred adalimumab product or ENBREL ***XOLAIR (omalizumab)** may receive approval if meeting the following based on prescribed indication: Chronic Rhinosinusitis with Nasal Polyps: • Member is 18 years of age or older **AND** • Medication is being prescribed as add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids **AND** • Member has tried and failed‡ therapy with at least two intranasal corticosteroid regimens Chronic Idiopathic Urticaria (CIU): • Member is 12 years of age or older **AND** • Member is diagnosed with chronic idiopathic urticaria **AND** • Member is symptomatic despite H1 antihistamine treatment **AND** • Member has tried and failed‡ at least three of the following: ○ High-dose second generation H1 antihistamine ○ H2 antihistamine ○ First-generation antihistamine ○ Leukotriene receptor antagonist ○ Hydroxyzine or doxepin (must include) **AND**

		• Prescriber attests that the need for continued therapy will be periodically reassessed (as the appropriate duration of Xolair therapy for CIU has currently not been evaluated). <u>IgE-Mediated Food Allergy</u>: • Medication is being prescribed for reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy. All other preferred agents (preferred adalimumab products, ENBREL, OTEZLA) may receive approval for use for FDA-labeled indications. **<u>Non-Preferred Agents:</u>** **ARCALYST (rilonacept)** may receive approval if meeting the following: • Medication is being prescribed for one of the following autoinflammatory periodic fever syndromes (approval for all other indications is subject to meeting non-preferred criteria listed below): o Cryopyrin-associated Autoinflammatory Syndrome (CAPS), including: ▪ Familial Cold Autoinflammatory Syndrome (FCAS) ▪ Muckle-Wells Syndrome (MWS) o Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg o Treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children ≥ 12 years of age **AND** • Member has trialed and failed‡ colchicine **AND** • Initial approval will be given for 12 weeks and authorization approval for continuation will be provided based on clinical response. **ILARIS (canakinumab)** may receive approval if meeting the following: • Medication is being prescribed for one of the following (approval for all other indications is subject to meeting non-preferred criteria listed below): o Familial Mediterranean Fever (FMF) o Hyperimmunoglobulinemia D syndrome (HIDS) o Mevalonate Kinase Deficiency (MKD) o Neonatal onset multisystem inflammatory disease (NOMID) o TNF Receptor Associated Periodic Syndrome (TRAPS) o Cryopyrin-associated Autoinflammatory Syndrome (including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome) o Symptomatic treatment of adult patients with gout flares in whom NSAIDs and colchicine are contraindicated, are not tolerated, or do not

		provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate (limited to four 150mg doses per one year approval) **AND** • Member has trialed and failed‡ colchicine. • Quantity Limits: o Cryopyrin-associated periodic syndrome: 600mg (4mL) every 8 weeks o All other indications: 300mg (2mL) every 4 weeks **KINERET (anakinra)** may receive approval if meeting the following: • Medication is being prescribed for one of the following indications (approval for all other indications is subject to meeting non-preferred criteria below): o Neonatal onset multisystem inflammatory disease (NOMID). o Familial Mediterranean Fever (FMF) **AND** • Member has trialed and failed‡ colchicine. **NUCALA (mepolizumab)** may receive approval if meeting the following based on prescribed indication (for any FDA-labeled indications in this subclass category that are not listed, approval is subject to meeting non-preferred criteria listed below): <u>Chronic Rhinosinusitis with Nasal Polyps</u>: • Member is 18 years of age or older **AND** • Medication is being prescribed as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP) **AND** • Member has a baseline bilateral endoscopic nasal polyps score (NPS; scale 0-8) **AND** nasal congestion/obstruction score (NC; scale 0-3) averaged over 28-day period **AND** • Member has trialed and failed‡ therapy with three intranasal corticosteroids (see PDL Class) **AND** • Medication is being prescribed by or in consultation with a rheumatologist, allergist, ear/nose/throat specialist or pulmonologist **AND** • Initial authorization will be for 24 weeks, for additional 12-month approval member must meet the following criteria: o NC and NPS scores are provided and show a 20% reduction in symptoms from baseline **AND** o Member continues to use primary therapies such as intranasal corticosteroids. <u>Eosinophilic Granulomatosis with polyangiitis (EGPA):</u> • Member is 18 years of age or older **AND**

		• Member has been diagnosed with relapsing or refractory EGPA at least 6 months prior to request as demonstrated by ALL the following:
		  o Member has a diagnosis of asthma **AND**
		  o Member has a blood eosinophil count of greater than or equal to 1000 cells/mcL or a blood eosinophil level of 10%
		AND
		• Member has the presence of two of the following EGPA characteristics:
		  o Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
		  o Neuropathy
		  o Pulmonary infiltrates
		  o Sinonasal abnormality
		  o Cardiomyopathy
		  o Glomerulonephritis
		  o Alveolar hemorrhage
		  o Palpable purpura
		  o Antineutrophil cytoplasmic antibody (ANCA) positive
		AND
		• Member has trialed and failed‡ Fasenra (benralizumab) **AND**
		• Dose of NUCALA (mepolizumab) 300 mg once every 4 weeks is being prescribed.
		
		<u>Hypereosinophilic Syndrome (HES):</u>
		• Member is 12 years of age or older **AND**
		• Member has a diagnosis for HES for at least 6 months that is nonhematologic secondary HES **AND**
		• Member has a blood eosinophil count of greater than or equal to 1000 cells/mcL **AND**
		• Member has a history of two or more HES flares (defined as worsening clinical symptoms or blood eosinophil counts requiring an increase in therapy) **AND**
		
		• Member has been on stable dose of HES therapy for at least 4 weeks, at time of request, including at least one of the following:
		  o Oral corticosteroids
		  o Immunosuppressive therapy
		  o Cytotoxic therapy
		AND
		• Dose of 300 mg once every 4 weeks is being prescribed.
		
		All other non-preferred agent indications may receive approval for FDA-labeled use following trial and failure‡ of all preferred agents that are FDA-indicated or have strong

		evidence supporting use for the prescribed indication from clinically recognized guideline compendia (only one preferred adalimumab product trial required). ‡Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction. Continuation of therapy: Members currently taking a preferred agent may receive approval to continue therapy with that agent. Members with current prior authorization approval on file for a non-preferred agent will be subject to meeting reauthorization criteria above when listed for the prescribed indication, or if reauthorization criteria are not listed for the prescribed indication, may receive approval for continuation of therapy. *Note: Prior authorization requests for OLUMIANT (baricitinib) prescribed solely for treating alopecia areata will not be approved.* *The Department would like to remind providers that many products are associated with patient-centered programs that are available to assist with drug administration, education, and emotional support related to our members' various disease states.*

X. Miscellaneous

Therapeutic Drug Class: **EPINEPHRINE PRODUCTS** -*Effective 1/1/2025*		
No PA Required *Brand/generic changes effective 02/22/2024**	**PA Required**	Non-preferred products may be approved if the member has failed treatment with one of the preferred products. Failure is defined as allergy to ingredients in product or intolerable side effects.
*Epinephrine 0.15mg/0.15ml, 0.3mg/0.3ml auto-injector *(Mylan only)*	AUVI-Q (epinephrine) auto-injector	Quantity limit: 4 auto-injectors per year unless used / damaged / lost
EPIPEN 0.3 mg/0.3 ml (epinephrine) auto-injector	Epinephrine 0.15mg/0.15ml, 0.3mg/0.3ml auto-injector (All other manufacturers; generic Adrenaclick, Epipen)	
EPIPEN JR 0.15 mg/0.15 ml, (epinephrine) auto-injector	SYMJEPI 0.15mg/0.3ml, 0.3mg/0.3ml (epinephrine) syringe	

Therapeutic Drug Class: **NEWER HEREDITARY ANGIOEDEMA PRODUCTS** -*Effective 1/1/2025*		
PA Required for all agents in this class		Medications Indicated for Routine Prophylaxis: Members are restricted to coverage of one medication for routine prophylaxis at one time. Prior authorization approval will be for one year. **HAEGARDA** (C1 esterase inhibitor - human) may be approved for members meeting the following criteria:
Preferred	**Non-Preferred**	
Prophylaxis: CINRYZE (C1 esterase inhibitor) kit	*Prophylaxis:* ORLADEYO (berotralstat) oral capsule TAKHZYRO (lanadelumab-flyo) syringe, vial	

HAEGARDA (C1 esterase inhibitor) vial *Treatment:* BERINERT (C1 esterase inhibitor) kit, vial FIRAZYR (icatibant acetate) syringe [BNR]	*Treatment:* Icatibant syringe (generic FIRAZYR) RUCONEST (C1 estera se inhibitor, recomb) vial	○ Member has a diagnosis of HAE Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical presentation **AND** ○ Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND ○ Member meets at least one of the following: ▪ Haegarda is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR** ▪ Haegarda is being used for long-term prophylaxis and member meets one of the following: ○ History of ≥1 attack per month resulting in documented ED admission or hospitalization **OR** ○ History of laryngeal attacks **OR** ○ History of ≥2 attacks per month involving the face, throat, or abdomen **AND** ○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** ○ Prescriber acknowledges that the member will receive information and/or counseling regarding the information from the FDA-labeled package insert outlining transmission of infectious agents with a medication made from human blood. Maximum Dose: 60 IU/kg Minimum Age: 6 years **CINRYZE** (C1 esterase inhibitor - human) may be approved for members meeting the following criteria: ○ Member has history of trial and failure of Haegarda. Failure is defined as lack of efficacy allergy, intolerable side effects, or a significant drug-drug interaction **AND** ○ Member has a diagnosis of HAE Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical presentation **AND** ○ Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND ○ Member meets at least one of the following: ▪ Cinryze is being used for short-term prophylaxis to undergo a surgical procedure or major dental work **OR** ▪ Cinryze is being used for long-term prophylaxis and member meets one of the following:

		○ History of ≥1 attack per month resulting in documented ED admission or hospitalization **OR** ○ History of laryngeal attacks **OR** ○ History of ≥2 attacks per month involving the face, throat, or abdomen **AND** ○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** ○ Prescriber acknowledges that the member will receive information and/or counseling regarding the information from the FDA-labeled package insert outlining transmission of infectious agents with a medication made from human blood. Minimum age: 6 years Maximum dose: 100 Units/kg **ORLADEYO** (berotralstat) may be approved for members meeting the following criteria: ○ Member has history of trial and failure of HAEGARDA. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND** ○ Member has a diagnosis of HAE Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical presentation **AND** ○ Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND** ○ ORLADEYO is prescribed by or in consultation with an allergist or immunologist **AND** ○ Appropriate drug interaction interventions will be made for members using concomitant medications that may require dose adjustments (such as cyclosporine, fentanyl, pimozide, digoxin) **AND** ○ Member meets at least one of the following: ▪ ORLADEYO is being used for short-term prophylaxis to undergo a surgical procedure or major dental work ▪ ORLADEYO is being used for long-term prophylaxis and member meets one of the following: • History of ≥ 1 attack per month resulting in documented ED admission or hospitalization **OR** • History of laryngeal attacks **OR** • History of ≥ 2 attacks per month involving the face, throat, or abdomen **AND** • Member is not taking medications that may exacerbate HAE, including ACE inhibitors and estrogen-containing medications Minimum age:12 years

		Maximum dose: 150 mg once daily **TAKHZYRO** (lanadelumab-flyo) may be approved for members meeting the following criteria: o Member has history of trial and failure of Haegarda. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND** o Member has a diagnosis of HAE Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical presentation **AND** o Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema **AND** o Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications Minimum age: 2 years Maximum dose: The recommended starting dose is 300mg every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (attack free) for more than 6 months **Medications Indicated for Treatment of Acute Attacks:** Members are restricted to coverage of one medication for treatment of acute attacks at one time. Prior authorization approval will be for one year. **FIRAZYR** (icatibant acetate) may be approved for members meeting the following criteria: o Member has a diagnosis of HAE Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical presentation **AND** o Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND o Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications Minimum age: 18 years Maximum dose: 30mg **BERINERT** (C1 esterase inhibitor - human) may be approved for members meeting the following criteria:

		○ Member has a diagnosis of HAE Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical presentation **AND** ○ Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND ○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications **AND** ○ Prescriber acknowledges that the member will receive information and/or counseling regarding the information from the FDA-labeled package insert outlining transmission of infectious agents with a medication made from human blood. Minimum age: 6 years Max dose: 20 IU/kg **RUCONEST** (C1 esterase inhibitor - recombinant) may be approved for members meeting the following criteria: ○ Member has a history of trial and failure of Firazyr OR Berinert. Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction **AND** ○ Member has a diagnosis of HAE Type I or Type II confirmed by laboratory tests obtained on two separate instances at least one month apart (C4 level, C1-INH level) OR has a diagnosis of HAE Type III based on clinical presentation **AND** ○ Member has a documented history of at least one symptom of a moderate to severe HAE attack (moderate to severe abdominal pain, facial swelling, airway swelling) in the absence of hives or a medication known to cause angioedema AND ○ Member is not taking medications that may exacerbate HAE including ACE inhibitors and estrogen-containing medications Minimum age: 13 years Maximum dose: 4,200 Units/dose All other non-preferred agents may be approved if the member has trialed and failed at least two preferred agents with the same indicated role in therapy as the prescribed medication (prophylaxis or treatment). Failure is defined as lack of efficacy, allergy, intolerable side effects, or a significant drug-drug interaction.
Therapeutic Drug Class: **PHOSPHATE BINDERS** -*Effective 10/1/2024*		
No PA Required	**PA Required**	Prior authorization for non-preferred products in this class may be approved if member meets all the following criteria:

Calcium acetate capsule PHOSLYRA (calcium acetate) solution Sevelamer carbonate tablet, powder pack	AURYXIA (ferric citrate) tablet Calcium acetate tablet CALPHRON (calcium acetate) tablet FOSRENOL (lanthanum carbonate) chewable tablet, powder pack Lanthanum carbonate chewable tablet RENVELA (sevelamer carbonate) powder pack, tablet Sevelamer HCl tablet VELPHORO (sucroferric oxide) chewable tablet XPHOZAH (tenapanor) tablet	• Member has diagnosis of end stage renal disease AND • Member has elevated serum phosphorus [> 4.5 mg/dL or > 1.46 mmol/L] AND • Provider attests to member avoidance of high phosphate containing foods from diet AND • Member has trialed and failed‡ one preferred agent (lanthanum products require trial and failure‡ of a preferred sevelamer product). **Auryxia** (ferric citrate) may be approved if the member meets all the following criteria: • Member is diagnosed with end-stage renal disease, receiving dialysis, and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L). AND • Provider attests to counseling member regarding avoiding high phosphate containing foods from diet AND • Member has trialed and failed‡ three preferred agents with different mechanisms of action prescribed for hyperphosphatemia in end stage renal disease **OR** • Member is diagnosed with chronic kidney disease with iron deficiency anemia and is not receiving dialysis AND • Member has tried and failed‡ at least two different iron supplement product formulations (OTC or RX) **Velphoro** (sucroferric oxyhydroxide tablet, chewable) may be approved if the member meets all of the following criteria: • Member is diagnosed with chronic kidney disease and receiving dialysis and has elevated serum phosphate (> 4.5 mg/dL or > 1.46 mmol/L). AND • Provider attests to counseling member regarding avoiding high phosphate containing foods from diet AND • Member has trialed and failed‡ two preferred agents, one of which must be a preferred sevelamer product Maximum Dose: Velphoro 3000mg daily Members currently stabilized on a non-preferred lanthanum product may receive approval to continue therapy with that product. ‡Failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction. *Note: Medications administered in a dialysis unit or clinic are billed through the Health First Colorado medical benefit or Medicare with members with dual eligibility.*
Therapeutic Drug Class: **PRENATAL VITAMINS / MINERALS** -*Effective 10/1/2024*		
Preferred ***Must meet eligibility criteria**	**Non-Preferred** **PA Required**	

COMPLETE NATAL DHA pack M-NATAL PLUS tablet NESTABS tablets PRENATAL VITAMIN PLUS LOW IRON tablet (*Patrin Pharma only)* SE-NATAL 19 chewable tablet[BNR] TARON-C DHA capsule THRIVITE RX tablet TRINATAL RX 1 tablet VITAFOL gummies WESNATAL DHA COMPLETE tablet WESTAB PLUS tablet	All other rebateable prescription products are non-preferred	*Preferred and non-preferred prenatal vitamin products are a benefit for members from 11-60 years of age who are pregnant, lactating, or trying to become pregnant. Prior authorization for non-preferred agents may be approved if member fails 7-day trial with four preferred agents. Failure is defined as: allergy, intolerable side effects, or significant drug-drug interaction.

XI. Ophthalmic

Therapeutic Drug Class: **OPHTHALMIC, ALLERGY** -*Effective 4/1/2024*

No PA Required	**PA Required**	
ALREX[BNR] (loteprednol) 0.2% Azelastine 0.05% Cromolyn 4% Ketotifen 0.025% (OTC) LASTACAFT (alcaftadine) 0.25% (OTC)	ALAWAY (ketotifen) 0.025% (OTC) ALOCRIL (nedocromil) 2% ALOMIDE (lodoxamide) 0.1% Bepotastine 1.5% BEPREVE (bepotastine) 1.5%	Non-preferred products may be approved following trial and failure of therapy with two preferred products (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions).

Olopatadine 0.1%, 0.2% (OTC) (generic Pataday Once/Twice Daily)	Epinastine 0.05% Loteprednol 0.2% Olopatadine 0.1%, 0.2% (RX) PATADAY ONCE DAILY (olopatadine) 0.2% (OTC) PATADAY TWICE DAILY (olopatadine) 0.1% (OTC) PATADAY XS ONCE DAILY (olopatadine) 0.7% (OTC) ZADITOR (ketotifen) 0.025% (OTC) ZERVIATE (cetirizine) 0.24%	
Therapeutic Drug Class: **OPHTHALMIC, IMMUNOMODULATORS -***Effective 4/1/2024*		
No PA Required RESTASIS[BNR] (cyclosporine 0.05%) vials	**PA Required** CEQUA (cyclosporine) 0.09% solution Cyclosporine 0.05% vials MIEBO (Perfluorohexyloctane/PF) RESTASIS MULTIDOSE (cyclosporine) 0.05% TYRVAYA (varenicline) nasal spray VERKAZIA (cyclosporin emulsion) VEVYE (cyclosporine) 0.1% XIIDRA (lifitegrast) 5% solution	Non-preferred products may be approved for members meeting all of the following criteria: ● Member is 18 years and older **AND** ● Member has a diagnosis of chronic dry eye **AND** ● Member has failed a 3-month trial of one preferred product. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions **AND** ● Prescriber is an ophthalmologist, optometrist or rheumatologist <u>Maximum Dose/Quantity:</u> 60 single use containers for 30 days 5.5 mL/20 days for Restasis Multi-Dose and Vevye 3mL/30 days for Miebo
Therapeutic Drug Class: **OPHTHALMIC, ANTI-INFLAMMATORIES -***Effective 4/1/2024*		
NSAIDs		
No PA Required	**PA Required**	

Diclofenac 0.1% Flurbiprofen 0.03% Ketorolac 0.5%, Ketorolac LS 0.4% NEVANAC (nepafenac) 0.1%	ACULAR (ketorolac) 0.5%, LS 0.4% ACUVAIL (ketorolac/PF) 0.45% Bromfenac 0.07%, 0.075%, 0.09% BROMSITE (bromfenac) 0.075% ILEVRO (nepafenac) 0.03% PROLENSA (bromfenac) 0.07%	**Durezol (difluprednate)** may be approved if meeting the following criteria: • Member has a diagnosis of severe intermediate uveitis, severe panuveitis, or severe uveitis with the complication of uveitic macular edema AND has trialed and failed prednisolone acetate 1% (failure is defined as lack of efficacy, allergy, contraindication to therapy, intolerable side effects, or significant drug-drug interaction) OR • Members with a diagnosis other than those listed above require trial and failure of three preferred agents (failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction).
Corticosteroids		
No PA Required	**PA Required**	**Eysuvis (loteprednol etabonate)** may be approved if meeting all of the following: • Member is ≥ 18 years of age AND • Eysuvis (loteprednol etabonate) is being used for short-term treatment (up to two weeks) of the signs and symptoms of dry eye disease AND • Member has failed treatment with one preferred product in the Ophthalmic Immunomodulator therapeutic class. Failure is defined as lack of efficacy with a 3-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction) AND • Member does not have any of the following conditions: • Viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella OR • Mycobacterial infection of the eye and fungal diseases of ocular structures • Quantity limit: one bottle/15 days
FLAREX (fluorometholone) 0.1% Fluorometholone 0.1% drops FML FORTE (fluorometholone) 0.25% drops LOTEMAX[BNR] (loteprednol) 0.5% drops, gel LOTEMAX (loteprednol) 0.5% ointment MAXIDEX (dexamethasone) 0.1% PRED MILD (prednisolone) 0.12% Prednisolone acetate 1%	Dexamethasone 0.1% Difluprednate 0.05% DUREZOL (difluprednate) 0.05% EYSUVIS (loteprednol) 0.25% FML LIQUIFILM (fluorometholone) 0.1% drop FML S.O.P (fluorometholone) 0.1% ointment INVELTYS (loteprednol) 1% LOTEMAX SM (loteprednol) 0.38% gel Loteprednol 0.5% drops, 0.5% gel PRED FORTE (prednisolone) 1% Prednisolone sodium phosphate 1%	**Lotemax SM (loteprednol etabonate)** or **Inveltys (loteprednol etabonate)** may be approved if meeting all of the following: • Member is ≥ 18 years of age AND • Lotemax SM or Inveltys (loteprednol etabonate) is being used for the treatment of post-operative inflammation and pain following ocular surgery AND • Member has trialed and failed therapy with two preferred loteprednol formulations (failure is defined as lack of efficacy with 2-week trial, allergy, contraindication to therapy, intolerable side effects, or significant drug-drug interaction) AND • Member has trialed and failed therapy with two preferred agents that do not contain loteprednol (failure is defined as lack of efficacy with 2-week trial,

		contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction) AND
		• Member does not have any of the following conditions:
		  o Viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella OR
		  o Mycobacterial infection of the eye and fungal diseases of ocular structures
		
		Verkazia (cyclosporine ophthalmic emulsion) may be approved if the following criteria are met:
		• Member is ≥ 4 years of age AND
		• Verkazia is being used for the treatment of vernal keratoconjunctivitis (VKC) AND
		• Member has trialed and failed therapy with three agents from the following pharmacologic categories: preferred dual-acting mast cell stabilizer/antihistamine from the Ophthalmics-Allergy PDL class, oral antihistamine, preferred topical ophthalmic corticosteroid from the Ophthalmics-Anti-inflammatories PDL class. Failure is defined as lack of efficacy with 2-week trial, allergy, contraindication to therapy, intolerable side effects, or significant drug-drug interaction
		• Quantity limit: 120 single-dose 0.3 mL vials/15 days
		
		All other non-preferred products may be approved with trial and failure of three preferred agents (failure is defined as lack of efficacy with 2-week trial, allergy, contraindication, intolerable side effects, or significant drug-drug interaction).

Therapeutic Drug Class: **OPHTHALMIC, GLAUCOMA -***Effective 4/1/2024*		
Beta-blockers		
No PA Required Levobunolol 0.5% Timolol (generic Timoptic) 0.25%, 0.5%	**PA Required** Betaxolol 0.5% BETIMOL (timolol) 0.25%, 0.5% BETOPIC-S (betaxolol) 0.25% Carteolol 1%	Non-preferred products may be approved following trial and failure of therapy with three preferred products, including one trial with a preferred product having the same general mechanism (such as prostaglandin analogue, alpha2-adrenergic agonist, beta-blocking agent, or carbonic anhydrase inhibitor). Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions. Non-preferred combination products may be approved following trial and failure of therapy with one preferred combination product AND trial and failure of individual products with the same active ingredients as the combination product being requested (if

	ISTALOL (timolol) 0.5% Timolol (generic Istalol) 0.5% drops Timolol GFS 0.25%, 0.5% Timolol/PF (generic Timoptic Ocudose) 0.25%, 0.5% TIMOPTIC, TIMOPTIC OCUDOSE (timolol) 0.25%, 0.5% TIMOPTIC-XE (timolol GFS) 0.25%, 0.5%	available) to establish tolerance. Failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects or significant drug-drug interactions. Preservative free products may be approved with provider documentation of adverse effect to preservative-containing product.
Carbonic anhydrase inhibitors		
No PA Required	**PA Required**	
AZOPT[BNR] (brinzolamide) 1% Dorzolamide 2%	Brinzolamide 1%	
Prostaglandin analogue		
No PA Required	**PA Required**	
Latanoprost 0.005% LUMIGAN[BNR] (bimatoprost) 0.01% TRAVATAN Z[BNR] (travoprost) 0.004%	Bimatoprost 0.03% IYUZEH (latanoprost/PF) 0.005% Tafluprost 0.0015% Tafluprost PF 0.0015% Travoprost 0.004% VYZULTA (latanoprostene) 0.024% XALATAN (latanoprost) 0.005% XELPROS (latanoprost) 0.005% ZIOPTAN (tafluprost PF) 0.0015%	
Alpha-2 adrenergic agonists		

No PA Required	PA Required
ALPHAGAN P[BNR] 0.1%, 0.15% (brimonidine) Brimonidine 0.2%	Apraclonidine 0.5% Brimonidine 0.1%, 0.15% IOPIDINE (apraclonidine) 0.5%, 1%

Other ophthalmic, glaucoma and combinations

No PA Required	PA Required
COMBIGAN[BNR] 0.2%-0.5% (brimonidine/timolol) Dorzolamide/Timolol 2%-0.5% RHOPRESSA (netarsudil) 0.02% ROCKLATAN (netarsudil/latanoprost) 0.02%-0.005%	Brimonidine/Timolol 0.2%-0.5% COSOPT/COSOPT PF (dorzolamide/timolol) 2%-0.5% Dorzolamide/Timolol PF 2%-0.5% PHOSPHOLINE IODIDE (echothiophate) 0.125% Pilocarpine 1%, 2%, 4% SIMBRINZA (brinzolamide/brimonidine) 1%-0.2% VUITY (pilocarpine) 1.25%

XII. Renal/Genitourinary

Therapeutic Drug Class: **BENIGN PROSTATIC HYPERPLASIA (BPH) AGENTS** -*Effective 10/1/2024*

No PA Required	PA Required	
Alfuzosin ER tablet	AVODART (dutasteride) softgel	Prior authorization for non-preferred products in this class may be approved if member meets all of the following criteria: ● Member has tried and failed‡ three preferred agents AND ● For combinations agents, member has tried and failed‡ each of the individual agents within the combination agent and one other preferred agent. ‡Failure is defined as lack of efficacy with 8-week trial, allergy, intolerable side effects, contraindication to, or significant drug-drug interaction.
Doxazosin tablet	CARDURA (doxazosin) tablet	
Dutasteride capsule	CARDURA XL (doxazosin ER) tablet	
Finasteride tablet	*CIALIS (tadalafil) 2.5 mg, 5 mg tablet	
Tamsulosin capsule	Dutasteride/tamsulosin capsule	

Terazosin capsule	FLOMAX (tamsulosin) capsule PROSCAR (finasteride) tablet RAPAFLO (silodosin) capsule Silodosin capsule *Tadalafil 2.5 mg, 5 mg tablet	***CIALIS** (tadalafil) may be approved for members with a documented diagnosis of BPH who have failed a trial of finasteride (at least 3 months in duration) AND either a trial of a nonselective alpha blocker (therapeutic dose for at least two months) OR a trial of tamsulosin (therapeutic dose for at least one month). Documentation of BPH diagnosis will require BOTH of the following: ● AUA Prostate Symptom Score ≥ 8 AND ● Results of a digital rectal exam. Cialis (tadalafil) will not be approved for any patient continuing alpha-blocker therapy as this combination is contraindicated in this population. Doses exceeding 5mg per day of Cialis (tadalafil) will not be approved.

Therapeutic Drug Class: **ANTI-HYPERURICEMICS** -*Effective 10/1/2024*		
No PA Required	**PA Required**	Non-preferred xanthine oxidase inhibitor products (allopurinol or febuxostat formulations) may be approved following trial and failure of preferred allopurinol. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. If member has tested positive for the HLA-B*58:01 allele, it is not recommended that they trial allopurinol. A positive result on this genetic test will count as a failure of allopurinol. Prior authorization for all other non-preferred agents (non-xanthine oxidase inhibitors) may be approved after trial and failure of two preferred products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. **GLOPERBA (colchicine)** oral solution may be approved for members who require individual doses <0.6 mg **OR** for members who are unable to use a solid oral dosage form. Colchicine tablet quantity limits: • Chronic hyperuricemia/gout prophylaxis: 60 tablets per 30 days • Familial Mediterranean Fever: 120 tablets per 30 days
Allopurinol 100 mg, 300 mg tablets Colchicine tablet Febuxostat tablet Probenecid tablet Probenecid/Colchicine tablet	Allopurinol 200 mg tablets Colchicine capsule COLCRYS (colchicine) tablet GLOPERBA (colchicine) oral solution MITIGARE (colchicine) capsule ULORIC (febuxostat) tablet	

Therapeutic Drug Class: **OVERACTIVE BLADDER AGENTS** -*Effective 10/1/2024*		
No PA Required	**PA Required**	Non-preferred products may be approved for members who have failed treatment with two preferred products. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Members with hepatic failure can receive approval for trospium (Sanctura) or trospium extended release (Sanctura XR) products without a trial on a Preferred product.
Fesoterodine ER tablet GELNIQUE (oxybutynin) gel MYRBETRIQ (mirabegron) tablet [BNR] Oxybutynin IR, ER tablets, syrup Solifenacin tablet	Darifenacin ER tablet DETROL (tolterodine) tablet DETROL LA (tolterodine) ER capsule Flavoxate tablet GEMTESA (vibegron) tablet Mirabegron tablet	

Tolterodine tablet, ER capsule	MYRBETRIQ (mirabegron) suspension Oxybutynin 2.5 mg tablet OXYTROL (oxybutynin patch) TOVIAZ (Fesoterodine ER) tablet Trospium ER capsule, tablet VESICARE (solifenacin) tablet VESICARE LS (solifenacin) suspension	

XIII. RESPIRATORY

Therapeutic Drug Class: **RESPIRATORY AGENTS** -*Effective 1/1/2025*

Inhaled Anticholinergics

Preferred **No PA Required** **(Unless indicated*)**	**Non-Preferred** **PA Required**	
Solutions Ipratropium solution **Short-Acting Inhalation Devices** ATROVENT HFA (ipratropium) **Long-Acting Inhalation Devices** SPIRIVA Handihaler[BNR] (tiotropium) *SPIRIVA RESPIMAT (tiotropium)	**Solutions** YUPELRI (revefenacin) solution **Short-Acting Inhalation Devices** **Long-Acting Inhalation Devices** INCRUSE ELLIPTA (umeclidinium) Tiotropium DPI TUDORZA PRESSAIR (aclidinium)	***SPIRIVA RESPIMAT (tiotropium) 1.25 mcg** may be approved for members ≥ 6 years of age with a diagnosis of asthma (qualifying diagnosis verified by AutoPA). SPIRIVA RESPIMAT is intended to be used by members whose asthma is not controlled with regular use of a combination medium-dose inhaled corticosteroid and long-acting beta agonist (LABA). ***SPIRIVA RESPIMAT (tiotropium)** 2.5 mcg may be approved for members with a diagnosis of COPD who have trialed and failed SPIRIVA HANDIHALER. Failure is defined as intolerable side effects or inability to use dry powder inhaler (DPI) formulation. **LONHALA MAGNAIR** (glycopyrrolate) may be approved for members ≥ 18 years of age with a diagnosis of COPD including chronic bronchitis and emphysema who have trialed and failed‡ treatment with two preferred anticholinergic agents. Non-preferred single agent anticholinergic agents may be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have trialed and failed‡ treatment with two preferred agents, one of which must be SPIRIVA HANDIHALER. ‡Failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Inhaled Anticholinergic Combinations

No PA Required	PA Required	
Solutions Ipratropium/Albuterol solution **Short-Acting Inhalation Devices** COMBIVENT RESPIMAT (albuterol/ipratropium) **Long-Acting Inhalation Devices** ANORO ELLIPTA (umeclidinium/vilanterol)	**Solutions** **Short-Acting Inhalation Devices** **Long-Acting Inhalation Devices** BEVESPI AEROSPHERE (glycopyrrolate /formoterol fumarate) BREZTRI AEROSPHERE (budesonide/glycopyrrolate/ formoterol) DUAKLIR PRESSAIR (aclidinium/formoterol) STIOLTO RESPIMAT (tiotropium/olodaterol)	**BREZTRI AEROSPHERE** (budesonide/glycopyrrolate/formoterol) may be approved for members ≥ 18 years of age with a diagnosis of COPD who have trialed and failed‡ treatment with two preferred anticholinergic-containing agents. **DUAKLIR PRESSAIR** (aclidinium/formoterol) may be approved for members ≥ 18 years of age with a diagnosis of COPD who have trialed and failed‡ treatment with two preferred anticholinergic-containing agents. All other non-preferred inhaled anticholinergic combination agents may be approved for members with a diagnosis of COPD including chronic bronchitis and/or emphysema who have trialed and failed‡ treatment with two preferred inhaled anticholinergic combination agents OR three preferred inhaled anticholinergic-containing agents (single ingredient or combination). Members who are currently stabilized on Bevespi Aerosphere may receive approval to continue therapy with that product. ‡Failure is defined as lack of efficacy with 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

Inhaled Beta2 Agonists (short acting)

No PA Required	PA Required	
Solutions Albuterol solution, for nebulizer **Inhalers** VENTOLIN BNR HFA (albuterol)	**Solutions** Levalbuterol solution **Inhalers** AIRSUPRA (budesonide/albuterol) Albuterol HFA Levalbuterol HFA PROAIR RESPICLICK (albuterol) XOPENEX (levalbuterol) Inhaler	Non-preferred short acting beta-2 agonists may be approved for members who have failed treatment with one preferred agent. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. MDI formulation quantity limits: 2 inhalers / 30 days **AIRSUPRA** (budesonide/albuterol) Airsupra minimum age: 18 years old

Inhaled Beta2 Agonists (long acting)

Preferred	Non-Preferred PA Required	
Solutions **Inhalers**	**Solutions** Arformoterol solution BROVANA (arformoterol) solution	Non-preferred agents may be approved for members with moderate to severe COPD, AND members must have failed a trial of Serevent. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, or significant drug-drug interaction.

SEREVENT DISKUS (salmeterol) inhaler	Formoterol solution PERFOROMIST (formoterol) solution **Inhalers** STRIVERDI RESPIMAT (olodaterol)	For treatment of members with diagnosis of asthma needing add-on therapy, please refer to preferred agents in combination Long-Acting Beta Agonist/Inhaled Corticosteroid therapeutic class.
Inhaled Corticosteroids		
No PA Required **Solutions** Budesonide nebules **Inhalers** ARNUITY ELLIPTA (fluticasone furoate) ASMANEX HFA (mometasone furoate) inhaler ASMANEX Twisthaler (mometasone) FLOVENT DISKUS (fluticasone)[BNR] FLOVENT HFA (fluticasone)[BNR] PULMICORT FLEXHALER (budesonide) QVAR REDIHALER (beclomethasone)	**PA Required** **Solutions** PULMICORT (budesonide) respules **Inhalers** ALVESCO (ciclesonide) inhaler Fluticasone propionate diskus *Fluticasone propionate HFA	Non-preferred inhaled corticosteroids may be approved in members with asthma who have failed an adequate trial of two preferred agents. An adequate trial is defined as at least 6 weeks. (Failure is defined as: lack of efficacy with a 6-week trial, allergy, contraindication to, intolerable side effects, or significant drug-drug interactions, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.) ***FLUTICASONE PROPIONATE HFA** is available to members without prior authorization for: • Members with a diagnosis of eosinophilic esophagitis (EoE) **OR** • Members ≤ 12 years of age. Maximum Dose: Pulmicort (budesonide) nebulizer suspension: 2mg/day Quantity Limits: Pulmicort flexhaler: 2 inhalers / 30 days
Inhaled Corticosteroid Combinations		
No PA Required **(*Must meet eligibility criteria)** ADVAIR DISKUS[BNR] (fluticasone/salmeterol) ADVAIR HFA[BNR] (fluticasone/salmeterol)	**PA Required** BREO ELLIPTA (vilanterol/fluticasone furoate) Budesonide/formoterol (generic Symbicort) Fluticasone/salmeterol (generic Airduo/Advair Diskus) Fluticasone/salmeterol HFA (generic Advair HFA)	***TRELEGY ELLIPTA** (fluticasone furoate/umeclidinium/vilanterol) may be approved if the member has trialed/failed one preferred agent. Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form. Non-preferred inhaled corticosteroid combinations may be approved for members meeting both of the following criteria: • Member has a qualifying diagnosis of asthma or severe COPD; **AND**

AIRDUO RESPICLICK [BNR] (fluticasone/salmeterol) DULERA (mometasone/formoterol) SYMBICORT[BNR] (budesonide/formoterol) inhaler *TRELEGY ELLIPTA (fluticasone furoate/ umeclidinium/vilanterol)	Fluticasone/vilanterol (generic Breo Ellipta) WIXELA INHUB (fluticasone/salmeterol)	• Member has failed two preferred agents (Failure is defined as lack of efficacy with a 6-week trial, allergy, intolerable side effects, significant drug-drug interactions, or dexterity/coordination limitations (per provider notes) that significantly impact appropriate use of a specific dosage form.
Phosphodiesterase Inhibitors (PDEIs)		
No PA Required Roflumilast tablet	**PA Required** DALIRESP (roflumilast) tablet OHTUVAYRE (ensifentrine) suspension	Requests for use of the non-preferred brand product formulation may be approved if meeting criteria outlined in the Appendix P "Generic Mandate" section.

Appendix P

Colorado Medical Assistance Program
Prior Authorization Procedures, Coverage Policies and Drug Utilization Criteria
Health First Colorado Pharmacy Benefit
For Physicians and Pharmacists

Drug products requiring a prior authorization for the Health First Colorado pharmacy benefit are listed in this document. Prior authorization criteria are based on FDA product labeling, CMS approved compendia, clinical practice guidelines, and peer-reviewed medical literature.

Prior Authorization Procedures:

- Prior authorizations may be submitted to the helpdesk by:
  - Phone: 1-800-424-5725
  - Fax: 1-888-424-5881
  - Electronic Prior Authorization Requests (ePA) are supported by CoverMyMeds and may be submitted via Electronic Health Record (EHR) systems or through the CoverMyMeds provider portal.
- Products qualify for a 3-day emergency supply in an emergency situation. In this case, call the helpdesk for an override.
- Prior authorization (PA) forms are available by visiting https://www.colorado.gov/hcpf/pharmacy-resources .
- PA forms can be signed by anyone who has authority under Colorado law to prescribe the medication. Assistants of authorized persons cannot sign the PA form.
- Physicians or assistants who are acting as the agents of the physicians may request a PA by phone.
- Pharmacists from long-term-care pharmacies and infusion pharmacy must obtain a signature from someone who is authorized to prescribe drugs before they submit PA forms.
- Pharmacists from long-term-care pharmacies and infusion pharmacies can request a PA by phone if specified in the criteria.
- Please note that initiating therapy with a requested drug product, including non-preferred drugs, prior to a PA request being reviewed and approved does not necessitate approval of the PA request. This includes initiating therapy by administration in the inpatient setting, by using office samples, or by any other means.
- All PA requests are coded online into the PA system.
- A provider may request a step therapy exception for the treatment of a serious or complex medical condition pursuant to section 25.5-4-428, C.R.S. Serious or complex medical condition means the following medical conditions: serious mental illness, cancer, epilepsy, multiple sclerosis, or human immunodeficiency virus (HIV)/ acquired immune deficiency syndrome (AIDS), or a condition requiring medical treatment to avoid death, hospitalization, or a worsening or advancing of disease progression resulting in significant harm or disability. The step therapy exception request form is available by visiting https://hcpf.colorado.gov/pharmacy-resources .

Early Refill Limitations:

- Non-controlled prescriptions may be refilled after 75% of previous fill is used. Controlled substance prescriptions (DEA Schedule 2 through 5) may be refilled after 85% of the previous fill is used. Synagis may be refilled after 92.5% of the previous fill is used.

Medical Supply Products and Medications:

- All supplies, including insulin needles, food supplements and diabetic supplies are not covered under the pharmacy benefit, but are covered as medical supply items through the Durable Medical Equipment (DME) benefit.
- If a medical benefit requires a PA, the PA request can be submitted through the provider application available at http://www.coloradopar.com/
- DME questions should be directed to Gainwell Technologies (Formerly DXC Technology) 1-844-235- 2387. Only policy questions regarding Durable Medical Equipment should be directed to the state at 303-866-3406.

Physician Administered Drugs and Medical Billing:

- Physician administered drugs (PADs) include any medication or medication formulation that is administered intravenously or requires administration by a healthcare professional (including cases where FDA package labeling for a medication specifies that administration should be performed by or under the direct supervision of a healthcare professional). PAD criteria listed on

Appendix P apply specifically to drug products when billed through the Health First Colorado pharmacy benefit. Only PADs administered by a healthcare professional in the member's home or in a long-term care facility should be billed through the Health First Colorado pharmacy benefit (see "Physician Administered Drugs" section below). PADs administered by a healthcare professional in the office, clinic, dialysis unit, or outpatient hospital settings should be billed through the Health First Colorado medical benefit using the standard buy-and-bill process and following procedures outlined in the PAD Billing Manual (found on the PAD Resources Page at https://www.colorado.gov/hcpf/physician-administered-drugs).

Prescription Drug Monitoring Program (PDMP):

- Effective October 1, 2021, Medicaid providers permitted to prescribe controlled substances must query the Colorado Prescription Drug Monitoring Program (PDMP) before prescribing controlled substances to Medicaid members, in accordance with Section 5042 of the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act." The requirement to check the PDMP does not apply when a member:
  - Is receiving the controlled substance in a hospital, skilled nursing facility, residential facility, or correctional facility
  - Has been diagnosed with cancer and is experiencing cancer-related pain
  - Is undergoing palliative care or hospice care
  - Is experiencing post-surgical pain that, because of the nature of the procedure, is expected to last more than 14 days
  - Is receiving treatment during a natural disaster or during an incident where mass casualties have taken place
  - Has received only a single dose to relieve pain for a single test or procedure
  - In the case that a provider is not able to check the PDMP before prescribing a controlled substance, despite a good faith effort, the State shall require the provider to document the effort, including the reasons why the provider was not able to conduct the check (the State may require the provider to submit, upon request, such documentation to the State).
- Additional information about the Colorado PDMP is available by visiting https://dpo.colorado.gov/PDMP

Drug Product(s)	Criteria	PA Approval Length
ACETAMINOPHEN CONTAINING PRODUCT MAXIMUM DOSING	A prior authorization is required for dosages of acetaminophen exceeding 4000mg/day. Doses over 4000mg/day are not qualified for emergency 3-day supply approval	

ACTHAR (corticotropin)	**Acthar** (corticotropin) may be approved for members that meet the following criteria:
	• Member has a diagnosis of Infantile Spasms (West Syndrome) and meets <u>all</u> the criteria below:
	  ○ Member is < 2 years of age
	  ○ Member has electroencephalogram documenting diagnosis
	  ○ Acthar is being used as monotherapy
	  ○ Member does not have suspected congenital infection
	  ○ Prescribed by or in consultation with a neurologist or epileptologist
	OR
	• Member has diagnosis of multiple sclerosis and is experiencing an acute exacerbation **AND**
	• Member does not have concomitant primary adrenocortical insufficiency or adrenocortical hyperfunction **AND**
	• Member has trialed and failed corticosteroid therapy prescribed to treat acute exacerbation due to multiple sclerosis. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND**
	• Member is not receiving concomitant live or live attenuated vaccines **AND**
	• Member does not have one of the following concomitant diagnoses:
	  ○ Scleroderma, osteoporosis, systemic fungal infections, ocular, herpes simplex, recent surgery, history of peptic ulcer disease, heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin. **AND**
		4 week supply

<table>
<tr><th>Drug Product(s)</th><th>Criteria</th><th>PA Approval Length</th></tr>
<tr><td></td><td>
Acthar (corticotropin) will be approved based on the following FDA recommended doses. (see Table 1)
<table>
<tr><th colspan="2">Table 1: FDA Recommended Dosing</th></tr>
<tr><th>Diagnosis</th><th>Dose</th></tr>
<tr><td>Infantile Spasms
(under age of 2 years)</td><td>75 units/m^2 IM twice daily for two weeks; After two weeks, dose should be tapered according to the following schedule: 30 U/m^2 IM in the morning for 3 days; 15 units/m^2 IM in the morning for 3 days; 10 units/m^2 IM in the morning for 3 days; and 10 units/m^2 IM every other morning for 6 days (3 doses).</td></tr>
<tr><td>Acute Exacerbation of Multiple Sclerosis</td><td>80-120 units IM or SQ daily for 2-3 weeks</td></tr>
</table>
Quantity Limits: 4 week supply
</td><td></td></tr>
<tr><td>ADAKVEO (crizanlizumab-tmca)</td><td>Adakveo (crizanlizumab-tmca) may be approved for members meeting the following criteria:
Medication is being administered in the member’s home or in a long-term care facility by a healthcare professional AND
Medication is being used to reduce the frequency of vasoocclusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease.
Maximum dose: Adakveo 5mg/kg every 2 weeks (IV Infusion)</td><td>One year</td></tr>
<tr><td>ADUHELM (aducanumab-avwa)</td><td>Aduhelm (aducanumab-avwa) may be approved if the following criteria are met:
For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member’s home or in a long-term care facility AND
Member has documented diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer’s disease, the population in which treatment was initiated in clinical trials, as evidenced by all of the following:
Positron Emission Tomography (PET) scan OR lumbar puncture positive for amyloid beta plaque AND
Clinical Dementia Rating global score (CDR-GS) of 0.5 or 1 (available at https://otm.wustl.edu/cdr-terms-agreement/) AND
Mini-Mental State Examination (MMSE) score of 24-30 OR Montreal Cognitive Assessment (moCA) Test score of 19-25
AND
Member is ≥ 50 years of age AND
The prescriber attests that member has been counseled on the approval and safety status of Aduhelm (aducanumab-avwa) being approved under accelerated approval based on reduction in amyloid beta plaques AND</td><td>See criteria</td></tr>
</table>

Drug Product(s)	Criteria	PA Approval Length
	• Prior to initiation of Aduhelm (aducanumab-avwa), the prescriber attests that the member meets both of the following: o Member has had a brain MRI within the prior one year to treatment initiation, showing no signs or history of localized superficial siderosis, ≥ 10 brain microhemorrhages, and/or brain hemorrhage > 1 cm AND o Attestation that MRI will be completed prior to the 7th (1st dose at 10 mg/kg) and 12th (6th dose at 10 mg/kg) infusion AND • Member <u>does not</u> have any of the following: o Any medical or neurological condition other than Alzheimer's Disease that might be a contributing cause of the subject's cognitive impairment including (but not limited to) stroke/vascular dementia, tumor, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD] or normal pressure hydrocephalus o Contraindications to PET, CT scan, or MRI o History of or increased risk of amyloid related imaging abnormalities ARIA-edema (ARIA-E) or ARIA-hemosiderin deposition (ARIA-H) o History of unstable angina, myocardial infarction, chronic heart failure, or clinically significant conduction abnormalities, stroke, transient ischemic attack (TIA), or unexplained loss of consciousness within 1 year prior to initiation of Aduhelm (aducanumab-avwa) o History of bleeding abnormalities or taking any form of anticoagulation therapy AND • The requested medication is being prescribed by or in consultation with a neurologist AND • The prescribed regimen meets FDA-approved labeled dosing: a. <u>Infusion 1 and 2</u>: 1 mg/kg over approximately 1 hour every 4 weeks b. <u>Infusion 3 and 4</u>: 3 mg/kg over approximately 1 hour every 4 weeks c. <u>Infusion 5 and 6</u>: 6 mg/kg over approximately 1 hour every 4 weeks d. <u>Infusion 7 and beyond</u>: 10 mg/kg over approximately 1 hour every 4 weeks. <u>Initial approval period</u>: 6 months <u>Second prior authorization</u>: an additional 6 months of Aduhelm (aducanumab-avwa) therapy may be approved with provider attestation that a follow-up MRI will be (or has been) completed prior to the 7th infusion <u>Subsequent approval</u>: an additional 6 months of Aduhelm (aducanumab-avwa) therapy may be approved with provider attestation that a follow-up MRI will be (or has been) completed prior to the 12th infusion <u>Maximum dose</u>: 10 mg/kg IV every 4 weeks The above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options and available peer-reviewed medical literature and clinical evidence. If request is for use outside of stated coverage standards, support with peer reviewed medical literature and/or subsequent clinical rationale shall be provided and will be evaluated at the time of request.	

Drug Product(s)	Criteria	PA Approval Length
	Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).	
ADZYNMA (apadamtase alfa)	**Adzynma** (apadamtase alfa) may be approved if the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Member is ≥ 2 years of age AND • Member has a diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) confirmed by genetic testing indicating severe deficiency of ADAMTS13 protease and/or based on clinical judgment, AND • The requested medication is being prescribed by or in consultation with a hematologist. Maximum dose: Prophylactic therapy: 40 IU/kg weekly On-demand therapy: 40 IU/kg/day	One year
AEMCOLO (rifamycin)	**Aemcolo** (rifamycin) may be approved if the following criteria are met: • The member is ≥ 18 years of age AND • The member has a diagnosis of travelers' diarrhea caused by a non-invasive strain of E. Coli, without fever and without bloody stool AND • The member has trialed and failed† treatment with oral azithromycin AND • The member is not allergic to the rifamycin drug class (such as rifamycin, rifaximin, rifampin). Maximum Dose: 4 tablets/day Quantity Limit: 12 tablets (3 day supply) †Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication, or significant drug-drug interaction.	Six months
AFINITOR DISPERZ (everolimus)	**Afinitor Disperz** (everolimus) tablet for suspension may be approved if the following criteria are met: • The member is ≥ 1 year of age and Afinitor Disperz (everolimus) is being prescribed for Tuberous Sclerosis Complex (TSC) for treatment of Subependymal Giant Cell Astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected OR • The member is ≥ 2 year of age and Afinitor Disperz (everolimus) is being prescribed for adjunctive treatment of TSC-associated partial-onset seizures.	One year
AGAMREE (vamorolone)	**Agamree** (vamorolone) may be approved when the following criteria are met: • Member is ≥ 2 years of age AND • Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) and is ambulatory AND • A baseline assessment of ambulatory function using the Time to Stand Test (TTSTAND) has been documented prior to initiating Agamree (vamorolone) therapy AND • Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (such as a cardiologist, pulmonologist, or physical medicine and rehabilitation physician AND	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member requires use of long-term corticosteroid therapy with Agamree (vamorolone) due to an inability to tolerate therapy with traditional corticosteroids AND • Member has received all appropriate immunizations according to current ACIP guidelines at least two weeks prior to (at least 4 to 6 weeks prior for live-attenuated or live vaccines) Agamree (vamorolone) initiation AND • Provider attests that member will be monitored for corticosteroid-related effects (such as Cushing's syndrome, hyperglycemia, behavioral/mood disturbances, or adrenal insufficiency after Agamree (vamorolone) therapy is withdrawn) AND • Provider attests that the dose of Agamree (vamorolone) will be appropriately reduced per product labeling for members who are concurrently taking strong CYP3A4 inhibitors (such as itraconazole, ketoconazole, diltiazem, ritonavir). Maximum dose: 7.5ml (300mg) per day <u>Reauthorization</u>: After one year of treatment with Agamree (vamorolone), the member may receive approval to continue therapy for one year if the following criteria are met: • Member has shown no clinically significant or intolerable adverse effects related to vamorolone treatment AND • Member demonstrates response to vamorolone treatment with clinical improvement in trajectory from baseline assessment in ambulatory function as measured by the Time to Stand Test (TTSTAND).	
ALBUMIN	Albumin products may be approved if meeting the following criteria: • Medication is given in the member's home or in a long-term care facility AND • Administration is for one of the following FDA-approved indications: o Hypoproteinemia o Burns o Shock due to: ▪ Burns ▪ Trauma ▪ Surgery ▪ Infection o Erythrocyte resuspension o Acute nephrosis o Renal dialysis o Hyperbilirubinemia o Erythroblastosis fetalis	One year
ALDURAZYME (laronidase)	**Aldurazyme** (laronidase) may be approved for members meeting the following criteria: • Aldurazyme (laronidase) is being administered in a long-term care facility or in a member's home by a healthcare professional AND • Member is 6 months of age or older AND • Member does not have acute febrile or respiratory illness AND • Member does not have progressive/irreversible severe cognitive impairment AND • Member has a diagnosis of Mucopolysaccharidosis, Type 1 confirmed by one of the following:	One year

<table>
<tr><th>Drug Product(s)</th><th>Criteria</th><th>PA Approval Length</th></tr>
<tr><td></td><td>

Detection of pathogenic mutations in the IDUA gene by molecular genetic testing OR
Detection of deficient activity of the α-L-iduronidase lysosomal enzyme

AND

Member has a diagnosis of one of the following subtypes:

Diagnosis of Hurler (severe) or Hurler-Scheie (attenuated) forms of disease OR
Diagnosis of Scheie (attenuated) form of disease with moderate to severe symptoms

AND
Alurazyme (laronidase) is being prescribed by or in consultation with a provider who specializes in inherited metabolic disorders AND
Member has a documented baseline value for urinary glycosaminoglycan (uGAG) AND
Member has a documented baseline value for one of the following based on age:

Members ≥ 6 years of age: percent predicted forced vital capacity (FVC) and/or 6- minute walk test OR
Members 6 months to 6 years of age: cardiac status, upper airway obstruction during sleep, growth velocity, mental development, FVC, and/or 6-minute walk test

<u>Reauthorization Criteria:</u>
After one year, member may receive approval to continue therapy if meeting the following:

Has documented reduction in uGAG levels AND
Has demonstrated stability or improvement in one of the following based on age:

Members ≥ 6 years of age: stability or improvement in percent predicted FVC and/or 6-minute walk test OR
Members 6 months to less than 6 years of age: stability or improvement in cardiac status, upper airway obstruction during sleep, growth velocity, mental development, FVC and/or 6-minute walk test

Max dose: 0.58 mg/kg as a 3 to 4-hour infusion weekly.
</td><td></td></tr>
<tr><td>ALINIA (nitazoxanide)</td><td>
Alinia (nitazoxanide) may be approved if meeting the following criteria:

ALINIA is being prescribed for diarrhea caused by Giardia lamblia or Cryptosporidium parvum AND
Member is 1 year of age or older AND
If treating diarrhea due to C. parvum in members with Human Immunodeficiency Virus (HIV) infection, the member is receiving antiretroviral therapy AND
Prescription meets the following FDA-labeled dosing:

<table>
<tr><th>Age (years)</th><th>Dosage of Nitazoxanide</th><th>Duration</th></tr>
<tr><td>1-3</td><td>5 mL (100mg) oral suspension every 12 hours with food</td><td></td></tr>
<tr><td>4-11</td><td>10 mL (200mg) oral suspension every 12 hours with food</td><td>3 days</td></tr>
<tr><td>>11</td><td>500mg orally every 12 hours with food</td><td></td></tr>
</table>
</td><td></td></tr>
</table>

Drug Product(s)	Criteria	PA Approval Length
ALLERGY EXTRACT PRODUCTS (Oral)	**Grastek** (timothy grass pollen allergen extract): Must be between 5 and 65 years old. Must not be pregnant or nursing. Must be prescribed by an allergist. Must have a documented diagnosis to ONLY timothy grass pollen allergen extract or the Pooideae family (meadow fescue, orchard, perennial rye, Kentucky blue, and red top grasses) confirmed by positive skin test or IgE antibodies. Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Must be willing to administer epinephrine in case of severe allergic reaction. Must take first dose in physician's office. Must be started 12 weeks prior to the season if giving only seasonally. May be taken daily for up to 3 consecutive years. Must NOT have: • Severe, unstable or uncontrolled asthma • Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat • Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before • Been diagnosed with eosinophilic esophagitis • Allergic to any of the inactive ingredients contained in Grastek which include gelatin, mannitol, and sodium hydroxide • A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension. • Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics. • Be taken with other immunotherapy (oral or injectable) **Odactra** (dermatophagoides pteronyssinus and dermatophagoides farinae): Must be between 5 and 65 years old. Must not be pregnant or nursing. Must be prescribed by an allergist. Must have a documented diagnosis to ONLY house dust mite induced allergic rhinitis confirmed by positive IgE antibody testing or positive skin testing to licensed house dust mite allergen extracts Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Must be willing to administer epinephrine in case of severe allergic reaction. Must take first dose in physician's office. Must be started 12 weeks prior to the season if giving only seasonally. May be taken daily for up to 3 consecutive years.	One year

Drug Product(s)	Criteria	PA Approval Length
	Must NOT have: • Severe, unstable or uncontrolled asthma • Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat • Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before • Been diagnosed with eosinophilic esophagitis • Allergic to any of the inactive ingredients contained in Grastek which include gelatin, mannitol, and sodium hydroxide • A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension. • Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics. • Be taken with other immunotherapy (oral or injectable) **Oralair** (sweet vernal, orchard, perennial rye, timothy, Kentucky blue grass mixed pollens allergen extract): Must be between 5 and 65 years old. Must not be pregnant or nursing. Must be prescribed by an allergist. Must have a documented diagnosis to ONLY Sweet Vernal, Orchard, Perennial Rye, Timothy, or Kentucky Blue Grass allergen extract confirmed by positive skin test or IgE antibodies. Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Must be willing to administer epinephrine in case of severe allergic reaction. Must take first dose in physician's office. Must NOT have: • Severe, unstable or uncontrolled asthma • Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat • Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before • Been diagnosed with eosinophilic esophagitis • Allergic to any of the inactive ingredients contained in Oralair which include mannitol, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, and lactose monohydrate. • A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension. • Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics.	

Drug Product(s)	Criteria	PA Approval Length
	• Be taken with other immunotherapy (oral or injectable) **Ragwitek** *(short ragweed pollen allergen extract):* Must be between 18 and 65 years old. Must be started 12 weeks prior to the season and only prescribed seasonally. Must not be pregnant or nursing. Must be prescribed by an allergist. Must have a documented diagnosis to ONLY short ragweed pollen allergen extract or the Ambrosia family (giant, false, and western ragweed) confirmed by positive skin test or IgE antibodies. Must have tried and failed allergy shots for reasons other than needle phobia. Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Must be willing to administer epinephrine in case of a severe allergic reaction. Must take first dose in physician's office. Must NOT have: • Severe, unstable or uncontrolled asthma • Had an allergic reaction in the past that included trouble breathing, dizziness or fainting, rapid or weak heartbeat • Ever had difficulty with breathing due to swelling of the throat or upper airway after using any sublingual immunotherapy before • Been diagnosed with eosinophilic esophagitis • Allergic to any of the inactive ingredients contained in Ragwitek which include gelatin, mannitol, and sodium hydroxide • A medical condition that may reduce the ability to survive a serious allergic reaction including but not limited to: markedly compromised lung function, unstable angina, recent myocardial infarction, significant arrhythmia, and uncontrolled hypertension. • Taking medications that can potentiate or inhibit the effect of epinephrine including but not limited to: beta-adrenergic blockers, alpha-adrenergic blockers, ergot alkaloids, tricyclic antidepressants, levothyroxine, monoamine oxidase inhibitors, certain antihistamines, cardiac glycosides, and diuretics. • Be taken with other immunotherapy (oral or injectable)	
ALPHA–1 PROTEINASE INHIBITORS	FDA approved indication if given in the member's home or in a long-term care facility: • **Aralast**: Chronic augmentation therapy in members having congenital deficiency of Alpha –1 Proteinase Inhibitor with clinically evident emphysema • **Prolastin**: Emphysema associated with Alpha-1 Antitrypsin Deficiency • **Zemaira**: Chronic augmentation and maintenance therapy in members with Alpha-1 Proteinase Inhibitor deficiency with clinically evident emphysema	Lifetime
ALVAIZ (eltrombopag choline)	**Alvaiz** (eltrombopag choline) may be approved if the following criteria are met: <u>For ALL Indications</u>: • Eltrombopag choline is not substitutable with other eltrombopag products on a mg-per-mg basis AND • Prescriber is aware that Alvaiz (eltrombopag choline) may increase the risk of severe and potentially life-threatening hepatotoxicity, and that hepatic function must be monitored before and during therapy AND	See criteria

Drug Product(s)	Criteria	PA Approval Length
	• Prescriber is aware that member will undergo ocular exams prior to initiation of therapy, during therapy, and will be regularly monitored for signs and symptoms of cataracts AND • Member has been counseled to take Alvaiz (eltrombopag choline) at least 2 hours before or 4 hours after any products containing polyvalent cations (such as iron, calcium, aluminum, magnesium, selenium, zinc, dairy products, and supplements containing minerals) to avoid a significant reduction in eltrombopag absorption, AND • Member is not breastfeeding AND • Alvaiz (eltrombopag choline) tablets should not be split, chewed, or crushed. Pediatric patients must be able to swallow tablets whole AND • Meets additional criteria for prescribed indication below. <u>Persistent or Chronic Immune Thrombocytopenia</u>: • Member is ≥ 6 years of age AND • Member has a confirmed diagnosis of persistent or chronic (> 3 months) immune thrombocytopenia AND • Member's degree of thrombocytopenia and clinical condition increase the risk (documented) of bleeding as demonstrated by the following lab values: o Platelet count less than 20,000/mm3 OR o Platelet count less than 30,000/mm3 accompanied by signs and symptoms of bleeding AND • Requested medication is being prescribed by a hematologist AND • Member has tried and failed‡ at least one of the following: o Systemic corticosteroid therapy within the past 6 months (such as prednisone 1-2 mg/kg for 2 to 4 weeks, or pulsed dexamethasone 40 mg daily for 4 days) o Immunoglobulin replacement o Splenectomy <u>Thrombocytopenia Associated with Hepatitis C</u>: • Member has a confirmed diagnosis of chronic hepatitis C associated thrombocytopenia AND • Member is ≥ 18 years of age AND • Requested medication is being prescribed by a gastroenterologist, infectious disease specialist, transplant specialist, or hematologist AND • Member has clinically documented thrombocytopenia (defined as platelets < 60,000 microL) AND • Prescriber acknowledges that safety and efficacy have not been established for the use of Alvaiz (eltrombopag choline) in combination with direct-acting antiviral agents used without interferon for the treatment of chronic hepatitis C infection AND • Prescriber is aware that in patients with chronic hepatitis C, Alvaiz (eltrombopag choline) used in combination with interferon and ribavirin may increase the risk of hepatic decompensation. <u>Severe Aplastic Anemia</u>: • Member has a confirmed diagnosis of severe aplastic anemia AND • Member is ≥ 18 years of age AND	

Drug Product(s)	Criteria	PA Approval Length
	• Requested medication is being prescribed by a hematologist AND • Member must have had a documented insufficient response to immunosuppressive therapy [antithymocyte globulin (ATG)], alone or in combination with cyclosporine and/or a corticosteroid. Maximum dose: • Persistent or chronic immune thrombocytopenia: 54 mg/day • Thrombocytopenia associated with hepatitis C: 72 mg/day • Severe aplastic anemia: 108 mg/day Initial approval: Initial prior authorization approval will be granted for 12 months. Reauthorization: Reauthorization approval for a maximum of 6 months will require documentation both of lab results and efficacy of treatment with Alvaiz (eltrombopag choline). ‡Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions.	
AMONDYS 45 (casimersen)	**Amondys 45** (casimersen) may be approved for members meeting the following criteria: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) AND • Member must have genetic testing confirming mutation of the DMD gene that is amenable to exon 45 skipping AND • Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (such as a cardiologist, pulmonologist, or physical medicine and rehabilitation physician or pulmonary specialist) AND • Provider attests that serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio (UPCR) and glomerular filtration rate (GFR) will be measured prior to initiation of and that the member will be monitored periodically for kidney toxicity during treatment AND • The member must be on corticosteroids at baseline or prescriber provides clinical rationale for not using corticosteroids AND • If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a baseline Brooke Upper Extremity Function Scale or Forced Vital Capacity (FVC) documented AND • Provider and patient or caregiver are aware that continued US FDA approval of Amondys 45 (casimersen) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in a confirmatory trial. <u>Reauthorization</u>: After one year of treatment with Amondys 45 (casimersen), the member may receive approval to continue therapy for one year if the following criteria are met: • Member has shown no intolerable adverse effects related to Amondys 45 (casimersen) treatment at a dose of 30mg/kg IV once a week AND • Member has normal renal function or stable renal function if known impairment AND	Initial: One year Continued: One year

Drug Product(s)	Criteria	PA Approval Length
	• Member demonstrates response to Amondys 45 (casimersen) treatment with clinical improvement in trajectory from baseline assessment in ambulatory function OR if not ambulatory, member demonstrates improvement from baseline on the Brooke Upper Extremity Function Scale or in Forced Vital Capacity (FVC). Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence. Maximum Dose: 30 mg/kg per week	
ANOREXIANTS	Medications prescribed for use for weight loss are not a covered benefit. **Adipex P** (phentermine) **Belviq** (lorcaserin) **Contrave** (naltrexone/bupropion) **Lomaira** (phentermine) **Phentermine** **Qsymia** (phentermine/topiramate ER) **Saxenda** (liraglutide) **Xenical** (Orlistat)	
ANTI-ANEMIA MEDICATIONS	Oral prescription iron products may be approved for members with a diagnosis of iron deficient anemia (applies to products available by prescription only) Injectable anti-anemia agents (such as **Infed®**, **Ferrlecit®**, **Venofer®, Dexferrum®**) may be approved for members meeting the following criteria: • Member has a diagnosis of iron deficient anemia **AND** • Oral preparations are ineffective or cannot be used **AND** • Medication is being administered in a long-term care facility or in the member's home by a home healthcare provider Note: For coverage criteria for OTC **f**errous sulfate and ferrous gluconate, refer to "OTC Products" section.	Lifetime
ANTIPSYCHOTIC LONG-ACTING INJECTABLE PRODUCTS	Effective October 1, 2024, coverage information and criteria for long-acting injectable antipsychotic medications is located on the Preferred Drug List (PDL).	
AQNEURSA (levacetylleucine)	**Aqneursa** (levacetylleucine) may be approved if the following criteria are met: • Member weighs ≥ 15 kg AND • Member has a documented diagnosis of Niemann-Pick disease type C, molecularly confirmed by genetic testing AND • Requested medication is being prescribed by a neurologist or other provider specializing in the treatment of Niemann-Pick disease type C AND • A baseline assessment of disability has been documented using a version of the NPC Clinical Severity Scale (NPCCSS) prior to initiating Aqneursa (levacetylleucine) therapy AND • Member is not pregnant AND • If member is breastfeeding, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for	6 months

Drug Product(s)	Criteria	PA Approval Length
	Aqneursa (levacetylleucine) and any potential adverse effects on the breastfed infant or from the underlying maternal condition AND • Members of childbearing potential been counseled that Aqneursa (levacetylleucine) may cause fetal harm and to use effective contraception during treatment and for 7 days after the last dose of Aqneursa, if therapy is discontinued AND • Members are limited to one prior authorization approval on file for Miplyffa (arimoclomol citrate) OR Aqneursa (levacetylleucine). Maximum Dose: 4 grams/day Maximum Quantity: 112 unit dose 1-gram packets/28 days Initial Approval: 6 months Reauthorization Approval: Continuation of therapy for 6 months may be approved if all of the following criteria are met: • Based on ongoing response to treatment, the provider attests there is medical necessity justifying continuation of drug therapy AND • Member has demonstrated response to treatment based on quantitative scores using the same scale(s) previously used to assess Aqneursa treatment (see bullet point 4 of the initial authorization criteria), AND • A brief explanation, including the provider name, must be submitted if a provider other than the one who initially performed the neurologic exam completes any follow-up exam(s) AND • A brief explanation must be submitted if an exam scale other than the scale used for initial authorization is used for reassessment.	
AVEED (testosterone undecanoate)	Claims for medications administered in a clinic or medical office are billed through the Health First Colorado medical benefit.	Product not eligible for pharmacy billing.
BACTROBAN (mupirocin) Cream and Nasal Ointment	**Bactroban Cream** (mupirocin calcium cream) must be prescribed for the treatment of secondarily infected traumatic skin lesions (up to 10 cm in length or 100 cm^2 in total area), impetigo, infected eczema or folliculitis caused by susceptible strains of Staphylococcus aureus and Streptococcus pyogenes. **Bactroban Nasal Ointment** (mupirocin calcium) must be prescribed for the eradication of nasal colonization with methicillin-resistant Staphylococcus aureus in adult patients and health care workers as part of a comprehensive infection control program to reduce the risk of infection among patients at high risk of methicillin-resistant S. aureus infection during institutional outbreaks of infections with this pathogen.	Cream: One year Nasal Ointment: Lifetime
BARBITURATES **Coverage for Medicare dual-eligible members**	Dual-eligible Medicare-Medicaid Beneficiaries: Effective 01/01/2013, barbiturates are no longer covered under the Health First Colorado pharmacy benefit for Medicare-Medicaid dual-eligible members.	
BENLYSTA (belimumab)	**Benlysta** (belimumab) may be approved if the following criteria are met: • For requests for the IV formulation, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND** • Member is age ≥ 5 years and has active, autoantibody-positive systemic lupus erythematosus (SLE) and receiving standard therapy OR has active lupus nephritis and is receiving standard therapy **AND**	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member has incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids; **AND** • Member maintains use of standard therapy while on Benlysta (belimumab) **AND** • Member is not receiving other biologics or intravenous cyclophosphamide **AND** • The product is NOT being prescribed for severe active lupus nephritis or severe active central nervous system lupus. Maximum dose: IV formulation: 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter. Subcutaneous formulation: 200 mg once weekly. If initiating therapy for active lupus nephritis, 400-mg dose (two 200 mg injections) once weekly for 4 doses followed by 200mg once weekly thereafter.	
BENZODIAZEPINES Coverage for Medicare dual-eligible members	Dual-eligible Medicare-Medicaid Beneficiaries: Benzodiazepines will no longer be a Medicaid benefit for Medicare-Medicaid enrollees (dual-eligible members). The claims are no longer excluded from Medicare part D coverage and therefore must be billed to Medicare part D. Colorado Medicaid will no longer cover these medications for these members beginning on January 1, 2013.	

BESREMI (ropeginterferon alfa-2b)	**Besrimi** (ropeginterferon alfa-2b) may be approved if the following criteria are met:
	• Member is ≥ 18 years of age AND
	• The requested medication is being prescribed for the treatment of polycythemia vera AND
	• The requested medication is being prescribed by a hematologist AND
	• Member does NOT meet any of the following:
	  ○ History of, or presence of, severe psychiatric disorders, particularly severe depression, suicidal ideation, or history of suicide attempt
	  ○ Moderate or severe hepatic impairment
	  ○ History of, or presence of, active serious or untreated autoimmune disease
	  ○ The member is an immunosuppressed transplant recipient
	AND
	• Prescriber attests that complete blood count (CBC) will be checked at least every 2 weeks during the titration phase and at least every 3 to 6 months during the maintenance phase after the patient's optimal dose is established AND
	• Prescriber attests that a pre-treatment pregnancy test will be performed, and that members of reproductive potential will be advised to use effective contraception during treatment and for at least 8 weeks after the final dose AND
	• Provider attests that assessments of psychiatric well-being will be performed at baseline and monitored periodically.
	
	Maximum Dose: 500 mcg every two weeks
	Quantity Limit: Four 500 mcg/mL prefilled syringes/30 days
	
	Reauthorization: If hematological stability has been achieved after at least 1 year of therapy on a two week dosing interval of BESREMi (ropeginterferon alfa-2b), provider attests to considering an expanded dosing interval of every 4 weeks.
		One year

BLOOD PRODUCTS	FDA approved indications if given in the member's home or in a long-term care facility:	Lifetime

Drug Product(s)	Criteria	PA Approval Length
	Plasma protein fraction; shock due to burns, trauma, surgery; hypoproteinemia; adult respiratory distress syndrome; cardiopulmonary bypass; liver failure; renal dialysis; or hemophilia.	
BONE RESORPTION SUPPRESSION AND RELATED AGENTS (Injectable Formulations) Aredia, Ganite, Hectorol, Ibandronate, Miacalcin, Pamidronate, Prolia, Reclast, Zemplar, Zometa	A prior authorization will only be approved as a pharmacy benefit when the medication is administered in a long-term care facility or in a member's home. **Prolia** (denosumab) will be approved if the member Meets the following criteria: • Member is in a long-term care facility or home health (this medication is required to be administered by a healthcare professional) AND • Member has one of the following diagnoses: o Postmenopausal osteoporosis with high fracture risk o Osteoporosis o Bone loss in men receiving androgen deprivation therapy in prostate cancer o Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer AND • Member has serum calcium greater than 8.5mg/dL AND • Member is taking calcium 1000 mg daily and at least 400 IU vitamin D daily AND • Has trial and failure of preferred bisphosphonate for one year AND (Failure is defined as: lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction) • Member meets ANY of the following criteria: o has a history of an osteoporotic vertebral or hip fracture o has a pre-treatment T-score of < -2.5 o has a pre-treatment T-score of < -1 but > -2.5 AND either of the following: • Pre-treatment FRAX score of > 20% for any major fracture • Pre-treatment FRAX score of > 3% for hip fracture Maximum dose of Prolia is 60mg every 6 months	One year
BOTULINUM TOXIN AGENTS (Botox, Dysport, Myobloc, Xeomin)	Botulinium toxin agents may receive approval if meeting the following criteria: • Medication is being administered in a long-term care facility or the member's home by a healthcare professional AND • Member has a diagnosis of cervical or facial dystonia ***Not approved for Cosmetic Purposes***	One year
BOWEL PREPERATION AGENTS	For the following Bowel Preparation Agents, members will require a prior authorization for quantities exceeding 2 units in 30 days. • Colyte • Gavilyte-C • Gavilyte-H • Gavilyte-N • Gialax • Golytely® • Moviprep • Peg-Prep • Suprep • Sutab • Trilyte	30 days

Drug Product(s)	Criteria	PA Approval Length
BRAND FAVORED MEDICATIONS	See "Brand Favored Product List" on the Pharmacy Resources webpage at https://www.colorado.gov/pacific/hcpf/pharmacy-resources .	
BREXAFEMME (ibrexafungerp)	**Brexafemme** (ibrexafungerp) may be approved if the following criteria are met: • The member is post-menarchal and ≥ 17 years of age AND • Brexafemme (ibrexafungerp) is being prescribed to treat vulvovaginal candidiasis AND • The member has trialed and failed† two azole antifungal products (oral and/or topical) AND • The member is not pregnant or breastfeeding Maximum Dose: 600 mg/day Quantity Limit: 120 tablets/30 days †Failure is defined as: lack of efficacy, allergy, intolerable side effects, contraindication, or significant drug-drug interaction.	One year
BRIUMVI (ublituximab-xiiy)	**Briumvi** (ublituximab-xiiy) may be approved if the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Member is ≥ 18 years of age AND • Member has a relapsing form of multiple sclerosis (MS) AND • Member has experienced at least one relapse in the prior year or two relapses in the prior two years AND • Member has had trial and failure with any two high efficacy disease modifying therapies (such as ofatumumab, fingolimod, rituximab, ocrelizumab, alemtuzumab). Failure is defined as allergy, intolerable side effects, significant drug-drug interaction, or lack of efficacy. Lack of efficacy is defined as one of the following: o On MRI, presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy OR o Signs and symptoms on clinical exam consistent with functional limitations that last one month or longer AND • Member does not have active hepatitis B virus (HBV) infection AND • The requested medication is prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis AND • Member does not have low serum immunoglobulins, based on quantitative tests performed before initiating treatment, AND • Prescriber attests that appropriate premedication (such as a corticosteroid and antihistamine) will be administered prior to each Briumvi (ublituximab-xiiy) infusion AND • For members of childbearing potential: o Member is not pregnant and prescriber acknowledges that pregnancy testing is recommended for members of reproductive potential prior to each infusion AND o Member has been counseled regarding the use of highly effective contraceptive methods while receiving treatment with Briumvi (ublituximab-xiiy) and for at least 6 months after stopping therapy. Quantity limit: Four 150 mg/6 mL single-dose vials for the first 2 weeks (initial dose), and three 150 mg/6 mL single-dose vials every 24 weeks thereafter.	One year

Drug Product(s)	Criteria	PA Approval Length
	Exemption: If member is currently receiving and stabilized on Briumvi (ublituximab-xiiy), they may receive prior authorization approval to continue therapy.	
BRONCHITOL (mannitol)	**Bronchitol** (mannitol) may be approved for members meeting the following criteria: • Bronchitol (mannitol) is being prescribed as an add-on therapy for cystic fibrosis (CF) AND • Member is an adult (≥ 18 years of age) with a confirmed diagnosis of cystic fibrosis AND • Member has severe lung disease as documented by bronchoscopy or CT scan AND • Member has an FEV1 between 40% and 89% of predicted value AND • Member is receiving other appropriate standard therapies for management of cystic fibrosis (such as inhaled antibiotic, airway clearance physiotherapy, inhaled beta2 receptor agonist) AND • Member has had an adequate trial and failure of nebulized hypertonic saline, or is currently using nebulized hypertonic saline on a regular basis AND • Member has trialed and failed twice-daily treatment with recombinant human deoxyribonuclease (dornase alfa, rhDNase). Failure is defined as allergy, intolerable side effects or inadequate response AND • Member has successfully passed the Bronchitol Tolerance Test (BTT) under the supervision of a healthcare practitioner AND • Member has been prescribed a short-acting bronchodilator to use 5 to 15 minutes before each dose of Bronchitol (mannitol). Maximum dose: 400mg twice a day by oral inhalation Quantity limit: One 4-week Treatment Pack (4 inhalers, 560 capsules) per 28 days	One year
BUPRENORPHINE-CONTAINING PRODUCTS (indicated for opioid use disorder/opioid dependency*)	**Bunavail** (buprenorphine/naloxone) buccal film may be approved for members who meet all of the following criteria: • The member has a diagnosis of opioid dependence AND • The member is 16 years of age or older AND • No claims data show concomitant use of opiates in the preceding 30 days unless the physician attests the member is no longer using opioids AND • The member must have tried and failed, intolerant to, or has contraindication to buprenorphine/naloxone SL tablets or films. **Buprenorphine Extended-Release Injection:** • **Brixadi** or **Sublocade** buprenorphine ER injection may be approved if the following criteria are met: ○ The requested medication is being dispensed directly to the healthcare professional (medication should not be dispensed directly to the member) AND ○ Provider attests to member's enrollment in a complete treatment program including counseling and psychosocial support AND ○ Member must have documented diagnosis of moderate to severe opioid use disorder AND ○ (Sublocade only) Member must have initiated therapy with a transmucosal buprenorphine-containing product and had dose adjustment for a minimum of 7 days.	One year

Drug Product(s)	Criteria	PA Approval Length
	○ Maximum dose: 128 mg monthly (Brixadi); 300 mg monthly (Sublocade) **Buprenorphine/Naloxone** sublingual film: • Effective 07/01/2023, prior authorization is not required for generic buprenorphine/naloxone sublingual film. • Maximum dose is 24mg of buprenorphine/day** **Buprenorphine/Naloxone** sublingual tablet: • Effective 04/12/2023, prior authorization is not required for buprenorphine/naloxone sublingual tablet. • Maximum dose is 24mg of buprenorphine/day. **Suboxone (brand name)** sublingual film: • Effective 07/01/2023, prior authorization is not required for generic buprenorphine/naloxone sublingual film. Requests for use of the brand product formulation are subject to meeting criteria outlined in the "Generic Mandate" section. • Maximum dose is 24mg of buprenorphine/day** **Subutex** (buprenorphine) sublingual tablet will be approved if all of the following criteria are met: • The member has an opioid dependency AND • The member is pregnant OR the member is unable to take naloxone due to allergy or intolerable side effects AND • Subutex will not be approved for the treatment of pain AND • Subutex will not be approved for more than 24mg/day** **Zubsolv** (buprenorphine/naloxone) sublingual tablet will be approved if all of the following criteria are met: • The member has a diagnosis of opioid dependence AND • The member is 16 years of age or older AND • No claims data show concomitant use of opiates in the preceding 30 days unless the physician attests the member is no longer using opioids AND • The member must have tried and failed, intolerant to, or has a contraindication to generic buprenorphine/naloxone SL tablets or Suboxone films. **Buprenorphine products indicated for treating pain are located on the preferred drug list (PDL).* ***Prior authorization requests for buprenorphine/naloxone SL film doses exceeding 24mg buprenorphine/day may be approved with provider attestation to clinical rationale supporting the need for doses exceeding the 24mg/day maximum (eligible for one year approval for up to 32mg buprenorphine/day dosing). Prior authorization requests for buprenorphine SL tablet for members that are pregnant or unable to tolerate naloxone due to allergy or intolerable side effects will also be eligible for one year approval.* *Note: Opioid claims submitted for members currently receiving buprenorphine-containing SUD medications will require entry of point-of-sale DUR service codes (Reason for Service, Professional Service, Result of Service) for override of drug-drug interaction (DD) with use of this drug combination (see "Opioid and Buprenorphine-*	

Drug Product(s)	Criteria	PA Approval Length
	Containing substance use disorder (SUD) Product Combination Effective 06/01/21" section on the PDL).	
BUTALBITAL-CONTAINING PRODUCTS WITHOUT CODEINE	Butalbital-containing combination products that do not contain codeine may be approved for the following (requests for all other uses will require manual clinical review): • Members with a diagnosis of epilepsy, cancer, or chronic mental health disorder OR • For the treatment of insomnia, tension headache, muscle contraction headache, or raised intracranial pressure OR • For use for sedation. *Note: Coverage information for barbiturate-containing medications that are labeled for use for the treatment of epilepsy, and multi-ingredient barbiturate-containing medications that contain codeine, can be found on the Health First Colorado Preferred Drug List (PDL).*	One year
BYNFEZIA (octreotide acetate)	**Bynfezia** (octreotide acetate) may be approved if all of the following criteria are met: • Member is an adult (≥ 18 years of age) with a confirmed diagnosis of acromegaly OR severe diarrhea and flushing episodes associated with metastatic carcinoid tumors OR vasoactive intestinal peptide tumors (VIPomas) AND • Bynfezia (octreotide acetate) is prescribed by, or in consultation with, an endocrinologist or oncologist AND • Member has trialed and failed octreotide acetate injection solution (vial). Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction AND • Provider confirms that member has had a baseline thyroid function test drawn prior to the initiation of Bynfezia (octreotide) and plans to monitor periodically during treatment AND • For treatment indication acromegaly, the following criteria are met: o The member has trialed and failed bromocriptine mesylate at maximally tolerated doses. Failure is defined as lack of efficacy, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction AND o The member cannot be treated with surgical resection or pituitary irradiation Maximum Dose: • Acromegaly: 1500 mcg/day (doses > 300 mcg/day may not result in additional benefit) • Carcinoid Tumors: 750 mcg/day • VIPomas: 750 mcg/day (doses > 450 mcg/day are generally not required)	One year
CABLIVI (caplacizumab)	**Cablivi** (caplacizumab) may be approved if all the following criteria have been met: • Member is 18 years or older **AND** • Member has a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) **AND** • Member is undergoing plasma exchange and is receiving immunosuppressive therapy **AND**	One year

Drug Product(s)	Criteria	PA Approval Length
	• Cablivi (caplacizumab) is being prescribed by or in consultation with a hematologist **AND** • Prescriber is aware that concomitant use of CABLIVI with any anticoagulant or underlying coagulopathy may increase the risk of severe bleeding, including epistaxis and gingival hemorrhage **AND** • Member has not experienced more than 2 recurrences of aTTP while on Cablivi (caplacizumab) **AND** • To bill for Cablivi (caplacizumab) under the pharmacy benefit, the medication must be administered in the member's home or in a long-term care facility. Maximum dose: • First day of treatment: 11 mg prior to plasma exchange, followed by 11 mg after plasma exchange • Subsequent days during treatment period: 11 mg once daily	
CAMZYOS (mavacamten)	**Camzyos** (mavacamten) may be approved if the following criteria are met: • Member is ≥ 18 years of age **AND** • Member is able to swallow capsules **AND** • Member is being treated for symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy AND has a left ventricular ejection fraction of ≥ 55% **AND** • The requested medication is being prescribed by, or in consultation with, a cardiologist **AND** • Echocardiogram assessment of LVEF has been performed prior to initiation of CAMZYOS (mavacamten) therapy and will be repeated periodically during treatment **AND** • Member has tried and failed **ALL** of the following, up to maximally indicated doses. (Failure is defined as contraindication, lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction): o Non-vasodilating beta blocker (any beta blocker except carvedilol or nebivolol) o Non-dihydropyridine calcium channel blocker (such as verapamil, diltiazem) **AND** • Due to increased risk of systolic heart failure, member's medication profile has been reviewed for potential drug interactions with CYP2C19 or CYP3A4 inhibitors (such as fluoxetine, omeprazole, esomeprazole, cimetidine, itraconazole, ketoconazole, fluconazole, ritonavir, diltiazem, verapamil) according to product labeling **AND** • Member does not have severe hepatic impairment (Child-Pugh C) **AND** • Members of reproductive potential have been counseled to use effective contraception during treatment with CAMZYOS (mavacamten) and for 4 months after the last dose. Maximum Dose: 25 mg/day (unless on certain interacting medications) Quantity Limit: 30 capsules/30 days Reauthorization: Approval for CAMZYOS may be reauthorized for 1 year if LVEF > 50% and member's clinical status is stable or improved.	Initial: 6 months Continued: One year

Drug Product(s)	Criteria	PA Approval Length
CERDELGA (eliglustat)	**Cerdelga** (eliglustat) may be approved if all of the following criteria are met: • Member has a diagnosis of Gaucher disease type 1 **AND** • Documentation has been provided to the Department that the member is a CYP2D6 extensive, intermediate, or poor metabolizer as detected by an FDA cleared test **AND** • Members who are CYP2D6 intermediate or poor metabolizers are not taking a strong CYP3A inhibitor (e.g, indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole, itraconazole, ketoconazole, nefazodone) **AND** • Members who are CYP2D6 extensive or intermediate metabolizers are not receiving strong or moderate CYP2D6 inhibitors (e.g, sertraline, duloxetine, quinidine, paroxetine, fluoxetine, buproprion, terbinafine) **AND** a strong or moderate CYP3A inhibitor (e.g, indinavir, nelfinavir, ritonavir, saquinavir, suboxone, erythromycin, clarithromycin, telithromycin, posaconazole, itraconazole, ketoconazole, fluconazole, nefazodone, verapamil, diltiazem) Quantity Limits: Max 60 tablets/30 days	One year
CHLOROQUINE	Effective 05/16/2023, prior authorization is no longer required for chloroquine.	N/A
CLIENT OVERUTILIZATION PROGRAM (COUP)	Effective 9/14/19, pharmacy claims for members enrolled in Health First Colorado's COUP (Client Overutilization Program) program may deny for these members when filling prescriptions at a pharmacy that is not their designated COUP lock-in pharmacy or filling a medication prescribed by a provider that is not their designated COUP lock-in prescriber. Health First Colorado Reginal Accountable Entity (RAE) organizations work with members enrolled in COUP to assist with coordinating care and improving services provided to these members. Members and providers should contact the member's RAE organization for questions regarding the COUP program.* Contact information for Health First Colorado RAE regions can be found at https://www.colorado.gov/pacific/hcpf/accphase2. Additional information regarding the COUP program and enrollment criteria can be accessed at https://www.colorado.gov/pacific/hcpf/client-overutilization-program. **For questions regarding pharmacy claims denials that are unable to be addressed during normal RAE organizational business hours (M-F 8:00 AM – 4:00 PM Mountain Standard Time), members and providers may contact the Prime Therapeutics Helpdesk at 1-800-424-5725.*	
COUGH AND COLD (Prescription Products)	Prescription cough and cold medications may be approved if meeting the following criteria: • For members < 21 years of age, no prior authorization is required OR for members ≥ 21 years of age, prior authorization may be approved with diagnosis of a chronic condition (such as COPD or asthma) AND • For members with dual Medicare eligibility, pharmacy claims for prescription cough and cold medications prescribed for chronic conditions should be billed to Medicare. Prescription cough and cold medications prescribed for dual Medicare eligible members for acute conditions are covered through the Health First Colorado pharmacy benefit with completion of prior authorization verifying use for acute illness.	One year

Drug Product(s)	Criteria	PA Approval Length
	Promethazine DM and Codeine/Hydrocodone-containing cough and cold liquid preparations are subject to meeting the following* *(Effective 5/12/23)*: • Subject to meeting quantity limits for products listed below OR diagnosis and clinical rationale is provided supporting the need for use of the requested product at doses exceeding quantity limitation AND • For requests for codeine-containing preparations for members < 18 years of age: o Member is 12 years to 17 years of age AND o Member does not have obstructive sleep apnea or severe lung disease AND o Member is not pregnant or breastfeeding AND o Renal function is not impaired (GFR > 50 mL/min) AND o Member is not receiving strong inhibitors of CYP3A4 AND o Request meets one of the following: ▪ Member has trialed codeine or codeine-containing products in the past with no history of allergy or adverse drug reaction to codeine OR ▪ Member has not trialed codeine or codeine-containing products in the past and the prescriber acknowledges reading the following statement: "Approximately 1-2% of the population metabolizes codeine in a manner that exposes them to a much higher potential for toxicity. Another notable proportion of the population may not clinically respond to codeine. We ask that you please have close follow-up with members newly starting codeine and codeine-containing products to monitor for safety and efficacy." <u>Quantity Limits:</u> Guaifenesin and codeine syrup – 180 mL/30 days Promethazine and codeine syrup – 180 mL/30 days Promethazine and dextromethorphan syrup – 180 mL/30 days Promethazine, phenylephrine and codeine syrup – 180 mL/30 days Hydrocodone polistirex/chlorpheniramine polistirex ER suspension – 120 mL/30 days Hydrocodone bitartrate and homatropine methylbromide syrup - 180mL/30 days *Note: For OTC cough and cold product coverage, see "OTC Products" section.*	
CRYSVITA (burosumab)	**Crysvita** (burosumab) may be approved if the following criteria are met: • Crysvita (burosumab) is being administered by a healthcare professional in the member's home or in a long-term care facility AND • The member is ≥ 6 months of age and has a diagnosis of X-linked hypophosphatemia (XLH) OR the member is ≥ 2 years of age and has a diagnosis of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized AND • The member has an estimated GFR of ≥ 30 mL/min AND • The member is not taking an oral phosphate product and/or an active vitamin D analog (such as calcitriol, paricalcitol, doxercalciferol or calcifediol). . Maximum Dose: 180 mg every two weeks Quantity Limit: Six 30 mg/mL single dose vials per 14 days	One year
CUVRIOR	**Cuvrior** (trientine tetrahydrochloride) may be approved if the following criteria are met:	One year

Drug Product(s)	Criteria	PA Approval Length
(trientine tetrahydrochloride)	• Member is ≥ 18 years of age AND • Member has a diagnosis of stable Wilson's Disease meeting at least one of the following criteria: o Hepatic parenchymal copper content of ≥250 mcg/g dry weight o Presence of Kayser-Fleischer ring in cornea o Serum ceruloplasmin level <50 mg/L o Basal 24-hour urinary excretion of copper > 100 mcg (1.6 micromoles) o Genetic testing results indicating mutation in ATP7B gene AND • Requested product is being prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant specialist AND • Member has failed a three-month trial of penicillamine. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions AND • Member has failed a three-month trial of trientine. Failure is defined as a lack of efficacy, allergy, intolerable side effect or significant drug-drug interaction. Maximum dose: 3,000 mg/day Quantity limit: 300 tablets/30 days	
CYSTADROPS (cysteamine hydrochloride)	**Cystadrops** (cysteamine hydrochloride) may be approved if the following criteria are met: • The member has a diagnosis of corneal cystine crystal deposits associated with cystinosis, AND • Cystadrops (cysteamine hydrochloride) are being prescribed by a physician experienced in the management of cystinosis AND • The member has been counseled to store unopened bottles in the refrigerator in the original carton (avoid freezing) AND • The member has been counseled to store the bottle of Cystadrops (cysteamine hydrochloride) currently in use in the original carton, tightly closed and at room temperature AND • The member has been counseled that each bottle of Cystadrops (cysteamine hydrochloride) should be discarded 7 days after first opening, even if there is medication left in the bottle AND • The member has been counseled to remove soft contact lenses prior to use of Cystadrops (cysteamine hydrochloride) and wait at least 15 minutes to reinsert lenses after use Maximum Dose: 1 drop in each eye 4 times a day (8 drops total/day) Quantity Limit: Four 5 mL bottles per 28 days	One year
DARAPRIM (pyrimethamine)	**Daraprim** (pyrimethamine) may be approved if all the following criteria are met: • Member is being treated for toxoplasmic encephalitis or congenital toxoplasmosis or receiving prophylaxis for congenital toxoplasmosis AND • Daraprim is prescribed in conjunction with an infectious disease specialist AND • Member does not have megaloblastic anemia due to folate deficiency AND • For prophylaxis, member has experienced intolerance to prior treatment with trimethoprim-sulfamethoxazole (TMP-SMX) meeting one of the following: o Member has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate	8 weeks

Drug Product(s)	Criteria	PA Approval Length
	○ Member has evidence of life threatening-reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g. toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome) OR • Member is being treated for acute malaria due to susceptible strains of plasmodia AND • Member has tried and had an inadequate response or intolerant to two other malaria treatment regimens (such as but not limited to atovaquone/proguanil, Coartem, chloroquine, hydroxychloroquine, chloroquine plus Primaquine, quinine plus clindamycin, quinidine plus doxycycline) AND • Daraprim is prescribed in conjunction with an infectious disease specialist with travel/tropical medicine expertise AND • Member does not have megaloblastic anemia due to folate deficiency Note: The Center for Disease Control does not recommend Daraprim for the prevention or the treatment of malaria	
DARTISLA (glycopyrrolate)	**Dartisla** (glycopyrrolate) may be approved if the following criteria are met: • Member is ≥ 18 years of age AND • Member has a diagnosis of peptic ulcer disease AND • Member has been tested for *H. pylori* and received eradication therapy if appropriate, AND • Member has had an adequate trial of a generic glycopyrrolate tablet regimen at maximally tolerated recommended doses and has failed to achieve a clinically significant response AND • The requested medication will be used as an adjunct treatment with a proton pump inhibitor (or H2 antagonist) and not as monotherapy Initial approval: 6 months Reauthorization: Prescriber attests that the member has experienced positive clinical response to therapy Maximum dose: 6.8 mg/day Quantity limit: 120 orally disintegrating tablets/30 days	Initial Approval: 6 months Continuation Approval: One year
DAYBUE (trofinetide)	**Daybue** (trofinetide) may be approved if the following criteria are met: • Member is ≥ 2 years of age AND • Member has been diagnosed with Rett syndrome with a documented mutation in the MECP2 gene AND • Member does not have moderate to severe renal impairment AND • Requested medication is being prescribed by or in consultation with a neurologist or developmental pediatrician AND • Member or parent/caregiver has been counseled regarding the potential risks of diarrhea and dehydration associated with trofinetide therapy and to avoid pre-treatment laxative use AND • Prescriber has performed baseline symptom assessment AND • Based on limited available clinical evidence for the use of trofinetide, the prescriber has engaged in shared decision making with the member/parent/caregiver prior to prescribing this medication.	Initial Approval: 3 months Continuation Approval: One year

<table>
<tr><th>Drug Product(s)</th><th>Criteria</th><th>PA Approval Length</th></tr>
<tr><td></td><td>
Initial approval: 3 months

Reauthorization: Reauthorization approval may be received for 1 year with provider attestation that:
• A follow-up symptom assessment has been performed, AND
• The member's clinical status is stable or improved and also free of persistent severe diarrhea, episodes of severe dehydration, or significant weight loss.

Quantity limit: four 450 mL bottles/14 days (1,800 mL/14 days)

Dosing limitations:

<table>
<tr><th>Weight</th><th>Dosage</th><th>Volume</th></tr>
<tr><td>9 kg to less than 12 kg</td><td>5,000 mg twice daily</td><td>25 mL twice daily</td></tr>
<tr><td>12 kg to less than 20 kg</td><td>6,000 mg twice daily</td><td>30 mL twice daily</td></tr>
<tr><td>20 kg to less than 35 kg</td><td>8,000 mg twice daily</td><td>40 mL twice daily</td></tr>
<tr><td>35 kg to less than 50 kg</td><td>10,000 mg twice daily</td><td>50 mL twice daily</td></tr>
<tr><td>50 kg or more</td><td>12,000 mg twice daily</td><td>60 mL twice daily</td></tr>
</table>

Members currently stabilized on the requested medication may receive approval to continue treatment on that medication if the criteria for reauthorization are met.
</td><td></td></tr>
<tr><td>DESI DRUGS</td><td>DESI drugs (Drugs designated by the Food and Drug Administration as Less Than Effective Drug Efficacy Study Implementation medications) are not a covered benefit.</td><td></td></tr>
<tr><td>DIFICID (fidoxomicin)</td><td>
Dificid (fidoxomicin) may be approved if all the following criteria are met:
• Member is age ≥ 6 months AND
• Member has a documented diagnosis (including any applicable labs and/or tests) for Clostridium difficile-associated diarrhea AND
• Prescribed by or in conjunction with a gastroenterologist or an infectious disease specialist AND
• Member has failed at least a 10 day treatment course of oral vancomycin. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction.

Maximum quantity:
20 tablets per 30 days
136 mL per 10 days
</td><td>1 month</td></tr>
<tr><td>DOJOLVI (triheptanoin)</td><td>
Dojolvi (triheptanoin) may be approved if the following criteria are met:

• Member has a molecularly-confirmed diagnosis of long-chain fatty acid oxidation disorder (LC-FAOD) AND
• The requested drug is being prescribed by an endocrinologist, geneticist, metabolic physician, medical nutrition physician, or LC-FAOD expert, AND
• Member is experiencing symptoms of deficiency exhibited by the presence of at least one of the following:
  ○ Severe neonatal hypoglycemia
  ○ Hepatomegaly
</td><td>One year</td></tr>
</table>

Drug Product(s)	Criteria	PA Approval Length
	○ Cardiomyopathy ○ Exercise intolerance ○ Frequent episodes of myalgia ○ Recurrent rhabdomyolysis induced by exercise, fasting or illness **AND** • Member is not currently taking a pancreatic lipase inhibitor (such as orlistat) AND • Member does not have a diagnosis of pancreatic insufficiency AND • The requested drug will not be administered through a feeding tube made of PVC.	
DOPTELET (avatrombopag)	**Doptelet** (avatrombopag) prior authorization may be approved for members meeting the following criteria: • Member is 18 years of age or older AND • Member has a confirmed diagnosis of thrombocytopenia with chronic liver disease who is scheduled to undergo an elective procedure AND • Member has trial and failure of Mulpleta (lusutrombopag). Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions. • Quantity Limit: 5 day supply per procedure OR • Member is 18 years of age or older AND • Member has a documented diagnosis of chronic immune thrombocytopenia AND • Member has trial and failure of Promacta (eltrombopag). Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions. • Quantity Limit: 40mg daily	One year
DOXEPIN TOPICAL PRODUCTS	**Prudoxin** and generic doxepin 5% cream may be approved if the member meets the following criteria: • Member is 18 years of age or older AND • Member has a diagnosis of moderate pruritis with atopic dermatitis or lichen simplex chronicus AND • Member has trial and failure‡ of one prescription-strength topical corticosteroid AND one topical immunomodulator product (see PDL for preferred products) **Zonalon** may be approved if member has trial and failed‡ either doxepin 5% cream or Prudoxin® and meets all of the following criteria. • Member has a diagnosis of moderate pruritis with atopic dermatitis or lichen simplex chronicus AND • Member has trial and failure‡ of one prescription-strength topical corticosteroid AND one topical immunomodulator product (see PDL for preferred products) <u>Quantity Limit for Topical Doxepin Products:</u> 8 day supply per 30-day period	One year

Drug Product(s)	Criteria	PA Approval Length
	‡Failure is defined as: lack of efficacy of a three-month trial, allergy, intolerable side effects or significant drug-drug interaction.	
DUVYZAT (givinostat)	**Duvyzat** (givinostat) may be approved if the following criteria are met: • Member is ≥ 6 years of age AND • Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) and is ambulatory AND • Member is on a stable dose of corticosteroids AND • Requested medication is being prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (such as a cardiologist, pulmonologist, or physical medicine and rehabilitation physician) AND • Prescriber confirms that prior to initiating Duvyzat (givinostat) therapy, ambulatory function has been assessed and documented based on the 4-step Climb Test (4SC) or similar motor function test used for DMD AND • Prescriber confirms that a baseline triglyceride level has been drawn prior to initiation of Duvyzat (givinostat) and that triglycerides will be monitored at 1 month, 3 months, 6 months, and then every 6 months thereafter following initiation of therapy AND • Prescriber confirms that a baseline platelet count of >150 x 109/L has been confirmed prior to initiation of Duvyzat (givinostat) and that blood counts will be monitored every 2 weeks for the first 2 months of treatment, then monthly for the first 3 months, and every 3 months thereafter AND • Prescriber confirms that a baseline ECG has been performed if member has underlying cardiac disease OR if member is taking concurrently taking medication(s) that cause QT prolongation AND • Prescriber acknowledges that Duvyzat (givinostat) should be discontinued if the following clinical situations arise: o Hematological abnormalities worsen despite Duvyzat (givinostat) dose modification(s) per product labeling OR o Triglycerides remain elevated despite adequate dietary intervention and Duvyzat (givinostat) dose modification(s) per product labeling OR o Moderate or severe diarrhea persists despite Duvyzat (givinostat) dose modification(s) per product labeling OR o QTc interval is > 500 ms OR the QTc change from pre-treatment baseline is > 60 ms Maximum Dose: 53.2 mg (6 mL) twice daily Initial Approval: 6 months Reauthorization: The member may receive approval for one year for continuation of therapy if the following criteria are met: • Member has shown no clinically significant or intolerable adverse effects related to Duvyzat (givinostat) treatment AND • Member demonstrates response to Duvyzat (givinostat) treatment with clinical improvement in trajectory from the baseline assessment in ambulatory function conducted prior to initiation of Duvyzat (givinostat) therapy (see bullet point 5 of the initial authorization criteria).	Initial: 6 months Continued: One year
EGRIFTA (tesamorelin acetate)	**Egrifta** or **Egrifta SV** will be approved if all the following criteria is met:	6 months

Drug Product(s)	Criteria	PA Approval Length

	• Must be prescribed in consultation with a physician who specializes in HIV/AIDS AND
	• Member is 18 years of age or older AND
	• Member has a diagnosis of HIV-related lipodystrophy with excess abdominal fat meeting the following criteria:
	  o Male member must have a waist circumference of at least 95cm (37.4in) and a waist to hip ratio of at least 0.94 OR
	  o Female member must have a waist circumference of at least 94cm (37in) and a waist to hip ratio of at least 0.88 AND
	  o Baseline waist circumference and waist to hip ratio must be provided
	• Member is currently receiving highly active antiretroviral therapy including protease inhibitors, nucleoside reverse transcriptase inhibitor, or non-nucleoside reverse transcriptase inhibitors AND
	• Member does not have a diagnosis of hypophysectomy, hypopituitarism, pituitary surgery, head irradiation or head trauma AND
	• Member does not have any active malignancy or history of malignancy AND
	• For women of childbearing potential, member must have a negative pregnancy test within one month of therapy initiation	

ELESTRIN GEL (estradiol)	A prior authorization will only be approved if a member has tried and failed on generic oral estradiol therapy and diagnosed with moderate-to-severe vasomotor symptoms (hot flashes) associated with menopause. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year
ELFABRIO (pegunigalsidase alfa)	**Elfabrio** (pegunigalsidase alfa) may be approved if the following criteria are met: • For billing under the pharmacy benefit, medication is being administered in the member's home or in a long-term care facility (LTCF) by a healthcare professional AND • Member is ≥ 18 years of age AND • Member has a confirmed diagnosis of Fabry disease AND • The medication is being prescribed by or in consultation with a neurologist or metabolic disease provider AND • Member has an eGFR ≥ 30 mL/min AND • Member has been counseled regarding use of highly effective contraceptive method(s) while receiving treatment. Maximum dose: 1 mg/kg every two weeks, based on actual body weight	One year
EMFLAZA (deflazacort)	**Emflaza** (deflazacort) may be approved if all the following criteria are met: • Member is at least 2 years of age or older AND • Member has diagnosis of Duchenne muscular dystrophy and a documented mutation in the dystrophin gene AND • Member must have documented (per claims history or provider notes) adequate trial and/or failure to prednisone therapy, adequate trial duration is at least three month. (Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions) AND • The medication is prescribed by or in consultation with a physician who specializes in the treatment of Duchenne muscular dystrophy and/or neuromuscular disorders. AND • Serum creatinine kinase activity at least 10 times the upper limit of normal at some stage in their illness AND • Absence of active infection including tuberculosis and hepatitis B virus	One year

Drug Product(s)	Criteria	PA Approval Length
	Maximum dose: 0.9mg/kg daily for tablets and suspension (may be rounded up to nearest ml)	
EMPAVELI (pegcetacoplan)	**Empaveli** (pegcetacoplan) may be approved if all of the following criteria are met: • Member is 18 years of age or older AND • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional OR the member has received proper training for administration of subcutaneous infusion AND • Member is not pregnant AND • Member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by high-sensitivity flow cytometry AND • Member has received vaccination against encapsulated bacteria (such as *Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae* type b) at least 2 weeks prior to initiation of Empaveli therapy, unless treatment cannot be delayed OR if the vaccines were administered within the last 2 weeks, member has received 2 weeks of antibacterial drug prophylaxis AND • Member does not have any active infections caused by encapsulated bacteria (such as *Streptococcus pneumoniae*, *Neisseria meningitidis* types A, C, W, Y, and B, and *Haemophilus influenzae* type b) AND • Member has a baseline lactate dehydrogenase result available and is being monitored by prescriber AND • Empaveli is not being used in combination with Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), or other medications to treat PNH (with exception of combination used during interval for switching between products) AND • Empaveli is being prescribed by, or in consultation with, a hematologist, immunologist, or nephrologist AND • Prescriber is enrolled in the Empaveli Risk Evaluation and Mitigation Strategy (REMS) program. Maximum dose: 1,080 mg (1 single-dose vial) every three days	One year
EMVERM (mebendazole)	**Emverm** (mebendazole) will be approved for members that meet the following criteria: • Member is 2 years or older AND • Member has a diagnosis of one of the following: Ancylostoma duodenale or Necator americanus (hookworm), Ascariasis (roundworm), Enterobiasis (pinworm), or Trichuriasis (whipworm) AND • Member has failed a trial of albendazole for FDA approved indication and duration (Table 1) (Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) AND • For diagnoses other than pinworm, Emverm is being prescribed by an infectious disease specialist AND • Female members have a negative pregnancy test AND • Emverm® Is being prescribed in accordance to FDA dosing and duration (Table 1) Quantity limits: Based on indication (Table 1)	See Table

<table>
<tr><th>Drug Product(s)</th><th>Criteria</th><th>PA Approval Length</th></tr>
<tr><td></td><td>
Table 1: Emverm FDA Approved Dosing and Duration in Adults and Children
<table>
<tr><th>Diagnosis</th><th>Dose</th><th>Duration</th><th>Quantity Limits</th></tr>
<tr><td>Ancylostoma duodenale or Necator americanus (hookworm)</td><td>100 mg twice daily</td><td>3 consecutive days, may be repeated in 3 weeks in needed.</td><td>6 tablets/member</td></tr>
<tr><td>Ascariasis (roundworm)</td><td>100 mg twice daily</td><td>3 consecutive days, may be repeated in 3 weeks if needed.</td><td>6 tablets/member</td></tr>
<tr><td>Enterobiasis (pinworm)</td><td>100 mg once</td><td>May give second dose in three weeks if needed.</td><td>2 tablets/member</td></tr>
<tr><td>Trichuriasis (whipworm)</td><td>100 mg twice daily</td><td>3 consecutive days, may be repeated in 3 weeks in needed.</td><td>6 tablets/member</td></tr>
</table>
</td><td></td></tr>
<tr><td>ENSPRYNG (satralizumab-mwge)</td><td>
Enspryng (satralizumab-mwge) may be approved if meeting the following criteria:
• Member is an adult (≥ 18 years of age) AND
• Member has a documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) that includes a positive serologic test for anti-aquaporin-4 (AQP4) antibodies AND
• Member has a past medical history of <u>at least one</u> of the following:
  o Optic neuritis
  o Acute myelitis
  o Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting
  o Acute brainstem syndrome
  o Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
  o Symptomatic cerebral syndrome with NMOSD-typical brain lesions
AND
• Member does not have any active infections, including localized infections AND
• Member does not have active Hepatitis B infection, as confirmed by negative surface antigen [HBsAg] and anti-HBV tests AND
• Member does not have active or untreated latent tuberculosis AND
• Provider confirms that member has a baseline Liver Function Panel drawn prior to initiation of ENGSPYNG treatment and member does not has an AST or ALT level greater than 1.5 times the upper limit of normal AND
• Provider confirms that neutrophil counts will be checked 4 to 8 weeks after initiation of ENSPRYNG therapy, and thereafter at regular clinically determined intervals to monitor for decreased neutrophil counts AND
• Provider has screened for immunizations the member is due to receive according to immunization guidelines AND
• Any live or live-attenuated vaccines will be administered at least 4 weeks prior to initiation of ENSPRYNG AND
</td><td>Initial:
6 months

Continued:
One year</td></tr>
</table>

Drug Product(s)	Criteria	PA Approval Length
	• Any non-live vaccines will be administered at least 2 weeks prior to initiation of ENSPRYNG (whenever possible) **AND** • ENSPRYNG is prescribed by or in conjunction with a neurologist. Reauthorization: After receiving initial six month approval, EYNSPRYNG (satralizumab-mwge) may be approved for one year if the following criteria: • Member has shown no adverse effects to ENGSPYNG treatment at a maintenance dose of 120 mg subcutaneously every 4 weeks **AND** • Member does not have any active infections (including localized infections) **AND** • Member does not have an AST or ALT level greater than 1.5 times the upper limit of normal **AND** • Provider confirms that neutrophil counts are currently within normal limits and will continue to be monitored at clinically determined intervals during ENSPRYNG therapy. Maximum dose: 120 mg subcutaneously every 2 weeks for three doses, followed by 120 mg subcutaneously every 4 weeks maintenance dose.	
EOHILIA (budesonide)	**Eohilia** (budesonide) oral suspension may be approved if the following criteria are met: • Member is ≥ 11 years of age AND • Member has a documented diagnosis of eosinophilic esophagitis (EoE), AND • Member is following appropriate dietary therapy interventions AND • Medication is being prescribed by or in consultation with a gastroenterologist, allergist or immunologist AND • Because the use of corticosteroids may cause a reduction of growth velocity, the growth of pediatric patients who are taking Eohilia (budesonide) will be monitored AND • Member (or parent/caregiver) has been counseled regarding the following: o Eohilia (budesonide) should not be given along with food or liquid AND o The member should not eat or drink for at least 30 minutes after each dose AND o After each dose, to rinse mouth with water and spit out contents without swallowing AND o To avoid consumption of grapefruit juice for the duration of therapy. Maximum dose: 4 mg (20 mL)/day Maximum quantity: 60 unit-dose packets/30 days Approval will be limited to one 12-week treatment course per year	One year (one 12-week treatment course)
ERECTILE DYSFUNCTION OR SEXUAL DYSFUNCTION PRODUCTS	Medications prescribed for use for erectile dysfunction or other sexual dysfunction diagnoses are not covered (these medications may be eligible for approval only when prescribed for other FDA-labeled or medically accepted indications). **Yohimbine** prior authorization may be approved for use as a mydriatic agent or a vasodilator (not related to erectile dysfunction). Prior authorizations for use of yohimbine for erectile dysfunction will not be approved.	See criteria Do not qualify for emergency

Drug Product(s)	Criteria	PA Approval Length
Caverject, Cialis, Edex, Imvexxy, Levitra, Muse, Viagra, Addyi, Osphena, Premarin Cream, Sildenafil, Tadalafil (generic Cialis), Staxyn, Stendra, Xiaflex, Yohimbine	**Sildenafil** prior authorization may be approved for off-label use for Raynaud's disease.	3 day supply
ESBRIET (pirenidone)	**Esbriet** (pirenidone) may be approved if the following criteria are met: • Member has been diagnosed with idiopathic pulmonary fibrosis AND • Is being prescribed by or in conjunction with a pulmonologist AND • Member is 18 years or older AND • Member has baseline ALT, AST, and bilirubin prior to starting therapy AND • Member does not have severe (Child Pugh C) hepatic impairment, severe renal impairment (Crcl<30 ml/min), or end stage renal disease requiring dialysis AND • Female members of reproductive potential must have been counseled regarding risk to the fetus AND • Member is not receiving a strong CYP1A2 inducer (e.g, carbamazepine, phenytoin, rifampin)	One year
EVRYSDI (risdiplam)	**Evrysdi** (risdiplam) may be approved if the following criteria are met: • Member has documented diagnosis of 5q-autosomal recessive spinal muscular atrophy (SMA) by genetic testing and SMN1 mutation (two or more SMN2 gene copies must be specified) **AND** • Treating and prescribing provider(s) is a neurologist or pediatrician experienced in treatment of SMA **AND** • The prescriber attests that the member will be assessed by <u>at least one</u> of the following exam scales at baseline and during subsequent office visits: o Hammersmith Infant Neurological Examination Module 2 (HINE2) o Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) o Hammersmith Functional Motor Scale Expanded (HFMSE) o Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III) o Motor Function Measure (MFM-32) o Revised Upper Limb Module (RULM) **AND** • Prior to the start of EVRYSDI treatment, the provider attests that the member meets all of the following: o Female members of childbearing potential have a documented negative pregnancy test within 2 weeks of initiating EVRYSDI therapy **AND** o Female members of childbearing potential have been instructed to use effective contraception during treatment with EVRYSDI and for at least 1 month after discontinuing treatment **AND** o Male members have been advised prior to initiation of therapy that their fertility may be compromised while being treated with EVRYSDI **AND** o Baseline liver function panel has been drawn and does not indicate hepatic impairment (EVRYSDI is extensively metabolized by the liver) **AND**	15 months

<table>
<tr><th>Drug Product(s)</th><th>Criteria</th><th>PA Approval Length</th></tr>
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Drug-drug interactions including (but not limited to) MATE substrates such as metformin, cimetidine, and acyclovir, have been screened for, addressed if needed, and will be continually monitored

AND

The following criteria are met:

The member is not on a treatment plan that includes concomitant or previous treatment with ZOLGENSMA (onasemnogene abeparvovec-xioi) AND
The member is not receiving concomitant treatment with SPINRAZA (nusinersen) OR the member was treated with SPINRAZA previously and had to discontinue use due to lack of efficacy, allergy, intolerable side effects, or a contraindication to receiving intrathecal injections AND
The member’s weight is provided and meets recommended daily dosing:

<table>
<tr><th>Age and Body Weight</th><th>Recommended Daily Dosage</th></tr>
<tr><td>2 months to less than 2 years of age</td><td>0.2 mg/kg</td></tr>
<tr><td>2 years and older, weighing less than 20 kg</td><td>0.25 mg/kg</td></tr>
<tr><td>2 years and older, weighing 20 kg or more</td><td>5 mg</td></tr>
</table>
Reauthorization criteria: After 15 months, members may receive approval to continue therapy if the following criteria are met:

The member has shown no adverse events to EVRYSDI treatment AND
The member has demonstrated response to treatment by showing significant clinical improvement or no decline documented using quantitative scores using the same exam scale(s) used prior to initiating EVRYSDI treatment (please see number 4 of initial authorization criteria). Improvement of SMA-related symptoms must be compared to the baseline assessment and motor function must be measured against the degenerative effects of SMA AND
The prescriber provides the following information:

A brief explanation, including the provider name, must be submitted if a provider other than the one who initially performed the motor exam completes any follow-up exam(s) AND
A brief explanation must be submitted if an exam scale other than the scale used for initial authorization is used for reassessment AND
The member does not have hepatic impairment AND
Member weight is provided and meets recommended daily dosing:

<table>
<tr><th>Age and Body Weight</th><th>Recommended Daily Dosage</th></tr>
<tr><td>2 months to less than 2 years of age</td><td>0.2 mg/kg</td></tr>
<tr><td>2 years and older, weighing less than 20 kg</td><td>0.25 mg/kg</td></tr>
<tr><td>2 years and older, weighing 20 kg or more</td><td>5 mg</td></tr>
</table>
Maximum dose: 5mg/day
</td><td></td></tr>
</table>

Drug Product(s)	Criteria	PA Approval Length
	Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.	
EXJADE (deferasirox)	Please see "Jadenu and Exjade"	
EXONDYS 51 (eteplirsen)	**Exondys 51** (eteplirsen) may be approved if the following criteria are met: • For billing under the pharmacy benefit, medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member must have genetic testing confirming mutation of the Duchenne Muscular Dystrophy (DMD) gene that is amenable to exon 51 skipping AND • Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e. neurologist, cardiologist, pulmonologist, or physical medicine and rehabilitation physician) AND • The member must be on corticosteroids at baseline or has a contraindication to corticosteroids AND • If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity (FVC) of 30% or more. Reauthorization: Provider attests that treatment with Exondys 51 (eteplirsen) is necessary to help member improve or maintain functional capacity based on assessment of trajectory from baseline for ambulatory or upper extremity function or Forced Vital Capacity (FVC). Maximum Dose: 30 mg/kg per week *(documentation of patient's current weight with the date the weight was obtained*) *Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.*	Initial: One year Continued: One year
EXTENCILLINE (benzathine benzylpenicillin)	Effective 5/9/24, the FDA-authorized imported drug due to shortage, Extencilline (benzathine benzylpenicillin), is eligible for coverage for Health First Colorado members. Claims submitted under the pharmacy benefit are eligible for coverage when administered by a healthcare professional in the member's home or in a long-term care facility.	.
FABHALTA (iptacopan)	**Fabhalta** (iptacopan) may be approved if the following criteria are met: • Member is ≥18 years of age AND • Member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by high-sensitivity flow cytometry AND • Member has an eGFR ≥30 mL/min AND • Member does not have severe hepatic disease (Child-Pugh Class C) AND • Member does not have any active infections caused by an encapsulated bacteria (such as Streptococcus pneumoniae and Neisseria meningitidis) AND • Member has received vaccination against encapsulated bacteria (such as Streptococcus pneumoniae and Neisseria meningitidis) at least 2 weeks prior to initiation of Fabhalta (iptacopan) therapy. If urgent iptacopan therapy is indicated in a patient who is not up to date with vaccines, or the vaccines were administered within the last 2 weeks, prescriber attests that the member will	Initial: 6 months Continued: One year

Drug Product(s)	Criteria	PA Approval Length
	receive appropriate antibacterial drug prophylaxis and the vaccines will be administered as soon as possible AND • Requested product is being prescribed by or in consultation with a hematologist, immunologist or nephrologist AND • Member has residual anemia (hemoglobin < 10 g/dL) at baseline AND • Fabhalta (iptacopan) is not being used in combination with an anti-C5 complement inhibitor that is used to treat PNH AND • Member's medication profile does not indicate any clinically significant interactions with CYP2C8 inducers (such as rifampin, phenobarbital, phenytoin) or strong CYP2C8 inhibitors (such as gemfibrozil, clopidogrel, fluticasone) AND • Prescriber is enrolled in the Fabhalta Risk Evaluation and Mitigation Strategy (REMS) program. Quantity limit: 60 capsules/30 days Maximum dose: 400 mg/day <u>Reauthorization</u>: Reauthorization may be approved for 1 year with prescriber attestation that member's hemoglobin has increased by ≥2 g/dL from baseline while on Fabhalta (iptacopan) therapy.	
FERRIPROX (deferiprone)	**Ferriprox** (deferiprone) may be approved if the following criteria are met: • Must be prescribed in conjunction with a hematologist or oncologist AND • Member's weight must be provided AND • Ferriprox (deferiprone) is being prescribed for one of the following indications: o Treatment of transfusion-related iron overload in patients with thalassemia syndromes OR o Treatment of transfusion-related iron overload in patients with sickle cell disease or other anemias AND • Member has an absolute neutrophil count > 1.5 x 109 AND • Member has failed or has had an inadequate response to Desferal (deferoxamine) AND Exjade (deferasirox) as defined by serum ferritin >2,500mcg/L before treatment with Ferriprox OR member has been intolerant to or experienced clinically significant adverse effects to Desferal (deferoxamine) or Exjade (deferasirox) such as evidence of cardiac iron overload or iron-induced cardiac dysfunction. Maximum dose: 99mg/kg/day	One year
FILSPARI (sparsentan)	**Filspari** (sparsentan) may be approved if the following criteria are met: • Member is ≥ 18 years of age AND • Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) and is at risk of rapid disease progression, AND • Member has a urine protein-to-creatinine ratio of ≥1.5 g/g AND • Member is not pregnant AND • Member does not have heart failure AND	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member has tried and failed† maximally tolerated dose of an immunosuppressant (such as corticosteroids, mycophenolate, tacrolimus, cyclosporine, leflunomide, cyclophosphamide, and azathioprine) AND • Member has tried and failed† maximally tolerated doses of an ACE inhibitor, angiotensin receptor blocker (ARB) or angiotensin receptor/neprilysin inhibitor (ARNI) AND • Member is not concurrently taking any of the following medications: o ACE inhibitor o Angiotensin receptor blocker (ARB) o Endothelin receptor antagonist (such as ambrisentan, atrasentan, bosentan) o Direct renin inhibitor (such as aliskiren) o Angiotensin receptor/neprilysin inhibitor (ARNI) AND • Provider attests that member's medication profile has been reviewed for drug interactions between Filspari (sparsentan) and strong/moderate CYP3A inhibitors, strong CYP3A inducers, CYP2B6 substrates, and other agents that may result in clinically significant interacting drugs, according to product labeling AND • Prior to initiation of Filspari (sparsentan) therapy, the member's hepatic aminotransferases (ALT, AST) are not greater than 3 times the upper limit of normal AND • Requested medication is being prescribed by or in consultation with a nephrologist or immunologist AND • Provider and patient or caregiver are aware that continued US FDA approval of Filspari (sparsentan) to slow kidney function decline in patients with IgAN may be contingent upon verification and description of clinical benefit in confirmatory trial(s). † Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Maximum dose: 400 mg daily Quantity limits: 200mg: 14-day supply per fill maximum 400mg: 30 tablets per 30 days Continuation of Therapy: Members who are currently stabilized on the requested medication may receive approval to continue treatment on that medication	
FILSUVEZ (birch triterpenes)	**Filsuvez** (birch triterpenes) may be approved if the following criteria are met: • Member is ≥ 6 months of age, AND • Member must have undergone testing confirming one of the following diagnoses and genetic mutations: o Dystrophic epidermolysis bullosa (DEB), based on mutation(s) in the collagen type VII alpha 1 chain (*COL7A1*) gene OR o Junctional epidermolysis bullosa (JEB), based on mutation(s) in the collagen type XVII gene (*COL17A1*), laminin 332 genes (*LAMA3, LAMB3 and LAMC2*), integrin α6β4 genes (*ITGA6 and ITGB4*) or the integrin α3 subunit (*IGTA3*) AND	See criteria

Drug Product(s)	Criteria	PA Approval Length
	• The requested medication is being prescribed by or in consultation with a provider who has expertise in treating epidermolysis bullosa. Initial approval: Approval will be limited to one 90-day treatment course per one year. Reauthorization: Reauthorization requests for an additional treatment course of Filsuvez (birch triterpenes) will undergo clinical review by a call center pharmacist on a case-by-case basis and require provider submission of clinical information (such as documentation from medical chart notes) demonstrating re-epithelialization without drainage or complete closure of the treated wounds(s) has been observed during the prior treatment course with Filsuvez. Claims limitation: 15-day supply per fill, up to one tube daily	
FIRDAPSE (amifampridine)	**Firdapse** (amifampridine) may be approved for members meeting the following criteria: • Member is an adult ≥ 18 years of age AND • Member has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) Maximum Dose: 80mg daily	One year
FLUORIDE PRODUCTS	Prescription fluoride products: • Prescription fluoride products will be approved for members less than 21 years of age without a prior authorization. • For members 21 years of age or older approval will be granted if using well water or living in an under-fluoridated area designated by the CDC*. • Approval for members not meeting these criteria will require a letter of necessity and will be individually reviewed. OTC fluoride products: • The following OTC fluoride products are eligible for prior authorization approval for all members using well water or living in an under-fluoridated area designated by the CDC*: fluoride chewable tablets, ludent fluoride chewable tablets, sodium fluoride 0.5mg/mL drops • Approval for members not meeting these criteria will require a letter of necessity and will be individually reviewed. *Information and reports regarding water fluoridation can be found on the CDC website at: https://nccd.cdc.gov/DOH_MWF/Default/CountyList.aspx?state=Coloradateid=8&stateabbr=CO&reportLevel=2.	One year

FUROSCIX (furosemide)	**Furoscix** (furosemide) on-body infusor may be approved if the following criteria are met:
	• Member is ≥ 18 years of age AND
	• Member has a documented diagnosis of NYHA Class II/III chronic heart failure AND
	• Member has tried and failed† at least one of the following oral therapies:
	  ○ furosemide ≥ 160 mg daily
	  ○ torsemide 40 mg daily
	  ○ bumetanide 4 mg daily
	AND
		One year

Drug Product(s)	Criteria	PA Approval Length
	• Member has tried and failed† the addition of oral metolazone to oral loop diuretic therapy AND • Prescriber confirms that the member has a history of at least one prior hospitalization or emergency department visit due to heart failure exacerbation and/or fluid overload AND • The requested medication is being prescribed by or in consultation with a cardiologist AND • Prescriber understands that the Furoscix (furosemide) is intended for short-term use in the outpatient setting AND • Provider attests that member will be educated on proper infusor placement on the body, instructions for starting the infusion, and safe disposal of the used infusor device. Quantity limit: 7 pre-filled 80 mg/10 mL cartridges plus infusors per 30 days †Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction	
FUZEON (enfuvirtide)	If administered in the physician's office or delivered to physician's office, physician must bill as a medical claim on the 1500 claim form **(no PA required).** If administered in the member's home or in a long-term care facility, a prior authorization is required and must meet the criteria below for approval. Based on clinical trial data, ENF should be used as part of an *optimized* background regimen for treatment-experienced members: • For treatment-experienced members with evidence of HIV-1 replication, treatment should include at least one antiretroviral agent with demonstrated HIV-1 susceptibility on the basis of genotypic/phenotypic *resistance* assays, and *two* "active" antiretroviral agents. o Members must have limited treatment options among currently commercially available agents. • Members must be 18 years of age or older with advanced HIV-1 infection, and not responding to approved antiretroviral therapy. • Members must have a CD4 lymphocyte count less than 100 cells/mm3 and a viral load greater than 10,000 copies/ml (measurement within the last 90 days). Past adherence must be demonstrated based on: • Attendance at scheduled appointments, and/or • Prior antiretroviral regimen adherence, and/or • Utilization data from pharmacy showing member's use of medications as prescribed • Ability to reconstitute and self-administer ENF therapy. At 24 weeks, members must experience at least ≥ 1 $\log_{10}$ decrease in HIV RNA or have HIV RNA below quantifiable limits to continue treatment with ENF. Members are not eligible if antiretroviral treatment-naive and/or infected with HIV-2. Pre-approval is necessary	Six months

Drug Product(s)	Criteria	PA Approval Length
	Practitioner must either be Board Certified in Infectious Disease, or be an HIV experienced practitioner. Verification must be produced with the prior approval documents. **These guidelines may be modified on the basis of other payer formularies and/or the emergence of new data.**	
GALAFOLD (migalastat hydrochloride)	**Galafold** (migalastat hydrochloride) prior authorization may be approved for members meeting the following criteria: ▪ Member is ≥ 12 years of age **AND** ▪ The medication is being prescribed by or in consultation with a neurologist **AND** ▪ Member has a confirmed diagnosis of Fabry's disease with an amenable galactose alpha gene (GLA) variant per in vitro assay data. (Amenable GLA variants are those determined by a clinical genetics professional as pathologic or likely pathologic) **AND** ▪ Member does not have severe renal impairment or end-stage renal disease requiring dialysis. Maximum dose: 123 mg once every other day	One year
GAMASTAN (immune globulin)	Prior authorization may be approved for FDA-labeled indication, dose, age, and role in therapy as outlined in package labeling.	One year
GATTEX (teduglutide)	**Gattex** (teduglitide) may be approved if all of the following criteria are met: • Member is one year of age or older AND • Member has documented short bowel syndrome AND • Member is dependent on parenteral nutrition/intravenous support for twelve consecutive months AND • The prescribing physician is a gastroenterologist AND • Medical necessity documentation has been received and approved by Colorado Medicaid clinical staff (please fax to 303-866-3590 attn: Clinical Pharmacy Staff) • The initial prior authorization will be limited to a two-month supply.	Two months initially; may be approved by State for up to one year
GENERIC MANDATE	<u>Brand Name Medications and Generic Mandate:</u> • Brand name drug products that have a therapeutically equivalent generic drug product (as determined by the FDA) will require prior authorization for brand product coverage and will be covered without a prior authorization if meeting one of the following exceptions: o The brand name drug is prescribed for the treatment of (and the prescriber has indicated dispense as written on the brand name prescription): ▪ Biologically based mental illness defined in 10-16-104 (5.5) C.R.S. ▪ Cancer ▪ Epilepsy ▪ HIV/AIDS o The Department has determined that the brand name product is lower cost than the therapeutically equivalent generic • Prior authorization for use of a brand name drug product that has a therapeutically equivalent generic (and does not meet exceptions above) may also be approved if: o The prescriber is of the opinion that a transition to the generic equivalent of the brand name drug would be unacceptably disruptive to the patient's stabilized drug regimen o The patient is started on the generic equivalent drug but is unable to continue treatment on the generic drug as determined by the prescriber	

Drug Product(s)	Criteria	PA Approval Length
GIMOTI (metoclopramide)	**Gimoti** (metoclopramide) may be approved for members meeting the following criteria: • Member is an adult (≥ 18 years of age) AND • Member has a confirmed diagnosis of acute or recurrent diabetic gastroparesis AND • Member has failed an adequate trial of metoclopramide solution. Failure is defined as allergy to inactive ingredients, inability to administer the solution through an enteral route (such as nasogastric or percutaneous endoscopic gastrostomy routes), or intolerable side effects AND • Member does not have a history of tardive dyskinesia AND • Member has not been diagnosed with a parkinsonian syndrome (such as Parkinson's disease, progressive supranuclear palsy, multiple system atrophy, or corticobasal degeneration) AND • Member does not have moderate to severe liver disease (Child Pugh B or C) AND • Member does not have moderate or severe renal impairment (creatinine clearance less than 60 mL/min) AND • Member is not a known poor metabolizer of CYP2D6, which may contribute to a higher potential for metoclopramide toxicity, including dystonias AND • For members ≥ 65 years of age, the following additional criteria are met: o Gimoti (metoclopramide) is not being prescribed as initial therapy for diabetic gastroparesis AND o Member has been stabilized on treatment with an oral metoclopramide dose of 10mg four times a day for at least 30 days prior to switching to Gimoti (metoclopramide) AND o Prescriber acknowledges that exceeding 12 weeks of <u>total</u> metoclopramide therapy (from all dosage forms and routes of administration) should be avoided in members who are ≥ 65 years of age due to risk of developing tardive dyskinesia. Maximum dose: One spray (15 mg) four times daily Duration limit (for members ≥ 65 years of age): Limited to 12-week supply per year	One year
GLYCATE (glycopyrollate)	**Glycate** (glycopyrollate) may be approved for members meeting the following criteria: • Member is 18 years of age or older AND • Member has a diagnosis of peptic ulcer disease AND • Member <u>does not</u> have any of the following conditions: o Glaucoma o Obstructive uropathy (such as bladder neck obstruction due to prostatic hypertrophy) o Obstructive disease of the gastrointestinal tract (such as achalasia, pyloroduodenal stenosis, etc.) o Paralytic ileus o Intestinal atony of the elderly or debilitated patient o Unstable cardiovascular status in acute hemorrhage o Severe ulcerative colitis o Toxic megacolon complicating ulcerative colitis o Myasthenia gravis AND	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member has tried and failed at least two proton pump inhibitors (failure is defined as lack of efficacy with 4 week trial, allergy, intolerable side effects, or significant drug-drug interaction) AND • Glycate (glycopyrollate) is being used as adjunctive therapy AND • Glycate (glycopyrollate) is being prescribed by or in consultation by a gastroenterologist	
HEMADY (dexamethasone)	**Hemady** (dexamethasone) may be approved for members meeting the following criteria: • Member is an adult (≥18 years of age) AND • Member has a confirmed diagnosis of multiple myeloma (MM) AND • Hemady (dexamethasone) is being prescribed in combination with other anti-myeloma treatment agents AND • Member does not have pheochromocytoma AND • Members of childbearing potential have been advised to use effective contraception during treatment and for at least one month after the last dose AND • Member has trialed and failed generic dexamethasone tablets. Failure is defined as allergy or intolerable side effects. Maximum dose: 40 mg/day	One year

HIGH COST CLAIMS	Effective 5/1/2023, pharmacy claims exceeding $9,999.00 require prior authorization and are subject to meeting the following per FDA product package labeling for approval with pharmacist review of requests:
	• Diagnosis/use for FDA-labeled indication AND
	• Based on prescribed indication, prescription meets the following per label:
	  ○ Dosing
	  ○ Strength
	  ○ Dosage form
	  ○ Quantity
	  ○ Days supply
	AND
	• If product is an IV formulation or product labeling indicates that the medication should be administered by a healthcare professional, must meet approval criteria for physician administered drugs (see "Physician Administered Drugs" section).
	
	The following drug categories are <u>not</u> subject (are exceptions) to the $9,999.00 claim limitation:
	• Products/drug classes listed on the Preferred Drug List (PDL)
	• Products/drug categories with PA criteria listed on the Appendix P
	• Oncology medications
	• Actimmune
	• Fabry disease treatments
	• Hemophilia treatments
	• Long-acting injectable antipsychotic medications
	• Medication-Assisted-Treatment (MAT) medications
	• Naloxone or Naltrexone
	• Medications used for the treatment or prevention of HIV	

Drug Product(s)	Criteria	PA Approval Length
Homozygous Familial Hypercholesterolemia (HoFH)	**Juxtapid** (lomitapide) may be approved if all of the following criteria are met: • Member is 18 years of age or older; • Member has documented diagnosis of homozygous familial hypercholesterolemia (HoFH); • Member has failed therapy with high dose statin therapy (e.g. atorvastatin 40mg or higher, Crestor 20mg or higher) • The prescribing physician is enrolled in the Juxtapid REMS program. **Kynamro** (mipomersen) may be approved for members meeting all of the following criteria: • Confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) as determined by either a or b a. Laboratory tests confirming diagnosis of HoFH: LDLR DNA Sequence Analysis OR LDLR Deletion/Duplication Analysis for large gene rearrangement testing---only if the Sequence Analysis is negative OR APOB and dPCSK9 testing if both of the above tests are negative but a strong clinical picture exists. b. Documentation is received confirming a clinical or laboratory diagnosis of HoFH • Has a history of therapeutic failure, contraindication, or intolerance to high dose statin therapy or cholesterol absorption inhibitor (ezetimibe or bile acid resin) AND • Is being prescribed by a physician specializing in metabolic lipid disorders AND • The prescriber is enrolled in the REMS program AND • Is not being used as monotherapy AND • Has baseline liver function (AST, ALT, ALK, and total bilirubin) AND • Does not have moderate or severe hepatic impairment or active liver disease.	One year
HORMONE THERAPY	**Depo Provera** (medroxyprogesterone) **intramuscular** injectable suspension may be approved if meeting the following criteria: • The requested medication is being administered by a healthcare professional in the member's home or in a long-term care facility (claims for medications administered in a clinic or medical office are billed through the Health First Colorado medical benefit) AND • Prescribed use is for FDA-labeled indications or indications supported by or included in certain compendia described in section 1927(g)(1)(B)(i) of the Social Security Act. **Depo Provera** (medroxyprogesterone) **subcutaneous** injectable suspension does not require prior authorization and pharmacy claims are eligible for 12-month supply coverage *(effective 07/01/22).* **Implanon (etonogestrel)** See PHYSICIAN ADMINISTERED DRUGS. Not a covered pharmacy benefit when implanted in the clinic or hospital outpatient center. **Nexplanon (etonogestrel)** See PHYSICIAN ADMINISTERED DRUGS. Not a covered pharmacy benefit when implanted in the clinic or hospital outpatient center.	One year
HYDROXYCHLOROQUINE	Effective 05/16/2023, prior authorization is no longer required for hydroxychloroquine.	

Drug Product(s)	Criteria	PA Approval Length

ILUMYA (tildrakizumab-asmn)	**Ilumya** (tildrakizumab-asmn) prior authorization may be approved for members meeting all of the following criteria:
	• Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND
	• Member is 18 years of age or older and has diagnosis of moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy AND
	• Member does not have guttate, erythrodermic, or pustular psoriasis AND
	• Provider attests to:
	  • Baseline Provider Global Assessment (PGA) score for plaque psoriasis severity of at least 3 (Scored 0-4, 4 being most severe) OR
	  • Baseline Psoriasis Area and Severity Index (PASI) score of 12 or greater
	AND
	• Medication is being prescribed by or in conjunction with a rheumatologist, allergist, or dermatologist AND
	• Member has tried and failed‡ ALL preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the same prescribed indication AND
	• Initial authorization will be for 12 weeks Continued authorization for 12 months will require prescriber attestation to PGA score reduction of 2 or more points OR PASI score reduction of 75% OR prescriber attestation to clinically meaningful improvement with Ilumya® regimen.
	
	Claims for medications administered in a clinic or medical office are billed through the Health First Colorado medical benefit.
		Initial: 12 weeks
		
		Continued: One year

IQIRVO (elabranor)	**Iqirvo** (elafibranor) may be approved if the following criteria are met:
	• Member is ≥ 18 years of age AND
	• Member has a diagnosis of primary biliary cholangitis and meets one of the following:
	  ○ Combined therapy: Requested medication will be used in combination with ursodiol (ursodeoxycholic acid) if the member had an inadequate response (lack of efficacy) following at least one year of treatment with ursodiol (ursodeoxycholic acid) alone OR
	  ○ Monotherapy: Requested medication will be used as monotherapy in members who have trialed and failed ursodiol (ursodeoxycholic acid) therapy. Failure is defined as allergy, intolerable side effects, or significant drug-drug interaction
	AND
	• Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND
	• Laboratory tests to evaluate ALT, AST, alkaline phosphatase and total bilirubin will be performed at baseline and during treatment with Iqirvo (elafibranor), according to product labeling AND
	• Prior to initiating therapy, the member does NOT have an elevated creatine phosphokinase (CPK) and/or signs/symptoms of muscle pain or myopathy, and prescriber attests that these parameters will be monitored throughout treatment with Iqirvo (elafibranor) AND
	• Member does not have complete biliary obstruction, cirrhosis, or other types of liver disease AND
		Initial: 6 months
		
		Continued: One year

Drug Product(s)	Criteria	PA Approval Length
	• Members without serologic evidence of immunity have received hepatitis A and hepatitis B vaccinations AND • Prescriber has considered the risk of fracture in members treated with Iqirvo (elafibranor) AND • Prescriber has counseled member to abstain from alcohol or avoid heavy alcohol use AND • Prescriber attests that a pre-treatment pregnancy test will be performed, and that members of reproductive potential will be advised to switch to effective non-hormonal contraceptives OR add a barrier method when using hormonal contraceptives and for at least 3 weeks after last dose of Iqirvo (elafibranor) AND • Prescriber attests that members of reproductive potential will be advised to avoid breastfeeding during treatment and for 3 weeks after last dose of Iqirvo (elafibranor) AND • Prescriber attests the member has been counseled that the approval and safety status of Iqirvo (elafibranor) is based on reduction of alkaline phosphatase. Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Maximum Dose: 80 mg/day Maximum Quantity: 30 tablets/30 days Initial Approval: 6 months Reauthorization: Member may receive approval for one year with provider attestation that a biochemical response (such as an alkaline phosphatase level less than 1.67-times the upper limit of normal) has been observed after 6 months of therapy.	

ISTURISA (osilodrostat)	**Isturisa** (osilodrostat) may be approved if the following criteria are met:
	
	• Member is ≥ 18 years of age AND
	• Member has a diagnosis of Cushing's disease AND
	• Pituitary surgery is not an option or the member had surgery and it was not curative AND
	• The requested drug is being prescribed by, or in consultation with, an endocrinologist AND
	• For initial dose titrations, one of the following are met:
	  ○ If the member has moderate hepatic impairment, the starting dose is 1 mg twice daily OR
	  ○ If the member has severe hepatic impairment, the starting dose is 1 mg once daily in the evening.
	
	Maximum Dose: 60 mg/day
		One year

IVERMECTIN	Effective 04/15/24, prior authorization is not required for ivermectin tablet.	
JESDUVROQ (daprodustat)	**Jesduvroq** (daprodustat) may be approved if meeting the following criteria: • Member is 18 years of age or older AND • Member has chronic kidney disease (CKD) and has been receiving dialysis for at least four months AND	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member is not taking a strong CYP2C8 inhibitor (such as gemfibrozil) AND • Member does not have uncontrolled hypertension, AND • Laboratory tests to evaluate ALT, AST, alkaline phosphatase, total bilirubin, hemoglobin and iron status will be performed at baseline and during treatment with Jesduvroq (daprodustat), according to product labeling, AND • The requested medication is not being prescribed as a substitute for red blood cell transfusions in patients who require immediate correction of anemia AND • The requested medication is not being prescribed for treatment of anemia of chronic kidney disease in patients who are not on dialysis AND • For members NOT being treated with an erythropoiesis stimulating agent (ESA), initial dosing will be based on the baseline hemoglobin level (g/dL) per product labeling AND • For members being switched from an ESA to Jesduvroq (daprodustat) therapy, the starting dose will be based on the dose of the ESA at the time of the switch. Maximum dose: 24 mg/day	
JADENU and EXJADE (deferasirox)	**Jadenu** (deferasirox) or **Exjade** (deferasirox) may be approved for members that meet the following criteria: • Must be prescribed in conjunction with a hematologist or oncologist AND • Member's weight must be provided AND • Member has a diagnosis for chronic iron overload due to blood transfusion AND • Member is 2 years of age or older AND • Member has consistently high serum ferritin levels > 1000 mcg/L (demonstrated by at least 2 values in the prior three months OR • Member has a diagnosis for chronic iron overload due to non-transfusion dependent thalassemia syndromes AND • Member is 10 years of age or older AND • Member has liver iron levels > 5 mg iron per gram of dry weight and serum ferritin levels > 300 mcg/L document in the prior three months Members must also meet the following additional criteria for all Jadenu and Exjade approvals: • Member does not have advanced malignancies and/or high-risk myelodysplastic syndromes AND • Member has a creatinine clearance > 40 ml/min AND • Member has a platelet count > 50 x 10^9/L Maximum Dosing: Maximum dose of Jadenu (deferasirox): 28mg/kg/day Maximum dose of Exjade (deferasirox): 40mg/kg/day	One year
JOENJA (leniolisib)	**Joenja** (leniolisib) may be approved if the following criteria are met: • Member is ≥ 12 years of age and weighs at least 45 kg AND • Member has been diagnosed with activated phosphoinositide 3-kinase delta (PI3K-delta) syndrome (APDS) with a documented variant in either PIK3CD or PIK3R1 AND	One year

Drug Product(s)	Criteria	PA Approval Length
	• Requested product is being prescribed by or in consultation with an immunologist AND • Member does not have moderate to severe hepatic impairment AND • Member is not pregnant AND • Member has not received a B-cell depleting medication within 6 months of starting leniolisib therapy AND • Member has not received an immunosuppressive medication or another PI3K-delta inhibitor within 6 weeks of starting leniolisib therapy AND • Members of reproductive potential have been advised to avoid breastfeeding and to use effective contraception during and after treatment with Joenja (leniolisib) in accordance with FDA product labeling. Maximum dose: 140 mg/day Quantity limit: 60 tablets/30 days	
JYNARQUE (tolvaptan)	**Jynarque** (tolvaptan) may be approved if the following criteria are met: • Member is an adult (≥ 18 years of age) AND • Member has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) and is at risk for rapid disease progression AND • Medication is being prescribed by a nephrologist AND • Member does not have a history or sign/symptoms of significant liver impairment or injury (uncomplicated polycystic liver disease is not a contraindication for therapy) AND • Member is not taking a strong Cytochrome 3A inhibitor (such as erythromycin, clarithromycin, telithromycin, itraconazole, ketoconazole, posaconazole, fluconazole, voriconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, conivaptan, delavirdine and milk thistle) AND • Member is not using desmopressin (dDAVP) AND • If member is taking a moderate Cytochrome 3A inhibitor (such as erythromycin, fluconazole, or verapamil) JYNARQUE (tolvaptan) will be prescribed at a reduced dose AND • Member has normal blood sodium concentrations, is able to sense or respond to thirst, and has a normal blood volume AND • Member does not have urinary outflow obstruction or anuria Maximum Dosing: 120mg per day	One year
KALYDECO (ivacaftor)	**Kalydeco** (ivacaftor) may be approved if all of the following criteria are met: • Member has been diagnosed with cystic fibrosis AND • Member is an adult or pediatric patient 1 month of age or older AND • Documentation has been provided to indicate one of the following gene mutation: in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, R117H, S549R or another FDA approved gene mutation.* AND • Documentation has been provided that baseline ALT and AST have been accessed and are within 2x normal limits (AST and ALT should be examined every 3 months for the first year and annually after that).	One year

Drug Product(s)	Criteria	PA Approval Length
	* If the member's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. The requested medication will only be approved at doses no more than 150 mg twice daily. Prior Authorizations need to be obtained yearly. The requested medication will not be approved for members who are concurrently receiving rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's Wort.	
KISUNLA (donanemab-azbt)	**Kisunla** (donanemab-azbt) may be approved if the member meets ALL the following criteria: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Member has documented diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease, the population in which treatment was initiated in clinical trials, as evidenced by ALL the following: o Positron Emission Tomography (PET) scan OR lumbar puncture positive for amyloid beta plaque o Mini-Mental State Examination (MMSE) score of 20-28 OR Montreal Cognitive Assessment (MoCA) Test score of 19-25 o Progressive change in memory function for at least 6 months AND • Member is 60 years of age or older AND • Medication is prescribed by or in consultation with a neurologist AND • Prior to initiation of medication, the prescriber attests that the member meets ALL the following: o Member has had a baseline brain MRI within the prior one year to treatment initiation, showing no signs or history of microhemorrhages and/or superficial siderosis o Attestation that MRI will be completed prior to the 2nd, 3rd, 4th, and 7th infusions o Member is negative for apolipoprotein E ε4 (ApoE ε4) homozygotes AND • Member does not have any of the following: o Any medical or neurological condition other than Alzheimer's Disease that might be a contributing cause of the subject's cognitive impairment including (but not limited to) stroke/vascular dementia, tumor, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD] or normal pressure hydrocephalus o Contraindications to PET, CT scan, or MRI o History of or increased risk of amyloid related imaging abnormalities ARIA-edema (ARIA-E) or ARIA-hemosiderin deposition (ARIA-H) o History of unstable angina, myocardial infarction, chronic heart failure, or clinically significant conduction abnormalities, stroke, transient ischemic attack (TIA), or unexplained loss of consciousness within 1 year prior to initiation of Kisunla (donanemab-azbt) o History of bleeding abnormalities or taking any form of anticoagulation therapy.	See criteria

Drug Product(s)	Criteria	PA Approval Length
	Maximum Dose: 700 mg every 4 weeks for the first 3 doses, followed by 1,400 mg every 4 weeks. Initial Approval: 6 months Second Prior Authorization Approval: An additional 6 months of therapy may be approved with provider attestation that a follow-up MRI will be (or has been) completed prior to the 7th infusion Third and Subsequent Prior Authorization Approval: Approval for 6 months for third and subsequent prior authorization requests may be approved with provider attestation that the member has demonstrated a positive clinical response to treatment.	
KUVAN (sapropterin dihydrochloride)	**Kuvan** (sapropterin dihydrochloride) may be approved if all the following criteria are met: • Member is > 1 month old AND • Member has been diagnosed with hyperphenylalaninemia due to tetrahydrobiopterin responsive phenylketonuria AND • Prescriber is a metabolic specialist AND • Phenylalanine levels must be greater than 6 mg/dL for neonates through 12 years of age OR • Phenylalanine levels must be greater than 10 mg/dL for members between 13 to 17 OR • Phenylalanine levels must be greater than 15 mg/dL for members 18 years and older AND • Must be in conjunction with dietary restriction of phenylalanine • Initial approval will be for 1 month. Authorization may be extended if: o Members on the 10mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month of treatment should increase to 20mg/kg/day. These members will be approved for another 1 month trial at the higher dose. o Members on the 20mg/kg/day dose whose blood phenylalanine levels have not decreased from baseline after 1 month are considered non-responders, and treatment will be discontinued. o Members responding to therapy receive additional authorization at 1-year intervals.	Initial approval one month
LAMPIT (nifurtimox)	**Lampit** (nifurtimox) may be approved if the following criteria are met: • Lampit (nifurtimox) is prescribed by or in conjunction with an infectious disease specialist, cardiologist or gastroenterologist AND • The member's age falls between term newborn and < 18 years of age AND • The member's weight is provided and is at least 2.5 kg (5.5 pounds) AND • The member has a diagnosis, documented and confirmed by blood smear, of Chagas disease (American Trypanosomiasis) caused by *Trypanosoma cruzi* AND • For pediatric members 2 to 12 years of age, the member has trialed and failed treatment with benznidazole. Failure is defined as lack of efficacy,	One year

<table>
<tr><th>Drug Product(s)</th><th>Criteria</th><th>PA Approval Length</th></tr>
<tr><td></td><td>contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction AND
• For female members of childbearing potential, a documented negative pregnancy test is obtained within 2 weeks of initiating therapy AND
• The member has received counseling (when appropriate) to not consume alcohol during treatment with Lampit (nifurtimox) AND
• The prescription meets the following recommended daily dosing:

<table><tr><td colspan="2">Lampit (nifurtimox) Dosing in Pediatric Patients</td></tr><tr><td>Body weight group</td><td>Total daily dose</td></tr><tr><td>40 kg or greater</td><td>8 to 10 mg/kg</td></tr><tr><td>Less than 40 kg</td><td>10 to 20 mg/kg</td></tr></table>
Maximum Dosing:
300mg three times a day (900mg/day) for 60 days</td><td></td></tr>
<tr><td>LEMTRADA (alemtuzumab)</td><td>Lemtrada (alemtuzumab) may be approved if the following criteria are met:
• For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member’s home or in a long-term care facility AND
• Member is 18 years of age or older AND
• Member has a relapsing form of multiple sclerosis AND
• Member has experienced one relapse within the prior year or two relapses within the prior two years AND
• Member has had trial and failure with Tysabri (natalizumab), Ocrevus (ocrelizumab), or two preferred agents in the “Disease Modifying Therapies” PDL drug class that are FDA-labeled for use for the same prescribed indication. Failure is defined as allergy, intolerable side effects, significant drug-drug interaction, or lack of efficacy. Lack of efficacy is defined as one of the following:
o On MRI, presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy OR
o Signs and symptoms on clinical exam consistent with functional limitations that last one month or longer
AND
• Lemtrada is prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis AND
• For members with known psychiatric conditions, prescriber acknowledges that consultation with the member’s behavioral health provider will be conducted prior to the member’s receiving treatment with a high dose corticosteroid as part of the Lemtrada premedication procedure AND
• Baseline skin exam and thyroid function assessment are completed and documented prior to initiation of treatment with Lemtrada AND
• Prescriber is enrolled in the Lemtrada Risk Evaluation and Mitigation Strategy (REMS) program.

Exemption: If member is currently receiving and stabilized on Lemtrada (alemtuzumab), they may receive prior authorization approval to continue therapy.</td><td>One year</td></tr>
</table>

Drug Product(s)	Criteria	PA Approval Length
LEQEMBI (lecanemab-irmb)	**Leqembi** (lecanemab-irmb) may be approved if the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Member has documented diagnosis of mild cognitive impairment or mild dementia stage of Alzheimer's disease as evidenced by all of the following: o Positron Emission Tomography (PET) scan OR lumbar puncture positive for amyloid beta plaque AND o Clinical Dementia Rating global score (CDR-GS) of 0.5 or 1 (available at https://otm.wustl.edu/cdr-terms-agreement/) AND o Mini-Mental State Examination (MMSE) score of 24-30 OR Montreal Cognitive Assessment (moCA) Test score of 19-25 AND • Member is ≥ 50 years of age AND • The prescriber attests that member has been counseled on the approval and safety status of Leqembi (lecanemab-irmb) being approved under accelerated approval based on reduction in amyloid beta plaques AND • Prior to initiation of Leqembi (lecanemab-irmb), the prescriber attests that the member meets both of the following: o Member has had a brain MRI within the prior one year to treatment initiation, showing no signs or history of localized superficial siderosis, ≥ 10 brain microhemorrhages, and/or brain hemorrhage > 1 cm AND o Attestation that MRI will be completed prior to the 5th, 7th and 14th infusions AND o Member is negative for apolipoprotein E ε4 (ApoE ε4) homozygotes AND • Member <u>does not</u> have any of the following: o Any medical or neurological condition other than Alzheimer's Disease that might be a contributing cause of the subject's cognitive impairment including (but not limited to) stroke/vascular dementia, tumor, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD] or normal pressure hydrocephalus o Contraindications to PET, CT scan, or MRI o History of or increased risk of amyloid related imaging abnormalities ARIA-edema (ARIA-E) or ARIA-hemosiderin deposition (ARIA-H) o History of unstable angina, myocardial infarction, chronic heart failure, or clinically significant conduction abnormalities, stroke, transient ischemic attack (TIA), or unexplained loss of consciousness within 1 year prior to initiation of Leqembi (lecanemab-irmb) o History of bleeding abnormalities or taking any form of anticoagulation therapy AND • The requested medication is being prescribed by or in consultation with a neurologist AND • The prescribed regimen meets FDA-approved labeled dosing. <u>Initial approval period:</u> 6 months	See criteria

Drug Product(s)	Criteria	PA Approval Length
	Subsequent approval: An additional 6 months of Leqembi (lecanemab-irmb) therapy may be approved with provider attestation that a follow-up MRI will be (or has been) completed prior to the 14th infusion. Maximum dose: 10 mg/kg IV every 2 weeks The above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options and available peer-reviewed medical literature and clinical evidence. If request is for use outside of stated coverage standards, support with peer reviewed medical literature and/or subsequent clinical rationale shall be provided and will be evaluated at the time of request. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).	
LEQVIO (inclisiran)	**Leqvio** (inclisiran) may be approved if the following criteria are met: • To bill for the requested drug under the pharmacy benefit, the drug is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Prescriber acknowledges that doses administered by a healthcare provider in the doctor's office or clinic are to be billed through the Health First Colorado medical benefit through the standard buy-and-bill process AND • Member is ≥ 18 years of age AND • The requested drug is being prescribed as an adjunct to diet and maximally tolerated statin therapy with ezetimibe for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD as defined below in Table 1), who require additional lowering of low-density lipoprotein cholesterol (LDL-C) AND • The requested drug is being prescribed by, or in consultation with, a cardiologist, Certified Lipid Specialist (CLS) or an endocrinologist AND • Member is concurrently adherent (> 80% of the past 180 days) on maximally tolerated dose of statin therapy (see Table 2 below), which should include a 30-day trial of either atorvastatin OR rosuvastatin. If intolerant to a statin due to side effects, member must have a one month documented trial with at least two other statins. For members with a past or current incidence of rhabdomyolysis, one month trial and failure of two statins is not required AND • Member must be concurrently treated (in addition to maximally tolerated statin) with ezetimibe AND have a treated LDL > 70 mg/dl for a clinical history of ASCVD or LDL > 100 mg/dl if familial hypercholesterolemia. For members who have an allergy, contraindication, or intolerable side effects to ezetimibe, concomitant use of ezetimibe is not required. Maximum Dose: 284 mg/90 days Quantity Limit: One 284 mg/1.5 mL prefilled syringe/90 days Reauthorization: Additional one year approval for continuation may be granted with provider attestation to safety and efficacy with initial medication therapy. **Table 1: Conditions Which Define Clinical Cardiovascular Disease**	Initial: 3 months Reauth: One year

<table>
<tr><th>Drug Product(s)</th><th>Criteria</th><th>PA Approval Length</th></tr>
<tr><td></td><td>

Acute coronary syndrome
History of myocardial infarction
Stable and unstable angina
Coronary or other arterial revascularization
Stroke
Transient ischemic attack
Peripheral arterial disease of atherosclerotic origin

<table>
<tr><th>Table 2: Maximum Daily Statin Doses</th></tr>
<tr><td>Atorvastatin 80 mg</td></tr>
<tr><td>Fluvastatin 80 mg</td></tr>
<tr><td>Lovastatin 80 mg</td></tr>
<tr><td>Pravastatin 80 mg</td></tr>
<tr><td>Rosuvastatin 40 mg</td></tr>
<tr><td>Simvastatin 40 mg (80 mg not used in practice)</td></tr>
</table>
</td><td></td></tr>
<tr><td>LHRH/GnRH
Luteinizing Hormone Releasing Hormone/Gonadotropin Releasing Hormone</td><td>All claims for medications administered in a hospital, clinic, or physician’s office are to be billed through the medical benefit. Claims billed through the pharmacy benefit may only receive approval if the medication is being administered in the member’s home by a home health agency/provider or administered in a long-term care facility (see “Physician Administered Drugs” section).

Prior authorization may be approved for FDA-labeled indications only.

• Eligard (leuprolide): Palliative treatment of advanced prostate cancer
• Fensolvi (leuprolide acetate): Central precocious puberty
• Lupaneta Pack (leuprolide and norethindrone): Endometriosis

• Lupron (leuprolide): Prostate cancer, endometriosis, uterine leiomyomata (fibroids), precocious puberty. Lupron may be approved for gender dysphoria based on the following criteria:
o The member has a diagnosis of gender dysphoria which is made by a mental health professional with experience in treating gender dysphoria. Where available, the mental health professional should ideally have training in child and adolescent developmental psychology AND
o The member should have at least 6 months of counseling and psychometric testing for gender identity prior to initiation of Lupron AND
o The prescribing provider has training in puberty suppression using a gonadotropin releasing hormone agonist AND
o Lupron may not be started until girls and boys exhibit physical changes of puberty (confirmed by levels of estradiol and testosterone, respectively) and no earlier than Tanner stages 2-3 (bilateral breast budding or doubling to tripling testicular size to 4-8 cc).
o Duration of treatment: Lupron will be covered to a maximum of 16 years of age for gender dysphoria.

• Synarel (nafarelin): Endometriosis, precocious puberty
• Trelstar (triptorelin): Palliative treatment of advanced prostate cancer
• Triptodur (triptorelin): Palliative treatment of advanced prostate cancer, precocious puberty</td><td>One year</td></tr>
</table>

Drug Product(s)	Criteria	PA Approval Length

LIVDELZI (seladelpar)	**Livdelzi** (seladelpar) may be approved if the following criteria are met:
	• Member is ≥ 18 years of age AND
	• Member has a diagnosis of primary biliary cholangitis and meets one of the following:
	  o Combined therapy: Requested medication will be used in combination with ursodiol (ursodeoxycholic acid) if the member had an inadequate response (lack of efficacy) following at least one year of treatment with ursodiol (ursodeoxycholic acid) alone OR
	  o Monotherapy: Requested medication will be used as monotherapy in members who have trialed and failed ursodiol (ursodeoxycholic acid) therapy. Failure is defined as allergy, intolerable side effects, or significant drug-drug interaction
	• AND
	• Medication is prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant provider AND
	• Laboratory tests to evaluate ALT, AST, alkaline phosphatase and total bilirubin will be performed at baseline and during treatment with Livdelzi (seladelpar), according to product labeling AND
	• Prior to initiating therapy, the member does NOT have an elevated creatine phosphokinase (CPK) and/or signs/symptoms of muscle pain or myopathy, and prescriber attests that these parameters will be monitored throughout treatment with Livdelzi (seladelpar) AND
	• Member does not have complete biliary obstruction, cirrhosis, or other types of liver disease AND
	• Members without serologic evidence of immunity have received hepatitis A and hepatitis B vaccinations AND
	• Prescriber has considered the risk of fracture in patients treated with the requested product AND
	• Due to the risk of adverse reactions that maybe be associated with significant increases in Livdelzi (seladelpar) exposure, member is not taking an OAT3 inhibitor (such as gemfibrozil, probenecid, teriflunomide) OR a strong CYP2C9 inhibitor (such as fluconazole, fluorouracil, gemfibrozil, metronidazole), and member's medication profile has been reviewed for other potential clinically significant drug interactions according to product labeling AND
	• Prescriber attests the member has been counseled that the approval and safety status of Livdelzi (seladelpar) is based on reduction of alkaline phosphatase. Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
	
	Maximum Dose: 10 mg/day
	
	Maximum Quantity: 30 tablets/30 days
	
	Initial Approval: 6 months
	
	Reauthorization: Member may receive approval for one year with provider attestation that a biochemical response (such as an alkaline phosphatase level less than 1.67-times the upper limit of normal) has been observed after 6 months of therapy.
		Initial: 6 months
		
		Continued: One year

LIVERVANT (diazepam)	**Libervant** (diazepam) buccal film may be approved if the following criteria are met: • Member is 2 to 5 years of age AND	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member has a diagnosis of epilepsy with intermittent, stereotypic episodes of frequent seizure activity (such as seizure clusters, acute repetitive seizures) that are distinct from their usual seizure pattern AND • Member does not have acute-narrow angle glaucoma AND • Due to increased risk of additive effects, prescriber attests that members on concomitant CNS depressants will be closely monitored for central nervous system and respiratory depression after administration of Libervant (diazepam buccal film) AND • Based on the member's concurrent medication profile, prescriber has evaluated potential interactions that may occur between diazepam and: o Inhibitors of CYP2C19 (such as cimetidine, quinidine, tranylcypromine) and CYP3A4 (such as ketoconazole, clotrimazole) that could increase adverse reactions with diazepam AND o Inducers of CYP2C19 (such as rifampin) and CYP3A4 (such as carbamazepine, phenytoin, dexamethasone, phenobarbital) that could decrease the efficacy of diazepam AND • Initial prescription for the requested product is ordered by or in consultation with a pediatric neurologist AND • Parent/caregiver has been educated about appropriate identification of seizure cluster signs and symptoms, and proper Libervant buccal film administration. Quantity Limit: 4 films per year unless used / damaged / lost Continuation of Therapy: Members who are currently stabilized on Libervant (diazepam) buccal films as part of their epilepsy treatment plan may receive approval to continue use of the product. Members are limited to one prior authorization approval on file for Libervant (diazepam), Nayzilam (midazolam) or Valtoco (diazepam).	
LIPIDS/AMINO ACIDS/PLASMA PROTEINS	Approval will be given if administered in the member's home or in a long-term care facility. If given in the hospital or physician's office, the claim must be billed as a medical expense.	Lifetime
LIVTENCITY (maribavir)	**Livtencity** (maribavir) may be approved if the following criteria are met: • Member is ≥ 12 years of age and weighs ≥ 35 kg, AND • Member has a diagnosis of post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet AND • Prescriber confirms that potentially significant drug-drug interactions (such as those with digoxin, anticonvulsants, rosuvastatin, strong CYP3A4 inducers, rifampin, and immunosuppressants) will be carefully evaluated prior to initiating therapy with Livtencity (maribavir), based on the current product labeling. Maximum Dose: • Usual dose: 800 mg/day • If co-administered with carbamazepine: 1,600 mg/day • If co-administered with phenytoin or phenobarbital: 2,400 mg/day Quantity Limits:	One year

Drug Product(s)	Criteria	PA Approval Length
	• Usual dose: 120 tablets/30 days • If co-administered with carbamazepine: 240 tablets/30 days • If co-administered with phenytoin or phenobarbital: 360 tablets/30 days	
LUCEMYRA (lofexidine)	**Lucemyra** (lofexidine) may receive prior authorization approval for members meeting all of the following criteria: • Member is 18 years of age or older **AND** • Lucemyra® is prescribed for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation **AND** • Member is not pregnant or nursing **AND** • Member is not experiencing withdrawal symptoms from substances other than opioids **AND** • Member is not currently taking monoamine oxidase inhibitors or allergic to imidazole drugs **AND** • Member does not have an abnormal cardiovascular exam prior to treatment: o Clinically significant abnormal ECG (e.g., second or third degree heart block, uncontrolled arrhythmia, or QTc interval > 450 msec for males, and > 470 msec for females) o Heart rate less than 45 bpm or symptomatic bradycardia o Systolic blood pressure < 90 mm Hg or symptomatic hypotension (diastolic blood pressure < 60 mm Hg) o Blood pressure > 160/100 mm Hg o Prior history of myocardial infarction **AND** • Member has two-day trial and failed clonidine IR for opioid withdrawal symptoms. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction. Approval for Lucemyra (lofexidine) will be 14 days	14 days
LUMIZYME (alglucosidase alfa)	**Lumizyme** (alglucosidase alfa) may be approved if the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Member has a definitive diagnosis of Pompe disease confirmed by <u>one</u> of the following: o Deficiency of acid alpha-glucosidase (GAA) enzyme activity OR o Detection of biallelic pathogenic variants in the GAA by molecular genetic testing AND • The request meets <u>one</u> of the following based on indicated use: o If being administered for <u>infantile-onset Pompe disease,</u> member has documented baseline age-appropriate assessments, including motor function tests, muscle weakness, respiratory function, cardiac involvement testing, percent predicted forced vital capacity (FVC), and 6-minute walk test (6MWT) OR o If being administered for <u>late-onset Pompe disease</u>, member has documented baseline age-appropriate assessments, including motor function tests, muscle weakness, respiratory function, cardiac involvement testing, FVC and 6MWT.	One year

Drug Product(s)	Criteria	PA Approval Length
	Reauthorization may be approved for one year if member met initial approval criteria at the time of initiation of therapy AND meets the following: • Member is being monitored for antibody formation and hypersensitivity AND • The request meets one of the following based on indicated use: o For infantile-onset Pompe disease: the member has shown clinical improvement defined as an improvement or stabilization in muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted FVC, and/or 6MWT OR o For late-onset Pompe disease: the member has shown clinical improvement defined as an improvement or stabilization in percent predicted FVC and/or 6MWT. Maximum dose: Lumizyme 20mg/kg every 2 weeks (IV Infusion)	
MAKENA (hydroxyprogesterone caproate)	**Makena** (hydroxyprogesterone caproate): Effective 04/06/23, Makena (hydroxyprogesterone caproate) is not eligible for coverage under the Health First Colorado pharmacy benefit based on the final decision by the U.S. Food and Drug Administration to withdraw approval for this medication.	See criteria
MALARIA PROPHYLAXIS EXCEEDING THIRTY DAYS	Prior authorization is required for claims exceeding a 30-day supply for medications used for malaria prophylaxis (e.g. atovaquone/proguanil, chloroquine, doxycycline, mefloquine, primaquine, tafenoquine) and may be approved for members meeting the following: • Prescriber verification that the member is traveling to a malaria endemic area for a period of time that requires duration of therapy exceeding thirty days. • Prescriber verification of member's duration of stay in the malaria endemic area and the total days needed for the malaria prophylaxis medication regimen. *Note: The Centers for Disease Control and Prevention recommendations for malaria prophylaxis therapy based on country of travel are available at www.cdc.gov*	See criteria
MIFEPRISTONE and MISOPROSTOL	**Cytotec** (misoprostol) – Effective 01/01/23, prior authorization may be approved if meeting the following criteria: • The requested medication is being prescribed for use for one of the following: o Prophylaxis for reducing risk of NSAID-induced gastric ulcers in patients at high risk of complications from gastric ulceration OR o Use for other off-label indications supported by clinical compendia, peer-reviewed medical literature, and medical necessity AND • For requests for use for termination of pregnancy or non-viable pregnancy, the request meets the following: o The requested medication is being billed as a pharmacy claim for administration by the patient (note that this request applies to pharmacy claims billing only. Medication administered by a healthcare professional in the office, clinic, or outpatient hospital setting should be billed through the medical benefit in accordance with claims billing processes outlined for medical) AND	One year unless specified in criteria

Drug Product(s)	Criteria	PA Approval Length
	○ The prescriber submits all required information contained within the posted "Certification Statement" form associated with the services provided in relation to this request to the Prime Therapeutics pharmacy helpdesk by fax at 1-800-424-5725 for review and approval (forms are located at https://hcpf.colorado.gov/provider-forms under "Claim Forms and Attachments"). Prior authorization approval will allow for one full treatment course of misoprostol. **Korlym** (mifepristone) - Prior authorization may be approved for members meeting the following: • Mifepristone is not being prescribed for use related to termination of pregnancy AND • Mifepristone is being prescribed for use for hyperglycemia secondary to hypercortisolism in adult patients with Cushing's Syndrome who have type 2 diabetes or glucose intolerance and have failed or are not candidates for surgery. **Mifeprex** (mifepristone) - Effective 07/01/23, prior authorization may be approved if meeting the following criteria: • The requested medication is being billed as a pharmacy claim for administration by the patient (Note that submission of this request applies to pharmacy claims billing only. Medication administered by a healthcare professional in the office, clinic, or outpatient hospital setting should be billed through the medical benefit in accordance with claim billing processes outlined for medical) AND • The requested medication is being prescribed as federally allowed for use for one of the following: ○ Abortion to save the life of the mother OR ○ Abortion for sexual assault (rape) or incest OR ○ Use for non-viable pregnancy (pregnancy loss, miscarriage, or anembryonic service) AND • The prescriber submits all required information contained within the posted "Certification Statement" form associated with the services provided in relation to this request to the Prime Therapeutics pharmacy helpdesk by fax at 1-800-424-5725 for review and approval (forms are located at https://hcpf.colorado.gov/provider-forms under "Claim Forms and Attachments"). Prior authorization approval will allow for one full treatment course of both mifepristone and misoprostol. *Note: See PDL for coverage information for misoprostol/NSAID combination products.*	
MIPLYFFA (arimoclomol citrate)	**Miplyffa** (arimoclomol citrate) may be approved if the following criteria are met: • Member is ≥ 2 years of age AND • Member has a documented diagnosis of Niemann-Pick disease type C, molecularly confirmed by genetic testing AND • Member is concurrently being treated with miglustat AND • Requested medication is being prescribed by a neurologist or other provider specializing in the treatment of Niemann-Pick disease type C AND • Prescriber attests that the member will be assessed using the NPC Clinical Severity Scale (NPCCSS) prior to initiating Miplyffa (arimoclomol citrate) therapy AND	6 months

Drug Product(s)	Criteria	PA Approval Length
	• For members with renal impairment (eGFR ≥ 15 to < 50 mL/min) the dose of Miplyffa (arimoclomol citrate) will be adjusted according to product labeling AND • Members of child-bearing potential been counseled that Miplyffa (arimoclomol citrate) may cause embryo-fetal harm and to consider pregnancy planning and prevention AND • Members are limited to one prior authorization approval on file for Miplyffa (arimoclomol citrate) OR Aqneursa (levacetylleucine). Maximum Dose: 372 mg/day Maximum Quantity: 90 tablets/30 days Initial Approval: 6 months Reauthorization: Members may receive approval for 6 months for continuation of therapy if all of the following criteria are met: • Based on ongoing response to treatment, the provider attests there is medical necessity justifying continuation of drug therapy AND • Member has demonstrated response to treatment based on quantitative scores using the same scale(s) previously used to assess Miplyffa (arimoclomol citrate) treatment (see bullet point 5 of the initial authorization criteria), AND • A brief explanation, including the provider name, must be submitted if a provider other than the one who initially performed the neurologic exam completes any follow-up exam(s) AND • A brief explanation must be submitted if an exam scale other than the scale used for initial authorization is used for reassessment.	
MOLNUPIRAVIR	Quantity limit: 40 capsules per 5 days	
MOXATAG (amoxicillin)	A prior authorization will only be approved if a member has an allergic/intolerance to inactive ingredients in immediate release amoxicillin.	One year
MULPLETA (lusutrombopag)	**Mulpleta** (lusutrombopag) prior authorization may be approved for members meeting the following criteria: • Member is 18 years of age or older AND • Member has a confirmed diagnosis of thrombocytopenia with chronic liver disease who is scheduled to undergo an elective procedure AND • Member has trialed and failed both dexamethasone and methylprednisolone (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions) AND • Mulpleta is being prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist AND • Member has a baseline platelet count no more than 2 days before procedure. AND • Mulpleta (lusutrombopag) will not be administered with a thrombopoietic agent or spleen tyrosine kinase inhibitor (such as Promacta (eltrombopag), Nplate (romiplostim), or Tavalisse (fotamatinib) Quantity limit: 7 day supply per procedure	One year
MYALEPT (metreleptin)	**Myalept** (metreleptin) may be approved if all of the following criteria are met:	Six Months

Drug Product(s)	Criteria	PA Approval Length
	• Prescriber is an endocrinologist who is enrolled in the Myalept REMS program AND • Member has a diagnosis of congenital or acquired generalized lipodystrophy AND • Member does not have HIV-related lipodystrophy AND • Member has a diagnosis of leptin deficiency AND • Member has been diagnosed with poorly controlled diabetes (HgA1c > 7) and/or hypertriglyceridemia (> 500 mg/dl) AND • Member has tried and failed two standard therapies for diabetes and/or hypertriglyceridemia	
MYCAPSSA (octreotide)	**Mycapssa** (octreotide) may be approved for members meeting the following criteria: • Member is an adult (≥ 18 years of age) with a confirmed diagnosis of acromegaly AND • Member has trialed and failed‡ treatment with bromocriptine mesylate at maximally tolerated doses AND • Member has responded to and tolerated 3 months of treatment with octreotide acetate injection (vial) OR lanreotide acetate injection AND • Member cannot be treated with surgical resection or pituitary irradiation AND • Member is not hypersensitive to octreotide of any components of Mycapssa (octreotide) capsules, which include but are not limited to gelatin, propylene glycol and povidone AND • Mycapssa (octreotide) is prescribed by, or in consultation with, an endocrinologist AND • Provider attests that insulin-like growth factor 1 (IGF-1) levels will be monitored every two weeks, along with member's signs and symptoms, during the dose titration period or as indicated, and that the Mycapssa (octreotide) dose will be adjusted based on these findings AND • Provider attests that blood glucose will monitored during initiation of treatment with Mycapssa (octreotide), and that blood glucose, thyroid function, and vitamin B12 levels will be monitored periodically during treatment AND • Provider confirms awareness of the potential for significant drug interactions between Mycapssa (octreotide) and other medications, including (but not limited to) cyclosporine, digoxin, lisinopril, oral contraceptives containing levonorgestrel, bromocriptine, beta blockers, and calcium channel blockers. Maximum Dose: 80 mg daily ‡Failure is defined as lack of efficacy with a 3-month trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interaction.	One year
MYFEMBREE (relugolix, estradiol hemihydrate, norethindrone acetate)	**Myfembree** (relugolix, estradiol hemihydrate, norethindrone acetate) may be approved if meeting the following criteria: 1. Member is 18 years of age or older AND 2. Member is pre-menopausal AND 3. Member has a confirmed diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) OR member has a diagnosis of moderate to severe pain associated with endometriosis AND 4. Member has tried and failed treatment with an estrogen-progestin contraceptive (oral tablets, vaginal ring, transdermal patch) OR a progestin releasing	6 months

Drug Product(s)	Criteria	PA Approval Length
	intrauterine device (IUD). Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy AND 5. The medication is prescribed by or in consultation with an obstetrician/gynecologist AND 6. Member does not have a high risk of arterial, venous thrombotic, or thromboembolic disorder, including: a. Women over 35 years of age who smoke OR b. Women with a past or current history of the following: i. DVT, PE, or vascular disease (such as cerebrovascular disease, coronary artery disease, peripheral vascular disease) OR ii. Thrombogenic valvular or thrombogenic rhythm diseases of the heart (such as subacute bacterial endocarditis with valvular disease, or atrial fibrillation) OR iii. Inherited or acquired hypercoagulopathies OR iv. Uncontrolled hypertension OR v. Headaches with focal neurological symptoms OR migraine headaches with aura if over age 35 AND 7. Member is not pregnant or breastfeeding AND 8. Member does not have known osteoporosis AND 9. Member does not currently have, or have a history of, breast cancer or other hormonally-sensitive malignancies AND 10. Member does not have known liver impairment or disease AND 11. Member will not receive Myfembree in combination with any medication that is contraindicated or not recommended per FDA labeling AND 12. Member has not previously received treatment with Orilissa (elagolix) 150 mg or Oriahnn (elagolix/estradiol/norethindrone acetate) for more than 24 months, or previous treatment with Orilissa (elagolix) 200 mg for more than 6 months AND 13. Member has been counseled that that Myfembree does not prevent pregnancy AND 14. Member has been instructed that only non-hormonal contraceptives should be used during Myfembree therapy and for at least 1 week following discontinuation AND 15. Prescriber acknowledges that assessment of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) is recommended at baseline and periodically thereafter, and discontinuation of Myfembree should be considered if the risk associated with bone loss exceeds the potential benefit of treatment. Reauthorization: Members with a current 6-month prior authorization approval on file may receive an additional 6-month approval to continue therapy. Prior authorization requests for Myfembree will take into account exposure to all GnRH receptor antagonist medications (such as elagolix and relugolix) and will not be approved for a total exposure that exceeds 24 months. Maximum dose: 1 tablet daily (relugolix 40 mg, estradiol 1 mg, norethindrone acetate 0.5 mg)	

Drug Product(s)	Criteria	PA Approval Length
NAGLAZYME (galsulfase)	**Naglazyme** (galsulfase) may be approved for members meeting the following criteria: • Naglazyme (galsulfase) is being administered in a long-term care facility or in a member's home by a healthcare professional AND • Member is 5 years of age or older AND • Member has a confirmed diagnosis of Mucopolysaccharidosis, Type VI confirmed by the following: o Detection of pathogenic mutations in the ARSB gene by molecular genetic testing OR o Arylsulfatase B (ASB) enzyme activity of <10% of the lower limit of normal in cultured fibroblasts or isolated leukocytes AND o Member has normal enzyme activity of a different sulfatase (excluding members with Multiple Sulfatase Deficiency) AND o Member has an elevated urinary glycosaminoglycan (uGAG) level above the upper limit of normal as defined by the reference laboratory AND • Member has a documented baseline 12-minute walk test (12-MWT), 3-minute stair climb test, and/or pulmonary function tests (such as FEV1) AND • Member has a documented baseline value for uGAG AND • Naglazyme (galsulfase) is being prescribed by or in consultation with a provider who specializes in inherited metabolic disorders <u>Reauthorization Criteria:</u> After one year, member may receive approval to continue therapy if meeting the following: • Has documented reduction in uGAG levels AND • Has demonstrated stability or improvement in one of the following: o 12-minute walk test OR o 3-minute stair climb test OR o Pulmonary function testing (such as FEV1) Max dose: 1 mg/kg as a 4-hour infusion weekly	One year
NAYZILAM (midazolam)	**Nayzilam** (midazolam) may be approved for members meeting the following criteria: • Member is 12 years of age or older AND • Nayzilam is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern and medical records are provided supporting this diagnosis AND • Member is stable on regimen of antiepileptic medications AND • Medication is being prescribed by or in conjunction with the same provider/provider team who manages the member's anti-epileptic regimen AND • Member is educated on appropriate identification of seizure cluster and Nayzilam (midazolam) administration not exceeding 2 doses per seizure cluster. Maximum dose: 4 nasal spray units per year unless used / damaged / lost	One Year

Drug Product(s)	Criteria	PA Approval Length
	Members are limited to one prior authorization approval on file for Valtoco (diazepam) and Nayzilam (midazolam). If member is currently receiving Nayzilam (midazolam) intranasal, they may receive prior authorization approval to continue.	
NEWLY APPROVED PRODUCTS AND CHANGE IN PRODUCT PRIOR AUTHORIZATION STATUS	Newly marketed or approved products that fall within a PDL drug class will be subject to non-preferred prior authorization criteria for the drug class and will be included as part of the next regularly scheduled P&T Committee and DUR Board reviews for that class. Newly marketed or approved products that fall within a drug category on appendix P (such as "Blood Products") will be subject to prior authorization criteria listed for medications in that drug category on Appendix P. For change in prior authorization status for a product that is not included in a PDL drug class or on Appendix P, notice will be given regarding DUR Board review of prior authorization criteria for the product as part of the posted DUR Board meeting agenda located at https://www.colorado.gov/pacific/hcpf/drug-utilization-review-board and posted at least 30 days prior to the DUR Board meeting during which the product is scheduled to be reviewed. Until such time that DUR Board review is conducted, products may receive prior authorization approval based on FDA-labeled indication, dose, age, and role in therapy as outlined in product package labeling. IV formulations or products where labeled use indicates that the medication should be administered by a healthcare professional will also be subject to meeting criteria for physician administered drugs (see "Physician Administered Drugs" section).	

NEXVIAZYME (avalglucosidase alpha)	**Nexviazyme** (avalglucosidase alpha) may be approved if the following criteria are met:
	• For claims billed through the pharmacy benefit, prescriber verifies that the product medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
	• Member is ≥ 1 year of age AND
	• Member has a definitive diagnosis of late-onset (non-infantile) Pompe disease confirmed by <u>one</u> of the following:
	  ○ Deficiency of acid alpha-glucosidase (GAA) enzyme activity
	  OR
	  ○ Detection of biallelic pathogenic variants in the GAA by molecular genetic testing
	AND
	• The requested medication <u>is not</u> being used in combination with other enzyme replacement therapies AND
	• Member has documented baseline age-appropriate assessments, including motor function tests, muscle weakness, respiratory function, cardiac involvement testing, percent predicted forced vital capacity (FVC), and 6-minute walk test (6MWT) AND
	• Product is being prescribed by a provider specializing in the treatment of Pompe disease AND
	• Prescriber acknowledges consideration for administering antihistamines, antipyretics, and/or corticosteroids prior to Nexviazyme (avalglucosidase alpha) administration to reduce the risk of severe infusion-associated reactions.
	
	Reauthorization may be approved for one year if member met initial approval criteria at the time of initiation of therapy AND meets the following:
		One year

Drug Product(s)	Criteria	PA Approval Length
	• Member has shown clinical improvement defined as an improvement or stabilization in percent predicted FVC and/or 6MWT AND • Member is being monitored for antibody formation and hypersensitivity Maximum Dose: Members ≥30 kg, 20 mg/kg administered every 2 weeks Members ≤30 kg, 40 mg/kg administered every 2 weeks	
NORTHERA (droxidopa)	**Northera** (droxidopa) will be approved if all the following is met: • Member has a diagnosis of symptomatic neurogenic orthostatic hypotension (NOH) as defined by one of the following when an upright position is assumed or when using a head-up tilt table testing at an angle of at least 60 degrees. o At least a 20 mmHg fall is systolic pressure o At least a 10 mmHg fall in diastolic pressure AND • NOH caused by one of the following: o Primary autonomic failure (e.g, Parkinson's disease, multiple system atrophy, and pure autonomic failure o Dopamine beta-hydroxylase deficiency o Non-diabetic autonomic neuropathy AND • Member does not have orthostatic hypotension due to other causes (e.g, heart failure, fluid restriction, malignanacy) AND • Members has tried at least three of the following non-pharmacological interventions: o Discontinuation of drugs which can cause orthostatic hypotension [e.g., diuretics, antihypertensive medications (primarily sympathetic blockers), anti-anginal drugs (nitrates, excluding SL symptom treatment formulations), alpha-adrenergic antagonists, and antidepressants] o Raising the head of the bed 10 to 20 degrees o Compression stockings o Increased salt and water intake, if appropriate o Avoiding precipitating factors (e.g., overexertion in hot weather, arising too quickly from supine to sitting or standing) AND • Northera (droxidopa) is being prescribed by either a cardiologist, neurologist, or nephrologist AND • Member has failed a 30 day trail, has a contraindication, or intolerance to both Florinef (fludrocortisone) and ProAmatine (midodrine).	3 months
NPLATE (romiplostin)	**Nplate** (romiplostim) may be approved if the following criteria are met: • Prescriber verifies that the requested medication will not be administered in a doctor's office, clinic, outpatient hospital, or dialysis unit (medication claims for administration in these settings are only to be billed through the Health First Colorado medical benefit using the standard buy-and-bill process) **AND** • Member does not have thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than immune thrombocytopenia **AND** • The requested medication is not being used in an attempt to normalize platelet counts **AND** • If being administered for hematopoietic subsyndrome of acute radiation syndrome, member has been acutely exposed to myelosuppressive radiation	One year

Drug Product(s)	Criteria	PA Approval Length
	levels greater than 2 gray (Gy) OR if being administered for <u>immune thrombocytopenia (ITP)</u>, the member meets the following: o Member has had an insufficient response to corticosteroids, immunoglobulins, or splenectomy **AND** o Member has ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding as indicated by a platelet count of ≤ 30,000/mm^3 **AND** o Laboratory value for platelet count is current (e.g., drawn within the previous 28 days) **AND** o If being administered for <u>Acute</u> ITP, member is at least 18 years of age or older OR if being administered for <u>Chronic</u> ITP, member meets both of the following: ▪ Member is at least 1 years of age or older AND ▪ Member has had chronic ITP for at least 6 months <u>Maximum Dose:</u> Hematopoietic Syndrome of Acute Radiation Syndrome: 10mcg/kg/dose ITP: 10 mcg/kg weekly <u>Reauthorization (ITP indication)</u>: Reauthorization may be approved for ITP if member met the initial indication-specific approval criteria above and member responded to treatment by achieving and maintaining a platelet count of ≥ 50,000/mm^3, but <450,000/mm^3	
NUEDEXTA (dextromethorphan /quinidine)	**Nuedexta** (dextromethorphan/quinidine) may be approved for members who meet the following criteria: • Nuedexta is being prescribed for diagnosis of pseudobulbar affect secondary to an underlying neurologic condition (such as MS, ALS, or other underlying neurologic condition) AND • Member has a Center for Neurologic Study-Lability Scale (CNS-LS) score of 13 or higher AND • Member has frequent episodes of inappropriate laughing or crying per day before therapy AND • Member has a baseline electrocardiogram (ECG) with no significant abnormalities and no history of QT prolongation syndrome AND • Nuedexta is prescribed by a neurologist or in conjunction with a neurologist AND Member has trailed and failed one tricyclic antidepressant and one selective serotonin reuptake inhibitor within the past year (failure is defined as lack of efficacy, allergy, intolerable side effects, contraindication to therapy, or significant drug-drug interactions) Initial approval will be given for 3 months and continued approval for one year may be given if member has 50% reduction in daily episodes at 3 months of therapy Nuedexta® Max Dose: 2 capsules (dextromethorphan 20mg/quinidine 10mg) per day given every 12 hours Renewal: members currently stabilized on this medication may continue to receive it with a documented diagnosis of pseudobulbar affect and evidence of efficacy (documentation of decrease in pseudobulbar episodes by 50% from baseline)	Initial Approval: 3 months Continuation Approval: One year

Drug Product(s)	Criteria	PA Approval Length
OCREVUS (ocrelizumab) **OCREVUS ZUNOVO (ocrelizumab and hyaluronidase)**	**Ocrevus** (ocrelizumab) may be approved if the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND** • The requested medication is being prescribed by a neurologist or in consultation with a neurologist **AND** • <u>If prescribed for Relapsing Forms of Multiple Sclerosis (MS):</u> o Member is 18 years of age or older **AND** o Member does not have active hepatitis B infection or hypogammaglobulinemia at baseline **AND** o Member has a diagnosis of a relapsing form of multiple sclerosis **AND** o Member has experienced one relapse within the prior year or two relapses within the prior two years **AND** o Request meets <u>one</u> of the following: ▪ Member has had a trial and failure* with any high-efficacy disease-modifying therapies OR trial and failure* of any preferred product in the PDL "Multiple Sclerosis Agents" drug class **OR** ▪ Member has a diagnosis of <u>highly active</u> relapsing MS (based on measures of relapsing activity and MRI markers of disease activity such as numbers of galolinium-enhanced lesions) • <u>If Prescribed for Primary Progressive Multiple Sclerosis:</u> o Member is 18 years of age or older **AND** o Member is not concomitantly taking other disease modifying therapies. <u>Maximum Dose:</u> 600mg every 6 months maintenance (Ocrevus) 920mg every 6 months (Ocrevus Zunovo) <u>Exemption</u>: If member is currently receiving and stabilized on Ocrevus (ocrelizumab), they may receive prior authorization approval to continue therapy. *Failure is defined as intolerable side effects, drug-drug interaction, contraindication, or lack of efficacy. Lack of efficacy is defined as one of the following: • On MRI, presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy **OR** • Signs and symptoms on clinical exam consistent with functional limitations that last one month or longer.	One year
OFEV (nintedanib)	**Ofev** (nintedanib) may be approved if all of the following criteria are met: • Member has been diagnosed with idiopathic pulmonary fibrosis, chronic fibrosing interstitial lung disease with a progressive phenotype, or systemic sclerosis-associated interstitial lung disease (SSC-ILD) AND • Is being prescribed by or in conjunction with a pulmonologist AND • Member is 18 years or older AND • Member has baseline ALT, AST, and bilirubin prior to starting therapy AND • Member does not have moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment AND	One year

Drug Product(s)	Criteria	PA Approval Length
	• Female members of reproductive potential must have been counseled regarding risk to the fetus and to avoid becoming pregnant while receiving treatment with Ofev and to use adequate contraception during treatment and at least 3 months after the last dose of Ofev AND • Member is not taking a P-gp or CYP3A4 inducer (e.g, rifampin, carbamazepine, phenytoin, St. John's Wort) Quantity Limits: 60 tablets/30 days	
OPIOID ANTAGONISTS (naloxone, naltrexone, nalmefene)	**Narcan** (naloxone) intranasal does not require prior authorization (including Rx and OTC naloxone intranasal formulations) **Zimhi** (naloxone) injection does not require prior authorization. **Naloxone** vial/prefilled syringe: • does not require prior authorization. • The atomizer device for use with naloxone can be obtained by the pharmacy billing as a DME claim code A4210. The unit limit is 1 atomizer per vial/syringe dispensed up to a total of 15 per year. A prior authorization is not required. **Opvee** (nalmefene) intranasal does not require prior authorization. **Vivitrol** (naltrexone ER) injection: • Effective 01/01/2019, pharmacies that have entered into a collaborative practice agreement with one or more physicians for administration of Vivitrol may receive reimbursement for enrolled pharmacists to administer Vivitrol. • Effective January 14, 2022, no place of service prior authorization is required for extended-release injectable medications (LAIs) used for the treatment of mental health or substance use disorders (SUD), when administered by a healthcare professional and billed under the pharmacy benefit. In addition, LAIs may be administered in any setting (pharmacy, clinic, medical office or member home) and billed to the pharmacy or medical benefit as most appropriate and in accordance with all Health First Colorado billing policies. See additional information regarding pharmacist enrollment and claims billing at https://hcpf.colorado.gov/pharm-serv. **Revia** (naltrexone) tablet does not require prior authorization. **Evzio** (naloxone) autoinjector – Product is not Medicaid rebate eligible per current status in Medicaid Drug Rebate Program (MDRP); product excluded. *Note: For buprenorphine/naloxone products, see "Buprenorphine-containing Products" section.*	
ORAL CONTRACEPTIVES	Effective 10/1/2023, prescription oral contraceptive products are covered and do not require prior authorization. Brand name products that have an equivalent generic available will continue to be subject to coverage policies outlined for use of brand in the "Generic Mandate" section of this document. Effective 7/1/2022, prescription contraceptive products are eligible to be filled for up to a twelve-month supply.	
ORILISSA (elagolix)	**Orilissa** (elagolix) may be approved for members meeting the following criteria:	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member is a premenopausal woman 18-49 years of age **AND** • Orilissa is not being prescribed for dyspareunia or any other sexual function related indication **AND** • Member has a definitive diagnosis of endometriosis as noted by surgical histology of lesions **AND** • Member has failed a 6-month trial of contraceptive agents (progestins, combined contraceptives, medroxyprogesterone acetate, levonorgestrel IUD). Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND** • Member has failed a 1 month trial of NSAIDs. Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND** • Member has failed a 3 month trial with a GnRH agonist (such as leuprolide). Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND** • Member is not pregnant, breast feeding, planning a pregnancy within the next 24 months, or less than 6 months post-partum, post-abortion, or post-pregnancy **AND** • Member has been instructed that only non-hormonal contraceptives should be used during therapy and for at least 1 week following discontinuation **AND** • Member does not have osteoporosis or severe hepatic impairment (Child-Pugh Class C) **AND** • Member is not concomitantly taking a OATP 1B1 inhibitor (such as gemfibrozil, cyclosporine, ritonavir, rifampin). Maximum Dose: 150mg tablet daily, or 200mg tablet twice daily Approval will be limited to a maximum treatment duration of 6 months for members with moderate hepatic impairment (Child-Pugh Class B).	6 months for moderate hepatic impairment (Child Pugh Class B)
ORKAMBI (lumacaftor/ivacaftor)	**Orkambi** (lumacaftor/ivacaftor) may be approved for members if the following criteria has been met: • Member must have diagnosis of cystic fibrosis with genetic testing performed to confirm that member is homozygous for the F508del mutation in the CFTR gene AND • Member is 1 year of age or older AND • Member is being treated by a pulmonologist AND • Member has < 5 times upper limit of normal (ULN) AST/ALT or < 3 times ULN AST/ALT if concurrently has > 2 times ULN bilirubin at time of initiation AND • Member has serum transaminase and bilirubin measured before initiation and every 3 months during the first year of treatment	One year
ORIAHNN (elagolix, estradiol, norethindrone acetate)	**Oriahnn** (elagolix, estradiol, norethindrone acetate) prior authorization may be approved for members meeting the following criteria: • Member is a woman 18 years of age or older **AND** • Member has a confirmed diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) **AND**	One year

Drug Product(s)	Criteria	PA Approval Length

	• Member has tried and failed treatment with an estrogen-progestin contraceptive (oral tablets, vaginal ring, transdermal patch) OR a progestin-releasing intrauterine device (IUD). Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND**
	• The medication is prescribed by or in consultation with an obstetrician/gynecologist **AND**
	• Member does not have a high risk of arterial, venous thrombotic, or thromboembolic disorder, including:
	  ○ Women over 35 years of age who smoke **OR**
	  ○ Women with a past or current history of the following:
	  ▪ DVT, PE, or cerebrovascular disease (such as cerebrovascular disease, coronary artery disease, peripheral vascular disease) **OR**
	  ▪ Thrombogenic valvular or thrombogenic rhythm diseases of the heart (such as subacute bacterial endocarditis with valvular disease, or atrial fibrillation) **OR**
	  ▪ Inherited or acquired hypercoagulopathies **OR**
	  ▪ Uncontrolled hypertension **OR**
	  ▪ Headaches with focal neurological symptoms OR migraine headaches with aura if over age 35
	AND
	• Member is not pregnant **AND**
	• Member does not have known osteoporosis **AND**
	• Member does not have current or history of breast cancer or other hormonally-sensitive malignancies **AND**
	• Member does not have known liver impairment or disease **AND**
	• Member is not concomitantly taking not an OATP 1B1 inhibitor (such as gemfibrozil, ritonavir, rifampin, cyclosporine) **AND**
	• Member has been counseled that that Oriahnn does not prevent pregnancy **AND**
	• Member has been instructed that only non-hormonal contraceptives should be used during Oriahnn therapy and for at least 1 week following discontinuation **AND**
	• Prescriber acknowledges that assessment of bone mineral density (BMD) by dual-energy X-ray absorptiometry (DXA) is recommended at baseline and periodically thereafter, and discontinuation of Oriahnn should be considered if the risk associated with bone loss exceeds the potential benefit of treatment.
	
	Reauthorization: Members with current one-year prior authorization approval on file may receive additional one-year prior authorization approval to continue therapy. Total duration for prior authorization approvals is limited to 2 years (or two one-year approvals).
	
	Maximum dose: 2 capsules daily (AM and PM daily doses supplied in blister pack)	

OTC PRODUCTS*	Select OTC products in the following therapeutic categories are covered on the preferred drug list (PDL) *(see PDL for specific product names and coverage information)*: • Antihistamines • Antihistamine/Decongestant combinations • Insulins • Intranasal corticosteroids	One year

Drug Product(s)	Criteria	PA Approval Length
	• Ophthalmic allergy drops • Proton pump inhibitors (PPIs) • Topical NSAIDs (diclofenac gel) The following non-PDL OTC products are covered without prior authorization: • Aspirin • Bisacodyl (oral and suppository) *Effective 03/01/19* • Children's dextromethorphan suspension for ages 4-11 years • Children's liquid and chewable acetaminophen for ages < 12 years (note: acetaminophen use in patients younger than 42 days is not recommended) • Children's liquid and chewable ibuprofen for ages 6 months – 11 years • Docusate (oral) *Effective 03/01/19* • Nicotine replacement therapies (OTC patch, gum, and lozenge) • Naloxone *Effective 09/01/23* • Oral emergency contraceptive products • Opill (norgestrel) oral daily contraceptive *Effective 09/01/23* • Polyethylene glycol powder laxatives • Vitamin D infant dops *Effective 09/01/23* The following non-PDL OTC products may be covered with prior authorization if meeting criteria listed below: • Bisacodyl enema may be approved following adequate trial and failure with a bisacodyl oral formulation and bisacodyl suppository (Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects, or significant drug-drug interactions). *Effective 03/01/19* • Choline oral tablets may be approved if meeting the following criteria (*Effective 10/01/24*): o Choline supplementation is directly related to one of the following conditions: ▪ Member is pregnant or planning to become pregnant ▪ Member is currently breastfeeding AND o Quantity limit is met (limited to quantity sufficient to achieve 550mg daily) AND o Choline prior authorization approvals are limited to the following OTC products (product list may be subject to change): ▪ Choline citrate 650 mg tablet (*Endurance manufacturer*): NDC 58487-0021-81 ▪ Choline SR 300 mg tablet (*Freeda Health manufacturer*): NDC 29135-0187-20 • Cough and Cold Products may be approved for members with a diagnosis of a chronic respiratory condition for which these medications may be prescribed or based on medical necessity supported by clinical practice recommendations • Cranberry tablets may be approved for urinary tract infections • Docusate enema may be approved following adequate trial and failure with a docusate oral formulation (Failure is defined as lack of efficacy with 10 day trial, allergy, intolerable side effects, or significant drug-drug interactions). *Effective 03/01/19* • Ferrous sulfate and ferrous gluconate may be approved with a diagnosis of iron deficient anemia OR anemia or unknown origin OR iron deficiency verified by	

Drug Product(s)	Criteria	PA Approval Length
	low serum ferritin OR "at risk" members < 2 years of age (such as preterm infants or exclusively breastfed members who are at least 4 months old and not yet on iron-enriched solid food). • Fluoride supplements: See "Fluoride Products" section of this document • Guaifenesin 600mg LA may be approved for members having an abnormal amount of sputum • L-methylfolate may be approved for members with depression who are currently taking an antidepressant and are partial or non-responders • Members with a diagnosis of erythema bullosum (EB) may be approved to receive OTC medications (any Medicaid rebate-eligible OTC medications) • Nicomide may be approved for the treatment of acne • Poly-Vi-Sol with Iron (multivitamin with iron) oral liquid may be approved if the following criteria are met (*Effective 01/01/25*): o Member is < 1 year of age AND o Member is being treated for a diagnosis of anemia of prematurity OR is considered clinically "at risk" and requiring supplementation with an oral iron-containing multivitamin medication. Long Term Care Facilities (LTCFs): Various OTC drugs and supplies for LTCF residents shall be furnished by the facility, within the per diem rate, at no charge to the resident pursuant to 10 CCR 2505-10 Skilled Nursing Facility: 8.440 NURSING FACILITY BENEFITS. These OTC drugs and supplies, known as products on a "floor stock list", are not covered or eligible for prior authorization under the pharmacy benefit for LTCF members. ** Coverage criteria outlined in this section apply to prescriptions written by non-pharmacist prescribers. For coverage relating to pharmacist prescribers please see "Pharmacist Prescriptions" section.*	
OXANDRIN (oxandrolone)	**Oxandrin** (oxandrolone) may be approved if meeting all of the following criteria: • Medication is being prescribed for one of the following indications: o As adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, severe trauma, and without definite pathophysiologic reasons to fail to gain or maintain normal weight o To offset the protein catabolism associated with prolonged administration of corticosteroids o For the relief of bone pain frequently accompanying osteoporosis AND • Member does not have any of the following medical conditions: o Hypercalcemia o Known or suspected carcinoma of the prostate or the male breast o Carcinoma of the breast in females with hypercalcemia o Nephrosis, the nephrotic phase of nephritis AND • If member is female, has had a negative pregnancy test within the past month AND • Medication is being prescribed by or in consultation with an endocrinologist. <u>Maximum Dose:</u> Adults: 20mg daily for 4 weeks Children: ≤ 0.1 mg/kg per day for 4 weeks Adults ≥ 65 years old: 10mg daily for 4 weeks	One year

Drug Product(s)	Criteria	PA Approval Length
OXBRYTA (voxelotor)	**Oxbryta** (voxelotor) prior authorization may be approved for members meeting the following criteria: • Member is ≥ 4 years of age **AND** • Member has a confirmed diagnosis of sickle cell disease **AND** • Member has a hemoglobin ≥ 5.5 g/dL **AND** • OXBRYTA is prescribed by or in consultation with hematologist/oncologist or sickle cell disease specialist **AND** • Prior to initiation of therapy, member had at least two episodes of sickle cell related pain crises in the past 12 months **AND** • Member has trialed and failed a six-month trial of hydroxyurea (intolerance or contraindication) or is continuing concomitant hydroxyurea therapy following a six-month trial. Failure is defined as lack of efficacy, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy **AND** • Member is not receiving chronic transfusion therapy **OR** • Member has severe renal disease (GFR <30 mL/min) Initial approval: 6 months Reauthorization: Member may receive reauthorization approval for 1 year if meeting the following: • Member has a reduction in vasoocclusive events and/or increased hemoglobin response rate defined as a hemoglobin increase of more than 1 g/dL. Maximum dose: 1,500 mg per day (2,500 mg per day may be approved for members taking concomitant strong or moderate CYP3A4 inducers (such as carbamazepine, oxcarbazepine, phenytoin, phenobarbital, rifaximin, rifampin or dexamethasone-containing products).	Initial: 6 months Continued: One year
OXERVATE (cenegermin-bkbj)	**Oxervate** (cenegermin-bkbi) prior authorization may be approved for members meeting the following criteria: • Member is 2 years of age or older **AND** • Member has a confirmed diagnosis of stage 2 neurotrophic keratitis (NK), persistent epithelial defect [PED], or stage 3 neurotrophic keratitis (corneal ulcers) **AND** • Oxervate is being prescribed in consultation with an ophthalmologist or optometrist **AND** • Member's PED and/or corneal ulcer have been present for at least two weeks **AND** • Member has trialed and failed one of the following conventional non-surgical treatments: preservative-free lubricant eye drops or ointment, therapeutic soft contact lenses, or topical autologous serum application. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND** • Member has decreased corneal sensitivity (≤4 cm using the Cochet-Bonnet esthesiometer) within the area of the PED or ulcer and outside the area of defect in at least one corneal quadrant **AND** • Prescriber attests to member's discontinued use of preserved topical agents that can decrease corneal sensitivity **AND** • Member does not have any of the following: ○ Active ocular infection or active inflammation not related to NK in the affected eye	8 weeks

<table>
<tr><th>Drug Product(s)</th><th>Criteria</th><th>PA Approval Length</th></tr>
<tr><td></td><td>

Schirmer test without anesthesia ≤3 mm/5 min in the affected eye
Any ocular surgery in the affected eye within the past 90 days that has not been determined to be the cause of NK
Corneal perforation, ulceration involving the posterior third of the corneal stroma, or corneal melting

Maximum dose: 12 drops daily
</td><td></td></tr>
<tr><td>OXLUMO (lumasiran)</td><td>
OXLUMO (lumasiran) may be approved if all the following criteria are met:

For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
Member has a diagnosis of Primary hyperoxaluria type 1 (PH1) confirmed by either:

Genetic testing that demonstrates a mutation of the alanine glyoxylate aminotransferase (AGXT) gene OR
Liver enzyme analysis demonstrating absent or significantly reduced AGXT

AND
Medication is being prescribed by, or in consultation with a nephrologist, neurologist, or other healthcare provider with expertise in treating PH1 AND
Member has documented baseline urinary oxalate excretion or plasma oxalate concentrations.

<u>Reauthorization</u>: Member demonstrates response to medication as indicated by a positive clinical response from baseline urinary oxalate excretion or plasma oxalate concentration

<u>Maximum Dose</u>: Weight-based dosing regimen as shown in the following table (documentation of patient's current weight with the date the weight was obtained).
<table>
<tr><th>Body Weight</th><th>Loading Dose</th><th>Maintenance Dose</th></tr>
<tr><td>Less than 10 kg</td><td>6 mg/kg once monthly for three doses</td><td>3 mg/kg once monthly, beginning one month after the last loading dose</td></tr>
<tr><td>10 kg to less than 20 kg</td><td>6 mg/kg once monthly for three doses</td><td>6 mg/kg once every three months, beginning one month after the last loading dose</td></tr>
<tr><td>20 kg and above</td><td>3 mg/kg once monthly for three doses</td><td>3 mg/kg once every three months, beginning one month after the last loading dose</td></tr>
</table>
Members currently stabilized on a Oxlumo (lumasiran) regimen may receive prior authorization approval for continuation of therapy if meeting reauthorization criteria listed above.
</td><td>One year</td></tr>
</table>

Drug Product(s)	Criteria	PA Approval Length
PALFORZIA (arachis hypogaea allergen powder-dnfp)	**Palforzia (**arachis hypogaea allergen powder-dnfp**)** prior authorization may be approved for members meeting the following criteria: • Member is 4 -17 years of age at initiation of therapy **AND** • Member has a documented diagnosis of peanut allergy within the past 2 years (ICD-10 Z91.010) **AND** • Diagnosis of peanut allergy is made by or in consultation with an allergist or immunologist **AND** • Palforzia will be used in conjunction with a peanut-avoidant diet **AND** • Member does not have a past or current history of any of the following: o Severe, unstable or uncontrolled asthma o Eosinophilic esophagitis or other eosinophilic gastrointestinal disease o Mast cell disorder including mastocytosis, urticarial pigmentosa, and hereditary or idiopathic angioedema o Severe or life-threatening anaphylaxis within the previous 60 days **AND** • Member has injectable epinephrine available for immediate use at all times and counseling regarding proper use has been provided **AND** • Prescriber acknowledges member preparedness to adhere to complex up-dosing schedule and frequent visits to the administering healthcare facility **AND** • Prescriber acknowledges that Palforzia doses administered by a healthcare provider in the doctor's office or clinic are to be billed through the Health First Colorado medical benefit through the standard buy-and-bill process. Reauthorization: Member may receive reauthorization approval for 1 year if meeting the following: • Palforzia continues to be used in conjunction with a peanut-avoidant diet **AND** • Member continues to tolerate the prescribed daily doses of Palforzia **AND** • Member continues to have injectable epinephrine available for immediate use at all times **AND** • Member has not experienced recurrent asthma exacerbations **AND** • Member does not have eosinophilic esophagitis or other eosinophilic gastrointestinal disease **AND** • Member does not have a mast cell disorder including mastocytosis, urticarial pigmentosa, and/or hereditary/idiopathic angioedema **AND** • Member has not experienced any treatment-restricting adverse effects (such as repeated systemic allergic reaction and/or severe anaphylaxis) Maximum dose (maintenance): 300 mg daily	One year
PALYNZIQ (pegvaliase-pqpz)	**Palynziq** (pegvaliase-pgpz) prior authorization may be approved for members meeting the following criteria: • Member is at 18 years of age or older **AND** • Member has a diagnosis of phenylketonuria (PKU) **AND** • Member has a blood phenylalanine concentration > 600 mcmol/L **AND** • Member is not receiving Palynziq in combination with Kuvan (sapropterin dihydrochloride) **AND** • Member is actively on a phenylalanine-restricted diet **AND**	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member will have a phenylalanine blood level measured at baseline prior to initiation and every four weeks until a maintenance dose is established **AND** • Prescriber acknowledges that first dose is being administered under the supervision of a healthcare provider equipped to manage anaphylaxis **AND** • Prescriber acknowledges that any doses administered in the doctor's office or clinic are to be billed to the Health First Colorado medical benefit through the standard buy-and-bill process. Reauthorization: Member may receive reauthorization approval for 1 year if meeting the following: • Member is showing signs of continuing improvement, as evidenced by one of the following: o Blood phenylalanine level decrease of at least 20% from pre-treatment baseline **OR** o Reduction of blood phenylalanine below 600 mcmol/L at current dose or maximum dose after 16 weeks of treatment. Maximum dose: 60 mg per day	
PAXLOVID* (nirmatrelvir/ritonavir) **FDA-approved NDA-labeled product formulations*	Quantity limits: 30 tablets per 5 days (300mg/100mg) 20 tablets per 5 days (150mg/100mg) Minimum age: 12 years *Note: Effective 01/01/2025, 340B pharmacy claims for the FDA-approved NDA-labeled Paxlovid may be submitted through the Health First Colorado pharmacy benefit instead of the Pfizer PAXCESS™ Patient Support Program.*	
PCSK9 INHIBITORS Praluent, Repatha	PCSK9 inhibitors may be approved for members that meet the following criteria: • Medication is prescribed for one of the following diagnoses: o **Praluent** (alirocumab): heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease o **Repatha** (evolocumab): heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (defined below) Conditions Which Define Clinical Atherosclerotic Cardiovascular Disease • Acute Coronary Syndrome • History of Myocardial Infarction • Stable or Unstable Angina • Coronary or other Arterial Revascularization • Stroke • Transient Ischemic Attach • Peripheral Arterial Disease of Atherosclerotic Origin • PCSK9 inhibitor therapy is prescribed by, or in consultation with, one of the following providers: o Cardiologist o Certified Lipid Specialist	Initial Approval: 3 months Continuation Approval: One year

<table>
<tr><th>Drug Product(s)</th><th>Criteria</th><th>PA Approval Length</th></tr>
<tr><td></td><td>

Endocrinologist AND

Member is concurrently adherent (>80% of the past 180 days) on maximally tolerated dose (see table below) of statin therapy (must include atorvastatin and rosuvastatin). If intolerant to a statin due to side effects, member must have a one month documented trial with at least two other statins. For members with a past or current incidence of rhabdomyolysis, one month failure is not required AND
Member must be concurrently treated (in addition to maximally tolerated statin) with ezetimibe AND have a treated LDL ≥ 70 mg/dl for a clinical history of ASCVD or LDL ≥ 100 mg/dl if familial hypercholesterolemia AND
PA will be granted for 3 months initially. Additional one year approval for continuation will be granted with provider attestation of safety and efficacy with initial medication therapy

<table>
<tr><td>Atorvastatin 80mg</td></tr>
<tr><td>Fluvastatin 80 mg</td></tr>
<tr><td>Lovastatin 80 mg</td></tr>
<tr><td>Pravastatin 80 mg</td></tr>
<tr><td>Rosuvastatin 40 mg</td></tr>
<tr><td>Simvastatin 40 mg (80 mg not used in practice)</td></tr>
</table>
</td><td></td></tr>
<tr><td>PHARMACIST PRESCRIPTIONS</td><td>
<u>OTC Products:</u>
The following <u>OTC products</u> are eligible for coverage with a written prescription by an enrolled† pharmacist:

Oral emergency contraceptive products
Opill (norgestrel) oral daily contraceptive (effective 09/01/2023)
Naloxone (effective 09/01/2023)
Nicotine replacement therapy products including:

Nicotine gum (up to 220 units/fill)
Nicotine patch (up to 30 patches/30days)
Nicotine lozenge (up to 288 units/fill)

Children’s dextromethorphan suspension for members age 4-11 years (up to 150 ml per 30 days)
Children’s liquid and chewable acetaminophen for members age 2-11 years (up to 240 ml per 30 days)
Children’s liquid and chewable ibuprofen for members age 6 months-11 years (up to 240 mL per 30 days)

<u>Prescription Products:</u>
The following <u>prescription products</u> are eligible for coverage with a written prescription by an enrolled† pharmacist:

Oral contraceptives
Topical patch contraceptives*
Vaginal ring contraceptives* (effective 11/30/22)
Depo medroxyprogesterone contraceptive injection (effective 11/30/22)
Oral HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) medications
Smoking cessation medications (Chantix, varenicline, generic Zyban)
Nicotine replacement therapy products (Nicotrol)
Naloxone product formulations FDA-approved for use for the emergency treatment of opioid overdose (effective 5/12/22; retroactive to 1/14/22)
Opvee (nalmefene) intranasal

</td><td></td></tr>
</table>

Drug Product(s)	Criteria	PA Approval Length
	• Paxlovid *(effective 7/26/22; retroactive to 7/6/22)* • Statins *(effective 11/30/22)* **Other Medications:** Effective November 15, 2023, pharmacists may be indicated as a prescribing provider for certain medications which fall outside of collaborative practice agreements and statewide protocols; and pharmacy claims where pharmacists are enrolled† and indicated as the prescribing provider for these medications must meet the following criteria (note: claims submitted for criteria 1, 2, and 3 for an enrolled† pharmacist prescriber will receive denial code 6Z/50602 - "Provider Not Elig To Perform Serv/Dispense Product" and the prescribing pharmacist must call the Prime Therapeutics pharmacy help desk at 1-800-424-5725 in order to complete a prior authorization for the claim): 1. The member is 12 years of age or older AND 2. The drug being prescribed is not a controlled substance AND 3. The condition does not require a new diagnosis, is minor and generally self-limiting or has a Clinical Laboratory Improvement Amendments (CLIA)-waived test which the pharmacist administers and uses to guide clinical decision-making. OR 4. The prescription falls within prescriptive authority as outlined under Department of Regulatory Agencies (DORA) Rules incorporated in 3 CCR 719-1 17.00.00. OR 5. The prescription is for a medication which has Emergency Use Authorization (EUA) issued by the US Food and Drug Administration (FDA) that supersedes state law and allows a pharmacist to prescribe said medication. *See Preferred Drug List (PDL) for listing of preferred products. †Additional information regarding pharmacist enrollment can be found at https://hcpf.colorado.gov/provider-enrollment	
PHYSICIAN ADMINISTERED DRUGS	Medications administered in a doctor's office, clinic, outpatient hospital, or dialysis unit are only to be billed by those facilities through the Health First Colorado medical benefit using the standard buy-and-bill process and following procedures outlined in the PAD Billing Manual (located at https://www.colorado.gov/hcpf/physician-administered-drugs). Physician administered drugs (PADs) include any medication or medication formulation that is administered intravenously or requires administration by a healthcare professional (including cases where FDA package labeling for a medication specifies that administration should be performed by or under the direct supervision of a healthcare professional) and may only be billed through the pharmacy benefit when given in a long-term care facility or when administered in the member's home by a healthcare professional or home health service. Prior authorization for physician administered drugs requires documentation of the following (in addition to meeting any other prior authorization criteria if listed): • For drugs administered in the member's home by a home health agency or healthcare professional (home health administered): 1. Name of home health agency or healthcare professional 2. Phone number	

Drug Product(s)	Criteria	PA Approval Length
	3. Date and authorization number for home health authorization on file (when applicable for home health agencies) • For drugs administered in a long-term care facility: 1. Name of long-term care facility 2. Phone number of long-term care facility Effective January 18, 2022, a select number of PADs billed through the medical benefit will be subject to prior authorization requirements. Additional policy and procedure information, including the list of PADs subject to the new utilization management policy, can be found on the PAD Resources Page at https://hcpf.colorado.gov/physician-administered-drugs. For policies and procedures regarding extended-release injectable medications (LAIs) used for the treatment of mental health or substance use disorders, please see the applicable Appendix P section(s) for these products.	
POMBILITI and OPFOLDA (cipaglucosidase alfa-atga and miglustat)	**Pombiliti** (cipaglucosidase alfa-atga) and **Opfolda** (miglustat) may be approved when the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Member is ≥18 years of age AND • Member has an actual body weight of ≥ 40 kg AND • Member has a definitive diagnosis of late-onset Pompe disease confirmed by one of the following: o Deficiency of acid alpha-glucosidase (GAA) enzyme activity OR o Detection of biallelic pathogenic variants in the GAA by molecular genetic testing AND • Requested product is being prescribed by a provider specializing in the treatment of Pompe disease AND • Member has tried and failed† Lumizyme (alglucosidase alfa) or Nexviazyme (avalglucosidase-ngpt) AND • Pombiliti (cipaglucosidase alfa-atga) and Opfolda (miglustat) will be used in combination according to the approved product labeling AND • The requested medications will not be used in combination with other lysosomal acid alpha glucosidase (GAA) enzyme replacement therapies AND • More frequent monitoring of vital signs will be performed during Pombiliti infusion for members who are susceptible to fluid volume overload and those with acute underlying respiratory illness or compromised cardiac or respiratory function AND • Member is not pregnant or breastfeeding, and member and partners have been counseled on appropriate use of contraception AND • Member has documented baseline age-appropriate assessments, including motor function tests, muscle weakness, respiratory function, cardiac involvement testing, percent predicted forced vital capacity (FVC), and 6-minute walk test (6MWT) AND • Prescriber acknowledges consideration for administering antihistamines, antipyretics, and/or corticosteroids prior to Pombiliti (cipaglucosidase alfa) administration to reduce the risk of severe infusion-associated reactions. <u>Reauthorization</u>:	One year

Drug Product(s)	Criteria	PA Approval Length
	Pombiliti (cipaglucosidase alfa) and Opfolda (miglustat) may be approved for one year if member met initial approval criteria at the time of initiation of therapy AND meets the following: • Member has shown clinical improvement defined as an improvement or stabilization in percent predicted FVC and/or 6MWT AND • Member is being monitored for antibody formation and hypersensitivity Maximum Dose: Pombiliti (cipaglucosidase alfa): Members ≥40 kg: 20 mg/kg administered every 2 weeks Opfolda (miglustat): 8 capsules per 28 days †Failure is defined as lack of efficacy or intolerable side effects.	
PRETOMANID	**Pretomanid** prior authorization may be approved for members meeting the following criteria: • Member is an adult (≥ 18 years of age) **AND** • Member has a confirmed diagnosis of multidrug resistant tuberculosis **AND** • Pretomanid is prescribed by or in conjunction with an infectious disease specialist **AND** • Pretomanid is prescribed in combination with bedaquiline and linezolid by directly observed therapy (DOT) **AND** • Prescriber acknowledges member readiness and anticipated compliance with undergoing directly observed therapy (DOT) **AND** • Prescriber acknowledges that Pretomanid doses administered by a healthcare provider in a hospital, doctor's office, or clinic are to be billed through the Health First Colorado medical benefit through the standard buy-and-bill process. Maximum dose: 200 mg orally once daily	One year
PREVYMIS (letermovir)	**Prevymis** (letermovir) may be approved for members that meet the following criteria: • Member is a CMV-seropositive transplant recipient and meets ALL of the following: o Member is 18 years or older. o Member has received an allogeneic hematopoietic stem cell transplant or kidney transplant. o Member does not have severe hepatic impairment (Child-Pugh Class C). o Member is not receiving pitavastatin or simvastatin co-administered with cyclosporine. o Member is not receiving pimozide or ergot alkaloids. AND • The requested drug is being prescribed by or in consultation with an oncologist, hematologist, infectious disease specialist, or transplant specialist. AND • Provider agrees to monitor for CMV reactivation. AND • Dosing does not exceed 480 mg orally or dose does not exceed 240mg if co-administered with cyclosporine. AND • If request is for the IV injectable formulation, must provide medical justification why the patient cannot use oral therapy. AND • If request is for the IV injectable formulation, must be administered in a long-term care facility or in a member's home by a home healthcare provider.	100 days

Drug Product(s)	Criteria	PA Approval Length
	Length of Approval: Prevymis® will only be approved for 100 days Renewal: Authorization may be reviewed every 100 days to confirm that current medical necessity criteria are met and that the medication is effective (e.g. no evidence of CMV viremia).	
PROCYSBI (cysteamine)	Approval will be granted if the member is 2 years of age or older **AND** Has a diagnosis of nephropathic cystinosis **AND** documentation is provided to the Department that treatment with cysteamine IR (Cystagon®) was ineffective, not tolerated, or is contraindicated.	One year

PROMACTA (eltrombopag)	**Promacta** (eltrombopag) prior authorization may be approved for members meeting criteria for the following diagnoses:
	
	<u>Chronic immune idiopathic thrombocytopenia purpura:</u>
	• Confirmed diagnosis of chronic (> 3 months) immune idiopathic thrombocytopenia purpura AND
	• Must be prescribed by a hematologist AND
	• Member is at risk (documented) of spontaneous bleed as demonstrated by the following labs: AND
	  ○ Platelet count less than 20,000/mm3 or
	  ○ Platelet count less than 30,000/mm3 accompanied by signs and symptoms of bleeding
	• In the past 6 months, member has tried and failed (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions) systemic corticosteroids (e.g. prednisone 1 to 2 mg/kg for 2 to 4 weeks, or pulse dexamethasone 40 mg daily for 4 days), immunoglobulin replacement, or splenectomy.
	
	<u>Thrombocytopenia associated with hepatitis C:</u>
	• Member must have confirmed diagnosis of chronic hepatitis C associated thrombocytopenia AND
	• Must be prescribed by a gastroenterologist, infectious disease specialist, transplant specialist or hematologist AND
	• Member has clinically documented thrombocytopenia defined as platelets < 60,000 microL AND
	• Patients' degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy
	
	<u>Severe aplastic anemia:</u>
	• Member must have confirmed diagnosis of severe aplastic anemia AND
	• Must be prescribed by a hematologist AND
	• Member must have had a documented insufficient response to immunosuppressive therapy [antithymocyte globulin (ATG)] alone or in combination with cyclosporine and/or a corticosteroid
		One year*

Drug Product(s)	Criteria	PA Approval Length
	*All initial prior authorization approvals will be granted for 12 months. Further approvals for a maximum of 6 months require lab results and documentation for efficacy.	
PROPECIA (finasteride)	***Not covered for hair loss*** *Not qualified for emergency 3 day supply PA*	One year
PULMOZYME (dornase alfa)	**Pulmozyme** (dornase alfa) may be approved for members that meet the following criteria: • Member has a diagnosis of cystic fibrosis AND • Member is five years of age or older o For children < 5 years of age, Pulmozyme will be approved if the member has severe lung disease as documented by bronchoscopy or CT scan Pulmozyme twice daily will only be approved if patient has tried and failed an adequate trial of once daily dosing for one month All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon documentation from the prescriber that the member continues to benefit from Pulmozyme therapy. Quantity Limits: 30 ampules (2.5 mg/2.5 ml) per month	
PYRUKYND (mitapivat)	**Pyrukynd** (mitapivat) may be approved if the following criteria are met: • Member is ≥ 18 years of age **AND** • The requested medication is being used for treatment of hemolytic anemia with pyruvate kinase deficiency with least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 is a missense variant **AND** • Member does not have moderate to severe hepatic impairment, **AND** • Due to the risk of developing acute hemolysis, provider confirms that member has been counseled to avoid abrupt discontinuation of PYRUKIND (mitapivat) therapy **AND** • Prescriber confirms that potentially significant drug-drug interactions (such as those with itraconazole, ketoconazole, fluconazole, rifampin, efavirenz and other CYP3A inhibitors and inducers) will be carefully evaluated prior to initiating therapy with PYRUKIND (mitapivat), based on the current product labeling <u>Maximum Dose</u>: 100 mg/day <u>Quantity Limit</u>: 2 tablets/day <u>Reauthorization</u>: Reauthorization may be approved for 12 months if prescriber attests to observed benefit after 24 weeks of Pyrukynd (mitapivat) therapy, based on hemoglobin and/or markers of hemolysis and transfusion requirements.	Initial: 6 months Continued: One year
QBREXZA (glycopyrronium)	**Qbrexza** (glycopyrronium) prior authorization may be approved for members meeting the following criteria: • Member is 9 years of age or older **AND**	Initial: 3 months

Drug Product(s)	Criteria	PA Approval Length
	• Member has a diagnosis of primary hyperhidrosis occurring more than once weekly and symptoms cease at night **AND** • Member has a documented Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4 **AND** • There is documentation that the axillary hyperhidrosis is severe, intractable and disabling in nature as documented by at least one of the following: o Significant disruption of professional and/or social life as a result of excessive sweating **OR** o The condition is causing persistent or chronic cutaneous conditions (such as skin maceration, dermatitis, fungal infections, secondary microbial infections) **AND** • Prescriber has considered a trial of OTC topical antiperspirants (such as 20% aluminum chloride hexahydrate,15% aluminum chloride hexahydrate, or 6.25% aluminum chloride hexahydrate) Initial approval: 3 months Reauthorization: Member may receive reauthorization approval for 1 year if meeting the following: • Member has documented improvement of at least two points in Hyperhidrosis Disease Severity Scale (HDSS) score following initiation (or ongoing use) of Qbrexza regimen. Maximum dose: 1 cloth per day	Continued: One year
RADICAVA (edaravone)	**Radicava** (edaravone) may be approved if meeting the following criteria: • Member is ≥ 18 years of age AND • For requests for the IV formulation, the medication is being administered in a long-term care facility or in a member's home by a home healthcare provider OR for requests for the oral suspension formulation, the prescriber attests that the member is not a candidate for use for the IV formulation of Radicava (edaravone) AND • Member has a "definite" or "probable" diagnosis of amyotrophic lateral sclerosis (ALS) based on medical history and diagnostic testing which may include imaging and nerve conduction conditions studies AND • The requested medication is prescribed by or in consultation with a neurologist AND • The request meets <u>all</u> of the following: o Member has a diagnosis of ALS for 2 or less years (for new starts only) AND o Diagnosis has been established by or with the assistance of a neurologist with expertise in ALS using El Escorial or Airlie House diagnostic criteria (ALSFRS-R) AND o Member has normal respiratory function as defined as having a percent-predicated forced vital capacity of greater than or equal to 80% AND o The ALSFRS-R score is greater than or equal to 2 for all items in the criteria AND o Member does not have severe renal impairment (CrCl< 30 ml/min) or end stage renal disease. <u>Quantity Limits:</u>	6 months

Drug Product(s)	Criteria	PA Approval Length
	• IV Formulation: 28 bags per 28 days (initial dose) for the first month and 20 bags per 28 days for the remainder of the 6 months. • Oral Suspension Initiation: 14 doses of 105 mg each (28-day supply): Two cartons, each containing one 35 mL bottle of oral suspension or one carton containing two 35 mL bottles of oral suspension. • Oral Suspension Maintenance: 10 doses of 105 mg each, within 14 days: One carton containing one 50 mL bottle Renewal: Authorization may be reviewed every six months to confirm that current medical necessity criteria are met and that the medication is effective per improvement in ALSFRS-R score.	
RANITIDINE Capsule/Solution	Prescription ranitidine capsule and liquid formulations require prior authorization. Ranitidine capsule: Require the prescribing provider to certify that capsules are medically necessary and that the member cannot use the tablets. Ranitidine liquid: A prior authorization will be approved for members with a feeding tube or who have difficulty swallowing. A prior authorization is not required for children under 12 years of age.	One year
RAVICTI (glycerol phenylbutyrate)	**Ravicti** (glycerol phenylbutyrate) will only be approved for members meeting the following criteria: • Member must have a documented diagnosis of urea cycle disorder (UCD) • Member must be on a dietary protein restriction (verified by supporting documentation) • Member must have tried and failed Buphenyl as evidenced by uncontrolled hyperammonia over the past 365 days • Medication must be prescribed by a physician experienced in the management of UCD (e.g., geneticist)	One year
REBATE DISPUTE DRUGS	Medical necessity. Not qualified for emergency 3 day supply PA	One year
RECORLEV (levoketoconazole)	**Recorlev** (levoketoconazole) may be approved if the following criteria are met: • Member is ≥ 18 years of age AND • Member has a diagnosis of endogenous hypercortisolemia with Cushing's syndrome AND • Pituitary surgery is not an option or the member had surgery and it was not curative AND • The requested drug is NOT being prescribed to treat a fungal infection AND • Member does not concomitantly take a proton pump inhibitor, H2-receptor antagonist, sucralfate, or have excessive alcohol intake AND • The requested drug is being prescribed by, or in consultation with, an endocrinologist AND • Member does not have cirrhosis, acute liver disease, poorly controlled chronic liver disease, extensive metastatic liver disease, recurrent symptomatic cholelithiasis, or a prior history of azole antifungal-induced liver injury AND • Provider attests that the member's care plan will include frequent monitoring for significant adverse events (such as hepatotoxicity, QTc prolongation,	One year

Drug Product(s)	Criteria	PA Approval Length
	hypercortisolism, low serum testosterone and major drug-drug interactions) as described in product labeling. Maximum Dose: 1,200 mg/day	
RELYVRIO (sodium phenylbutyrate / taurursodiol)	**Relyvrio** (sodium phenylbutyrate/taurursodiol) may be approved if the following criteria are met: • Member is ≥ 18 years of age **AND** • Member has a definite diagnosis of sporadic or familial ALS, as defined by the revised El Escorial (Airlie House) criteria, with symptom onset within the past 18 months (for new starts only), **AND** • ALS disease progression is recorded at baseline (prior to initiation) using the Revised ALS Functional Rating Scale (ALSFRS-R), **AND** • The requested medication is prescribed by or in consultation with a neurologist **AND** • Member has normal respiratory function, defined as having a forced vital capacity (FVC) ≥ 80% of predicted, **AND** • Due to the high sodium content of this product, provider attests that member does NOT have heart failure, hypertension, renal impairment or other salt-sensitive medical conditions. Initial Approval: 6 months Reauthorization: After 6 months, members may receive approval to continue therapy if the following criteria are met: • The member has shown no adverse events due to Relyvrio treatment AND • The member has demonstrated response to Relyvrio treatment by showing significant clinical improvement or no decline documented using the Revised ALS Functional Rating Scale (ALSFRS-R). Authorization may be reviewed every six months to confirm that current medical necessity criteria are met, and that the medication is effective based on improvement or no decline based on the ALSFRS-R score. Maximum dose: 2 packets (dissolved in water) per day Quantity limit: 60 packets/30 days The above coverage criteria will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options and available peer-reviewed medical literature and clinical evidence. If use outside of stated coverage standards is requested, support with peer reviewed medical literature and/or subsequent clinical rationale shall be provided and will be evaluated at the time of request. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).	Initial Approval: 6 months Continuation Approval: One year
REVCOVI (elapegademase-lvlr)	**Revcovi** (elepegademase-lvlr) may be approved if the following criteria are met: • Member has a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID).	One year

Drug Product(s)	Criteria	PA Approval Length
	Maximum Dose: 0.4mg/kg per week (based on ideal body weight, IM administration)	
REZDIFFRA (resmetirom)	**Rezdiffra** (resmetirom) may be approved if meeting the following criteria: • Member is ≥ 18 years of age AND • Member has a diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with stage F2 to F3 fibrosis that has been confirmed by clinical presentation along with laboratory findings and/or imaging and/or biopsy results AND • The member does not have decompensated cirrhosis AND • The member's cardiovascular risk factors (such as hypertension, dyslipidemia, diabetes) have been evaluated and appropriately treated AND • Members who are overweight or have obesity have been counseled regarding implementation of lifestyle interventions (diet modification and exercise) to promote weight loss AND • The medication is being prescribed by or in consultation with a gastroenterologist, hepatologist, endocrinologist, or obesity medicine specialist AND • If member is concurrently taking a CYP2C8 inhibitor (such as clopidogrel), the dose of Rezdiffra will be appropriately adjusted per product labeling AND • Regarding concurrent statin therapy, provider attests that: o If member is concurrently taking rosuvastatin or simvastatin, the dose of the statin will be limited to 20 mg/day OR o If member is concurrently taking pravastatin or atorvastatin, the dose of the statin will be limited to 40 mg/day AND • Prescriber acknowledges that continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Maximum Dose: 100 mg/day Quantity Limit: 30 tablets/30 days	One year
RIVFLOZA (nedosiran)	**Rivfloza** (nedosiran) may be approved if meeting the following criteria: • Member is 9 years of age or older AND • Member has a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by either: o Genetic testing that demonstrates a mutation of the alanine glyoxylate aminotransferase (*AGXT*) gene OR o Liver analysis demonstrating absent or significantly reduced AGXT enzyme AND • Member has relatively preserved kidney function (eGFR ≥ 30 mL/min/1.73 m^2) AND • Medication is being prescribed by, or in consultation with a nephrologist or other healthcare provider with expertise in treating PH1 AND • Member has documented baseline urinary oxalate excretion or plasma oxalate concentrations. Quantity limit: one single-dose vial or prefilled syringe/month Initial approval: one year	One year

Drug Product(s)	Criteria	PA Approval Length
	Reauthorization: Member demonstrates response to medication as indicated by a positive clinical response from baseline urinary oxalate excretion or plasma oxalate concentration Members currently stabilized on a Rivfloza (nedosiran) regimen may receive prior authorization approval for continuation of therapy if meeting reauthorization criteria listed above.	
ROLVEDON (eflapegrastim-xnst)	**Rolvedon** (eflapegrastim-xnst) may be approved if the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Member is ≥ 18 years of age AND • Member has been diagnosed with a non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia, AND • Member is receiving Rolvedon (eflapegrastim-xnst) to decrease the incidence of infection, as manifested by febrile neutropenia AND • Member does not have mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation AND • The requested medication is being prescribed by or in consultation with an oncologist, hematologist, or critical care provider AND • Member has failed† an adequate trial of one preferred product in the Colony Stimulating Factor therapeutic class on the Preferred Drug List (PDL) OR prescriber attests to the clinical necessity for use of the requested agent. Approval: 1 year Maximum dose: 13.2 mg/14 days Quantity limit: one 13.2 mg prefilled syringe/14 days †Failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interaction.	
RUZURGI (amifampridine)	**Ruzurgi** (amifampridine) may be approved for members meeting the following criteria: • Member is 6 to less than 17 years of age AND • Member has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) Maximum dose: 100mg daily	One year
RYSTIGGO (rozanolixizumab)	**Rystiggo** (rozanolixizumab) may be approved if the following criteria are met: • For billing under the pharmacy benefit, medication is being administered in the member's home or in a long-term care facility (LTCF) by a healthcare professional AND • Member is ≥ 18 years of age AND • Member has a diagnosis of generalized myasthenia gravis that falls within Myasthenia Gravis Foundation of America (MGFA) Class II to IVa disease, AND • Member has a positive serologic test for anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibodies AND • Requested product is being prescribed by or in consultation with a neurologist AND • A baseline Quantitative Myasthenia Gravis (QMG) assessment has been documented, AND	Initial Approval: 6 months Continuation Approval: One year

Drug Product(s)	Criteria	PA Approval Length
	• Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥3 (with at least 3 points from non-ocular symptoms), AND • Patient has failed† treatment over at least 1 year with at least 2 immunosuppressive therapies (such as azathioprine, cyclosporine, tacrolimus, mycophenolate), or has failed at least 1 immunosuppressive therapy and required chronic therapeutic plasma exchange or intravenous immunoglobulin (IVIG) AND • As a precaution, consider discontinuation or Rystiggo and use of alternative therapies in members receiving long term therapy with medications that bind to the human Fc receptor (such as IVIG, other immunoglobulins, or other C5 complement inhibitors). † Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction Maximum Dose: 840 mg (6 mL) by subcutaneous infusion every 6 weeks Quantity Limit: One single-dose vial weekly for 6 weeks Reauthorization: Reauthorization for one year may be approved with prescriber attestation that member has experienced a positive clinical response to rozanolixizumab based on documented Quantitative Myasthenia Gravis (QMG) assessment AND/OR MG-Activities of Daily Living (MG-ADL) score. Continuation of Therapy: Members who are currently stabilized on the requested medication may receive one year approval to continue treatment if meeting reauthorization criteria listed above.	
SANDOSTATIN (octreotide)	Approved for acromegaly; carcinoid tumors; and vasoactive intestinal peptide tumors.	Lifetime
SAPHNELO (anifrolumab)	**Saphnelo** (anifrolumab) may be approved if the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND** • Member is ≥ 18 years of age with active, autoantibody-positive, moderate to severe systemic lupus erythematosus (SLE) AND is currently receiving standard therapy **AND** • The product is NOT being prescribed for severe active lupus nephritis or severe active central nervous system lupus **AND** • Member has had incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids **AND** • Member will maintain standard therapy for SLE while receiving Saphnelo (anifrolumab) therapy **AND** • Prescriber acknowledges that there are limited human data available for the use of anifrolumab in pregnancy, and data are insufficient to inform on drug-associated risks. A registry monitors pregnancy outcomes in women exposed to anifrolumab during pregnancy. Maximum Dose: 300 mg IV every 4 weeks Quantity Limit: One 300 mg vial/28 days	One year

Drug Product(s)	Criteria	PA Approval Length
SIVEXTRO (tedizolid)	**Sivextro** (tedizolid) may be approved for members ≥ 12 years of age if all of the following criteria are met: • Member has diagnosis of acute bacterial skin and skin structure infection (ABSSSI) caused by one of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus* Group (including *Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus*), and *Enterococcus faecalis.* AND • Member has adequate trial and/or failure of linezolid 600mg twice daily for 10 days. Failure is defined as: lack of efficacy with 10 day trial, allergy, intolerable side effects or significant drug-drug interactions Maximum dosing: 200mg daily for 6 days total duration	Six months
SKYCLARYS (omaveloxolone)	**Skyclarys** (omaveloxolone) may be approved if the following criteria are met: • Member is ≥ 16 years of age AND • Member has a diagnosis of Friedreich's ataxia based on genetic testing confirming loss-of-function mutations in the frataxin (FXN) gene AND • Requested product is being prescribed by or in consultation with a neurologist or physical medicine and rehabilitation physician AND • Member does not have severe hepatic impairment (Child-Pugh Class C) AND • If the member is ambulatory, a baseline neuromuscular assessment that includes all of the following elements has been performed and documented: o Bulbar function (swallowing or speaking) o Upper limb coordination o Lower limb coordination o Upright stability AND • Member is not concurrently taking any of the following medications: o Moderate or strong CYP3A4 inhibitor o Moderate or strong CYP3A4 inducer Initial approval: 6 months First reauthorization after 6 months: Reauthorization approval may be received for 1 year with provider attestation that: • Member is being monitored for clinically significant adverse effects such as: o Elevated ALT or AST (>5 times the ULN) with no evidence of liver dysfunction o Elevated ALT or AST (>3 times the ULN) with evidence of liver dysfunction (such as elevated bilirubin) o Elevated B-type natriuretic peptide (BNP) o Lipid abnormalities Subsequent reauthorizations: Reauthorization approval may be received for 1 year with provider attestation that:	See criteria

Drug Product(s)	Criteria	PA Approval Length
	• Member has a demonstrated response to Skyclarys (omaveloxolone) treatment by showing clinical improvement or no decline in bulbar function, upper and lower limb coordination, and upright stability AND • Member is being monitored for clinically significant adverse effects such as: o Elevated ALT or AST (>5 times the ULN) with no evidence of liver dysfunction o Elevated ALT or AST (>3 times the ULN) with evidence of liver dysfunction (such as elevated bilirubin) o Elevated B-type natriuretic peptide (BNP) o Lipid abnormalities Maximum dose with normal hepatic function: 150 mg/day Maximum dose with hepatic impairment: 100 mg/day Quantity limit: 90 capsules/30 days	
SODIUM CHLORIDE (Inhalation)	Broncho Saline is not covered under the pharmacy benefit. Sodium chloride (inhalation use) must be billed through medical.	N/A
SOHONOS (palovarotene)	**Sohonos** (palovarotene) may be approved for members meeting the following criteria: • Member is 8 years and older if female and 10 years and older if male AND • Member has a confirmed diagnosis of fibrodysplasia ossificans progressiva (FOP) AND • For members of reproductive potential, a negative pregnancy test has been obtained within one week prior to initiating Sohonos (palovarotene) therapy AND • Member is not pregnant AND • Prescriber has evaluated, and member has received, all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment AND • Member is not taking a tetracycline derivative, strong CYP3A4 inhibitor (such as ketoconazole, itraconazole, voriconazole, ritonavir) or strong CYP3A4 inducer (such as carbamazepine, rifampin) AND • Members who are able to become pregnant have been counseled to use effective contraception starting at least one month before starting Sohonos (palovarotene) therapy, during treatment, and for at least one month after the last dose AND • Member (and/or parent or caregiver) has been counseled about the potential for premature epiphyseal closure and resulting growth failure, and provider attests that member will be monitored for this effect. Initial approval: 6 months Reauthorization: Sohonos (palovarotene) may be approved for one year if new heterotopic ossification is reduced in volume from baseline, as verified by imaging.	Initial Approval: 6 months Continuation Approval: One year
SOLIRIS (eculizumab)	**Soliris** (ecluizumab) may be approved for members meeting all of the following criteria: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member is diagnosed with either Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS), Generalized Mysthenia Gravis (gMG), or Neuromyleitis Optica Spectrum Disorder (NMOSD) AND • Member does not have a systemic infection AND	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member must be administered a meningococcal vaccine at least two weeks prior to initiation of Soliris therapy and revaccinated according to current medical guidelines for vaccine use AND • Prescriber is enrolled in the Soliris (eculizumab) Risk Evaluation and Mitigation Strategy (REMS) program AND • Medication is prescribed by or in conjunction with a hematologist for PNH and by or in conjunction with a hematologist or nephrologist for aHUS and by or in conjunction with a neurologist for gMG or NMOSD AND • Member meets criteria listed below based on specific diagnosis: <u>Paroxysmal Nocturnal Hemoglobinuria</u> • Member is 18 years of age or older AND • Diagnosis of PHN must be accompanied by detection of PNH clones by flow cytometry diagnostic testing AND • Member demonstrate the presence of at least 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g. CD55, CD59, etc.) within at least 2 different cell lines (granulocytes, monocytes, erythrocytes) AND • Member has one of the following indications for therapy: o Presence of a thrombotic event o Presence of organ damage secondary to chronic hemolysis o Patient is pregnant and potential benefit outweighs potential fetal risk o Patient is transfusion dependent o Patient has high LDH activity (defined as ≥1.5 x ULN) with clinical symptoms AND • Member has documented baseline values for one or more of the following: o Serum lactate dehydrogenase (LDH) o Hemoglobin level o Packed RBC transfusion requirement <u>Atypical Hemolytic Uremic Syndrome</u> • Member is 2 months or older AND • Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS13 level (ADAMTS-13 activity level > 10%); AND • Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS) has been ruled out; AND • Other causes have been ruled out such as coexisting diseases or conditions (e.g. bone marrow transplantation, solid organ transplantation, malignancy, autoimmune disorder, drug-induced, malignant hypertension, HIV infection, etc.), Streptococcus pneumonia or Influenza A (H1N1) infection, or cobalamin deficiency AND • Documented baseline values for one or more of the following: o Serum lactate dehydrogenase (LDH)	

Drug Product(s)	Criteria	PA Approval Length
	o Serum creatinine/eGFR o Platelet count o Plasma exchange/infusion requirement <u>Generalized Myasthenia Gravis</u> • Member is 18 years or older AND • Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; AND • Patient has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies; AND • Physician has assessed the baseline Quantitative Myasthenia Gravis (QMG) score; AND • Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥6; AND • Patient has failed treatment over at least 1 year with at least 2 immunosuppressive therapies (e.g. azathioprine, cyclosporine, mycophenolate, etc), or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) <u>Neuromyelitis Optica Spectrum Disorder</u> • Member is 18 years or older AND • Member has a past medical history of one of the following: o Optic neuritis o Acute myelitis o Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting o Acute brainstem syndrome o Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions o Symptomatic cerebral syndrome with NMOSD-typical brain lesions AND • Member has a positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMP-IgG antibodies; AND • Diagnosis of multiple sclerosis or other diagnoses have been ruled out AND • Member has not failed a previous course of Soliris (eculizumab) therapy AND • Member has a history of failure, contraindication, or intolerance to rituximab therapy AND • Member has at least one of the following: o History of at least two relapses during the previous 12 months prior to initiating Soliris (eculizumab) o History of at least three relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Soliris (eculizumab) AND	

Drug Product(s)	Criteria	PA Approval Length
	• Member is not receiving Soliris in combination with any of the following: o Disease modifying therapies for the treatment of multiple sclerosis (such as Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.) OR o Anti-IL6 therapy Maximum Dose: 900mg weekly for 4 weeks induction followed by 1200mg every 2 weeks maintenance dose.	
SOLOSEC (secnidazole)	**Solosec** (secnidazole) may be approved for members meeting the following criteria: • Solosec® is being prescribed for bacterial vaginosis in an adult female member AND • Member has adequately trialed and failed an oral OR topical formulation of metronidazole (Failure is defined as lack of efficacy of a 7 day trial, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy) AND • Member has adequately trialed and failed an oral OR topical formulation of clindamycin (Failure is defined as lack of efficacy of a 7 day trial, allergy, intolerable side effects, significant drug-drug interaction, or contraindication to therapy) Maximum Quantity: 1 packet of 2 grams per 30 days	One year
SOLU-CORTEF (hydrocortisone sodium succinate)	**Solu-Cortef** (hydrocortisone sodium succinate) injection may be approved if meeting the following criteria: • The requested medication is being prescribed for emergency use for adrenal insufficiency OR • The medication is being administered in the member's home or in a long-term care facility by a healthcare professional	One year
STRENSIQ (asfotase alfa)	**Strensiq** (asfotase alfa) may be approved if all of the following criteria are met: Member has a diagnosis of either perinatal/infantile- OR juvenile-onset hypophosphatasia (HPP) based on all of the following a. Member was ≤ 18 years of age at onset b. Member has/had clinical manifestations consistent with hypophosphatasia at the age of onset prior to age 18 (e.g. vitamin B6-dependent seizures, skeletal abnormalities: such as rachitic chest deformity leading to respiratory problems or bowed arms/legs, "failure to thrive"). c. Member has/had radiographic imaging to support the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g. infantile rickets, alveolar bone loss, craniosynostosis) d. Member has one of the following: elevated urine concentration of phosphoethanolamine (PEA), elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test, or elevated urinary inorganic pyrophosphate (PPi) AND e. Molecular genetic test has been completed confirming mutations in the ALPL gene that encodes the tissue nonspecific isoenzyme of ALP (TNSALP) within 30 days of initiation. If genetic test is negative, approval will not be granted past 30 days.	Six months

Drug Product(s)	Criteria	PA Approval Length
	f. Prescriber is a specialist in the area of the members disease (such as an endocrinologist)	

SYMDEKO (tezacaftor/ivacaftor and ivacaftor)	**Symdeko** (tezacaftor/ivacaftor and ivacaftor) may be approved for members that meet the following criteria:
	• The member has a diagnosis of cystic fibrosis AND
	• The member is 6 years of age or older AND
	• The member has one of the following mutations:
	  ○ Homozygous for the F508del mutation in the CFTR gene 2 OR
	  ○ Heterozygous for the F508del mutation in the CFTR gene and one of the following mutations: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D1270N, D579G, 711+3A-G, E831X, S945L, S977F, F1052V, K1060T, A1067T, R1070W, F1074L, D1152H, 3272-26A-G, 2789+5G-A, 3849-10kbC-T, or another FDA approved gene mutation
	  AND
	• Member has ALT, AST, and bilirubin at baseline and tested every 3 months for the first year AND
	• Member has a baseline ophthalmological examination and periodic follow-up exams for cataracts AND
	• Must be prescribed by or in consultation with a pulmonologist or gastroenterologist AND
	• Member is not receiving dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator AND
	• Member has had 2 negative respiratory cultures for any of the following organisms: *Burkholeria cenocepacia*, *Burkholderia dolosa*, or *Mycobacterium abscessus* in the past 12 months.
		One year

SYNAGIS (palivizumab)	**Pharmacy prior authorization requests for Synagis must be submitted by fax using the Synagis prior authorization form found at https://hcpf.colorado.gov/pharmacy-resources and is for home or long-term care facility administration only. The 2023-2024 Synagis season will begin October 1, 2023 and end April 1, 2024. The Department will continue to monitor RSV reporting and reassess Health First Colorado member needs based on CDC virology reporting and AAP guidance.** **Synagis given in a doctor's office, hospital or dialysis unit is to be billed directly by those facilities as a medical benefit. Medical prior authorization requests must be submitted at https://hcpf.colorado.gov/par. Synagis may only be a pharmacy benefit if the medication is administered in the member's home or long-term care facility.** **Key Points** 1. No more than five (5) doses per season. Five (5) doses provides more than six (6) months of protective serum concentration. 2. Synagis is not recommended for controlling outbreaks of health care-associated disease. 3. Synagis is not recommend for prevention of health care-associated RSV disease. 4. Infants born later in the season may require less than 5 doses to complete therapy to the end of the season.	Maximum of 5 doses per season

Drug Product(s)	Criteria	PA Approval Length
	5. Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization. 6. Synagis is not recommended to prevent wheezing, nosocomial disease, or treatment of RSV. 7. Synagis is not routinely recommended for patients with a diagnosis of Down syndrome unless they also have a qualifying indication listed below. 8. Synagis should not be administered if Beyfortus (nirsevimab) has been administered. 9. If Synagis is initiated for the season and <5 doses were administered, if nirsevimab is available the infant should receive one dose of nirsevimab. No further Synagis should be administered. In the **first year of life** Synagis is recommended for: a. For infants born before 29w 0d gestation. b. For infants born before 32w 0d **AND** with chronic lung disease (CLD) of prematurity **AND** requirements of >21% oxygen for at least 28 days after birth. c. For infants with hemodynamically significant heart disease (acyanotic heart disease who are receiving medication to control congestive heart failure (CHF) and will require cardiac surgical procedures or infants with moderate to severe pulmonary hypertension**) AND** born within 12 months of onset of the RSV season. d. Infants who undergo cardiac transplantation during the RSV season. e. For infants with cyanotic heart defects **AND** in consultation with a pediatric cardiologist **AND** requirements of >21% oxygen for at least 28 days after birth **AND** continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) f. Infants with neuromuscular disease or pulmonary abnormality **AND** is unable to clear secretions from the upper airways g. Infants who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy) h. An infant with cystic fibrosis with clinical evidence of CLD **AND/OR** nutritional compromise In the **second year of life** Synagis is recommended for: a. Children born before 32w 0d **AND** with CLD of prematurity **AND** requirements of >21% oxygen for at least 28 days after birth **AND** continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) b. A child who will be profoundly immunocompromised during the RSV season (solid organ or hematopoietic stem cell transplantation, receiving chemotherapy) c. Children with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities of chest radiography or chest computed tomography that persist when stable) **OR** weight for length less than the 10th percentile. d. Children who undergo cardiac transplantation during the RSV season. **Additional Prior Authorization Request (PAR) Instructions** • All pharmacy Synagis PARs must be signed by the prescribing physician, even if submitted by a home health agency or long-term care facility. • Members or providers may appeal Synagis prior authorization denials through the normal member appeals process. • Synagis given in a doctor's office, hospital or dialysis unit is to be billed directly by those facilities as a medical benefit. Synagis may only be a	

Drug Product(s)	Criteria	PA Approval Length
	pharmacy benefit if the medication is administered in the member's home or long-term care facility, or when administered in a doctor's office because the patient cannot access home health services.	
SYPRINE (trientine)	**Syprine** (trientine) may be approved if all of the following criteria are met: • Must be prescribed in conjunction with a gastroenterologist, hepatologist, or liver transplant specialist. **AND** • Member has a diagnosis of Wilson's Disease meeting at least one of the following criteria: o Hepatic parenchymal copper content of ≥250µg/g dry weight o Presence of Kayser-Fleischer Ring in cornea o Serum ceruloplasmin level <50mg/L o Basal 24-hour urinary excretion of copper >100µg (1.6 µmoles) o Genetic testing results indicating mutation in ATP7B gene **AND** • Member has failed a three-month trial or is intolerant to penicillamine. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions **AND** • Member has failed a three-month trial or is intolerant to generic trientine. Failure is defined as a lack of efficacy, allergy, intolerable side effects, contraindication to, or significant drug-drug interactions.	One year
TAVALISSE (fostamatinib)	**Tavalisse** (fostamatinib) prior authorization may be approved for members meeting the following criteria: • Member is 18 years of age or older AND • Member has a documented diagnosis of chronic immune thrombocytopenia AND • Member has trialed and failed at least ONE of the following therapies (Failure is defined as a lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions): o Promacta (eltrombopag) or other thrombopoietin receptor agonist o Corticosteroids o Immunoglobulin o Splenectomy AND • Baseline platelet count prior to initiation is less than $30x10^9$/L or $30x10^9$/L to $50x10^9$/L with symptomatic bleeding AND • Prescriber attests to monitoring liver function tests and CBC monthly until a stable dose is achieved AND • Tavalisse (fostamatinib) is not being used as dual therapy with a thrombopoietin receptor agonist AND • Tavalisse (fostamatinib) is being prescribed by or in consultation with a hematologist AND • Initial prior authorization approval will be for 3 months. Continuation may be approved with verification of documented platelet response (platelet count ≥50x109/L) Quantity Limit: 60 tablets per 30 days	Initial Approval: 3 months Continuation Approval: One year
TAVNEOS	**Tavneos** (avacopan) may be approved when the following criteria are met:	One year

Drug Product(s)	Criteria	PA Approval Length
(avacopan)	• Member is ≥18 years of age AND • Severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis AND • Member did not achieve sustained remission within one year of treatment with glucocorticoid therapy AND • Member is currently receiving, and will continue to be on a standard care plan for ANCA-associated vasculitis that includes a glucocorticoid AND • Member does not have active, untreated and/or uncontrolled chronic liver disease (such as chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis and cirrhosis) AND • A baseline liver panel (ALT, AST, alkaline phosphatase, total bilirubin) will be obtained before initiating Tavneos (avacopan), then every 4 weeks after start of therapy for the first 6 months of treatment and as clinically indicated thereafter AND • Labs to screen for Hepatitis B infection (HBsAg and anti-HBc) have been evaluated prior to initiation of Tavneos (avacopan) therapy AND • Member is not currently taking a strong CYP3A4 inducer (such as carbamazepine, phenytoin, rifampin, phenobarbital) AND • If member is on concurrent therapy with a strong CYP3A4 inhibitor (such as itraconazole, ketoconazole diltiazem, ritonavir), Tavneos (avacopan) dose will be adjusted according to the approved product labeling. Reauthorization: Tavneos (avacopan) may be approved for one year if: • Member met initial approval criteria at the time of initiation of therapy AND • Provider attests that sustained remission was achieved on Tavneos (avacopan) therapy within the previous 12 months. Maximum dose: 60 mg/day Quantity limit: 180 capsules/30 days Continuation of therapy: Members who are currently stabilized on Tavneos (avacopan) therapy may receive approval to continue that medication.	
TARGETED IMMUNE MODULATORS (IV and physician-administered products*) *Coverage criteria for self-administered formulations of products listed in this section are included on the Preferred Drug List (PDL).	**ACTEMRA** (tocilizumab) **IV injection** and biosimilar formulations (Tyenne, Tofidence) may be approved if meeting the following criteria: • For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • The requested medication is being prescribed for an FDA-labeled indication and within an FDA-approved age range (per product package labeling) AND • The member is not concomitantly receiving any other biological DMARDs AND • The member has trialed and failed‡ all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA labeled for use for the prescribed indication (with only one preferred TNF inhibitor trial required). Maximum Dose: 800 mg per infusion for cytokine release syndrome (CRS) or rheumatoid arthritis; and 162 mg once weekly for other indications **CIMZIA** (certolizumab pegol) **lyophilized powder for reconstitution** may be approved if meeting the following criteria:	One year (for Stelara, see criteria)

Drug Product(s)	Criteria	PA Approval Length
	• For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • The requested medication is being prescribed for use for an FDA-labeled indication (per product package labeling) AND • The member has trialed and failed† all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA labeled for use for the prescribed indication (with only one preferred TNF inhibitor trial required). Members currently receiving subcutaneous injections of CIMZIA from a health care professional using the lyophilized powder for injection dosage form may receive approval to continue therapy with that agent. **COSENTYX** (secukinumab) **IV injection** may be approved if meeting the following: • For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Request meets criteria listed for Cosentyx (secukinumab) on the Health First Colorado Preferred Drug List (PDL) for the requested FDA-approved indication. **ENTYVIO** (vedolizumab) **IV injection** may be approved if meeting the following criteria: • If billing under the pharmacy benefit, the medication is being administered in the member's home or in a long-term care facility AND • The member is ≥ 18 years of age with moderately-to-severely active ulcerative colitis or moderately-to-severely active Crohn's disease AND • The member has had an inadequate response with, is intolerance to, or had demonstrated dependence on corticosteroids AND • The member is not receiving Entyvio (vedolizumab) in combination with Cimzia, Enbrel, Humira, infliximab, Simponi or Tysabri AND For Members Treating Crohn's Disease: • Entyvio (vedolizumab) is initiated and titrated per FDA-labeled dosing for Crohn's disease AND • The member meets one of the following: o The member has trialed and failed‡ therapy with Humira (adalimumab) or an infliximab-containing product (such as Renflexis) OR o The member is ≥ 65 years of age with increased risk of serious infection For Members Treating Ulcerative Colitis: • Entyvio (vedolizumab) is initiated and titrated per FDA-labeled dosing for ulcerative colitis AND • The member meets one of the following: o The member has trialed and failed‡ therapy with Humira (adalimumab) or Simponi (golimumab) or an infliximab-containing product (such as Renflexis) OR o The member is ≥ 65 years of age with increased risk of serious infection. .	

Drug Product(s)	Criteria	PA Approval Length
	FASENRA (mepolizumab) **prefilled syringe** formulation may be approved if meeting the following: • For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Request meets all criteria listed for FASENRA (mepolizumab) on the Health First Colorado Preferred Drug List (PDL) for the requested indication. Members currently receiving subcutaneous injections of FASENRA (mepolizumab) from a health care professional using the prefilled syringe formulation may receive approval to continue therapy with that agent. **NUCALA** (mepolizumab) **lypholized powder vial for injection** may be approved if meeting the following: • For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Request meets criteria listed for NUCALA (mepolizumab) on the Health First Colorado Preferred Drug List (PDL) for the requested indication. Members currently receiving subcutaneous injections of NUCALA (mepolizumab) from a health care professional using the lyophilized powder vial for injection may receive approval if meeting reauthorization criteria. **OMVOH** (mirikizumab-mrkz) **IV injection** may be approved if meeting the following: • For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Request meets criteria listed for Omvoh (mirikizumab-mrkz) on the Health First Colorado Preferred Drug List (PDL) for the requested FDA-approved indication. **ORENCIA** (abatacept) **IV injection** may be approved if meeting the following criteria: • For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • The request meets one of the following: o Member has a diagnosis of moderate to severe rheumatoid arthritis or polyarticular juvenile idiopathic arthritis (pJIA) AND has trialed and failed* all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication OR o Member is an adult with a diagnosis of psoriatic arthritis AND has trialed and failed‡ Humira or Enbrel AND Xeljanz IR AND Taltz or Otezla OR o The requested medication is being prescribed for the prophylaxis of acute graft versus host disease (aGVHD) in combination with a calcineurin inhibitor and methotrexate in patients undergoing	

Drug Product(s)	Criteria	PA Approval Length
	hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor. **REMICADE** (infliximab brand/generic and biosimilar products) **IV injection** may be approved if meeting the following criteria: • If billing under the pharmacy benefit, the medication is being administered in the member's home or in a long-term care facility AND • The member has one of the following diagnoses: o Crohn's disease (and ≥ 6 years of age) o Ulcerative colitis (and ≥ 6 years of age) o Rheumatoid arthritis (and ≥ 4 years of age) o Psoriatic arthritis (and ≥ 18 years of age) o Ankylosing spondylitis (and ≥ 18 years of age) o Juvenile idiopathic arthritis (and ≥ 4 years of age) o Plaque psoriasis (and ≥ 18 years of age) o Hidradenitis suppurativa (HS) AND • The prescribed infliximab agent is Renflexis (infliximab-abda); OR if the prescribed infliximab agent is Remicade or a biosimilar other than Renflexis, then the member has trialed and failed‡ Renflexis AND • The member meets <u>one</u> of the following, based on prescribed indication: o For continuation of infliximab therapy that was initiated in the hospital setting for treating severe ulcerative colitis, no additional medication trial is required OR o For treatment of moderate to severe hidradenitis suppurativa, no additional medication trial is required OR o For all other prescribed indications, the member has trialed and failed‡ all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA labeled for use for the prescribed indication (with only one preferred TNF inhibitor trial required). <u>Maximum Dose</u>: 10 mg/kg **RITUXAN** (rituximab**) IV and subcutaneous injection** may be approved for administration in a long-term care facility or in a member's home by a home healthcare provider AND for members who meet one of the following: • Have diagnosis of moderate to severe rheumatoid arthritis AND have tried and failed both Enbrel and Humira OR • Have diagnosis of chronic lymphocytic leukemia OR • Have a diagnosis of Non-Hodgkins Lymphoma OR • Have a diagnosis of pemphigus vulgaris (PV) OR • Have a diagnosis of multiple sclerosis. **SIMPONI** (golimumab**) IV injection (Simponi Aria)** may be approved if meeting the following criteria: • For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND** • The request meets <u>one</u> of the following:	

Drug Product(s)	Criteria	PA Approval Length
	○ Member has a diagnosis of moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, or ankylosing spondylitis AND has trialed and failed‡ all preferred agents in the "Targeted Immune Modulators" PDL drug class that are FDA-labeled for use for the prescribed indication OR ○ Member is an adult with a diagnosis of psoriatic arthritis AND has trialed and failed‡ Humira or Enbrel AND Xeljanz IR AND Taltz or Otezla. **SPEVIGO** (spesolimab) **IV injection** may be approved if meeting the following criteria: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member is 12 years of age and older and weighing at least 40 kg AND • Member is experiencing a generalized pustular psoriasis (GPP) flare AND • Member has previously tried and failed‡ two of the following: oral cyclosporine, infliximab-containing product, adalimumab-containing product, or etanercept. Dosing Limit: 2700mg/90 days (900mg per submitted claim) **SKYRIZI** (risankizumab) **IV injection** may be approved if meeting the following criteria: • For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Member is ≥ 18 years of age AND • The requested medication is being prescribed for induction dosing for moderately-to-severely active Crohn's disease AND • The member has trialed and failed‡ all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA-labeled for use for the prescribed indication (Humira). **STELARA** (ustekinumab) **IV injection** may be approved if meeting the following criteria: • For billing under the pharmacy benefit, Stelara (ustekinumab) IV injection is being administered by a healthcare professional in the member's home or in a long-term care facility AND • The member is ≥ 18 years of age AND • The member has a diagnosis of moderate-to-severely active Crohn's disease or moderate-to-severely active ulcerative colitis AND • The member has trialed and failed‡ all preferred agents in the Targeted Immune Modulators PDL drug class that are FDA-labeled for use for the prescribed indication AND • The request meets one of the following: ○ The member has trialed and failed‡ Entyvio (vedolizumab) or an infliximab-containing product (such as Renflexis) OR ○ The prescriber confirms that maintenance subcutaneous dosing regimen of Stelara (ustekinumab) will be dispensed by a pharmacy for self-administration by the member or for administration in the member's home or LTCF AND	

Drug Product(s)	Criteria	PA Approval Length

	• If meeting criteria listed above, prior authorization approval will be placed based on one of the following:
	  ○ If maintenance subcutaneous therapy will be dispensed by a pharmacy for self-administration by the member or for administration in the member's home or LTCF, initial 16-week approval will be placed for both IV and subcutaneous formulations, and one-year prior authorization approval for subcutaneous maintenance therapy continuation may be provided based on clinical response OR
	  ○ If maintenance subcutaneous therapy will be billed as a medical claim for administration in the doctor's office or other clinical setting, initial 16-week approval will be placed for the IV formulation.
	
	Maximum Dose: 520 mg initial IV dose for members weighing > 85 Kg (187 pounds)
	Quantity Limit: For initial IV infusion, four 130 mg/26 mL single-dose vials
	
	TEZSPIRE (tezepelumab-ekko) **vial and pre-filled syringe** formulations may be approved if the following criteria are met (note: criteria for self-administered pre-filled pen formulation is located on Health First Colorado Preferred Drug List (PDL)):
	• For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND
	• Member is 12 years of age or older AND
	• Member has a diagnosis of severe asthma that is uncontrolled or inadequately controlled as demonstrated by 2 or more asthma exacerbations requiring use of oral or systemic corticosteroids and/or hospitalizations and/or ER visits in the year prior to medication initiation AND
	• The requested medication is being administered as add-on therapy (not monotherapy) AND
	• Member is taking a high dose inhaled corticosteroid and a long-acting beta agonist AND
	• The requested medication will not be used in concomitantly with other biologics indicated for asthma AND
	• Member is not taking maintenance oral corticosteroids AND
	• Member has documented baseline FEV1.
	
	Reauthorization may be approved if member has shown clinical improvement as documented by one of the following:
	• Improvement in lung function, measured in FEV1 OR
	• Reduction in the number of asthma exacerbations, defined as a decrease in use of oral or systemic corticosteroids and/or reduced asthma related hospitalizations and/or ER visits.
	
	Members currently stabilized on a Tezspire (tezepelumab-ekko) regimen that was initiated prior to 1/1/2023 may receive prior authorization approval for continuation of therapy.
	
	Maximum Dose: 210 mg once every 4 weeks
	
	XOLAIR (omalizumab) **lypholized powder vial for injection** may be approved if meeting the following:	

Drug Product(s)	Criteria	PA Approval Length
	• For billing under the pharmacy benefit, the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Request meets criteria listed for XOLAIR (omalizumab) on the Health First Colorado Preferred Drug List (PDL) for the requested indication. Members currently receiving subcutaneous injections of XOLAIR (omalizumab) from a health care professional using the lyophilized powder vial for injection may receive approval to continue therapy with that agent. ‡Failure is defined as lack of efficacy with a three-month trial, allergy, intolerable side effects, contraindication to therapy, or significant drug-drug interaction. Trial and failure of Xeljanz IR will not be required when the requested medication is prescribed for ulcerative colitis for members ≥ 50 years of age that have an additional CV risk factor. Trial and failure of preferred TNF inhibitors will not be required when the requested medication is prescribed for pJIA in members with documented clinical features of lupus.	
TARPEYO (budesonide)	**Tarpeyo** (budesonide) may be approved if the following criteria are met: • Member is ≥ 18 years of age **AND** • Member has proteinuria associated with primary immunoglobulin A nephropathy (IgAN) with a risk of rapid disease progression **AND** • The diagnosis has been confirmed by biopsy, **AND** • Most recent labs indicate a urine protein-to-creatinine ratio (UPCR) of ≥1.5 g/g, **OR** proteinuria > 0.75 g/day, **AND** • Member has been receiving the maximum (or maximally tolerated) dose of either an ACE inhibitor **OR** angiotensin receptor blocker (ARB) for at least 90 days, **AND** • Member has had an adequate trial of a generic oral budesonide regimen at maximally tolerated recommended doses and has failed to achieve a clinically significant response **AND** • The medication is prescribed by or in consultation with a nephrologist **AND** • Prescriber plans to reduce dosage from 16 mg/day to 8 mg/day during the final 2 weeks of the 9-month course of treatment • Approval will be limited to 10 months for completion of 9-month course of therapy. Maximum dose: 16 mg/day Quantity limit: 120 4 mg capsules/30 days This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether delayed-release budesonide slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.	10 months
TEPEZZA (teprotumumab)	**Tepezza** (teprotumumab) may be approved if the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long term care facility **AND**	See criteria

Drug Product(s)	Criteria	PA Approval Length
	• Member is 18 years of age or older **AND** • Member has a documented diagnosis of Thyroid Eye Disease (TED) **AND** • Member's prescriber must be in consultation with an ophthalmologist or endocrinologist **AND** • Member does not require immediate surgical ophthalmological intervention **AND** • Member does not currently require orbital (eye) surgery and is not planning corrective surgery/irradiation during therapy **AND** • Member is euthyroid, mild hypothyroid, mild hyperthyroid (defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits) or seeking care for dysthyroid state from an endocrinologist or other provider experienced in the treatment of thyroid diseases **AND** • Member does not have corneal decompensation unresponsive to medical management **AND** • Member had an inadequate response, or there is a contraindication or intolerance, to high-dose intravenous glucocorticoids **AND** • Member is not pregnant prior to initiation of therapy and effective forms of contraception will be implemented during treatment and for 6 months after the last dose of teprotumumab. If member becomes pregnant during treatment, Tepezza should be discontinued, **AND** • If member is diabetic, member is being managed by an endocrinologist or other provider experienced in the treatment and stabilization of diabetes **AND** • Authorization will be issued for one course of therapy of eight infusions Maximum Dose: Eight infusions per one year	
THIOLA EC (tiopronin DR)	**Thiola EC** (tiopronin DR) may be approved for members meeting the following criteria: Member is an adult or pediatric weighing 20kg or more AND Member has severe homozygous cystinuria AND Member has increased fluid intake and diet modifications have been implemented for the prevention of cysteine stone formation AND Member has trial and failure of urinary alkalization agent (such as potassium citrate or potassium bicarbonate) AND • Member has trial and failure of Thiola IR (tiopronin). Failure is defined as lack of efficacy with 14 day trial, allergy, intolerable side effects or significant drug-drug interactions. Maximum dose: Thiola EC 1500mg per day	One year
THROMBOLYTIC ENZYMES	Approved for **IV Catheter Clearance or Occluded AV Cannula** if given in member's home or long-term care facility.	One year
TOBACCO CESSATION	Effective 11/01/18 prior authorization will not be required for tobacco cessation medications including nicotine gum, nicotine patch, nicotine lozenge, nicotine inhaler (Nicotrol®), varenicline (Chantix®), and bupropion SR (Zyban®).	

Drug Product(s)	Criteria	PA Approval Length
	Smoking and tobacco cessation resources are available at no charge to members or providers through the Colorado QuitLine found at coquitline.org or by calling 1-800-QUIT-NOW.	
TOPICAL COMPOUND CLAIMS	Effective 7/1/2024, compound claims for topical formulations exceeding $200.00 require prior authorization and are subject meeting the following: • The prescriber attests that a reasonable effort has been made to use the more cost-effective compound product ingredient when multiple products with the same active ingredient are available, covered, and clinically appropriate for use in the compound AND • Each active ingredient in the compounded medication is FDA-approved or national compendia supported for the condition being treated AND • The compound ingredient therapeutic amounts and combinations are supported by national compendia or peer-reviewed literature for the condition being treated in the requested route of delivery AND • Any compound product ingredient requiring drug specific prior authorization will be subject to meeting criteria listed on the Health First Colorado Preferred Drug List or Appendix P.	One year
TPN PRODUCTS	Approval will be given if included as part of TPN therapy administered in the member's home or in a long-term care facility by a home healthcare provider. If given in the hospital or physician's office, the claim must be billed as a medical expense.	Lifetime
TRIKAFTA (elexacaftor, tezacaftor, ivacaftor)	**Trikafta** (elexacaftor, tezacaftor, ivacaftor) may be approved for members meeting the following criteria: • Member is ≥ 6 years of age (oral tablet) OR 2 to 5 years of age (oral granules) AND • Member has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CTFR) gene or a mutation in the CFTR gene that is responsive based on in vitro data AND • Member continues to receive standard of care CF therapies (such as bronchodilators, inhaled antibiotics, dornase alfa, and hypertonic saline) AND • If initiating therapy, member must have liver function tests checked within 3 months without abnormal results (ALT, AST, ALP, or GGT ≥ 3 × ULN, or total bilirubin ≥2 × ULN) AND • Baseline Forced Expiratory Volume (FEV1) must be collected Maximum Dose: 84 tablets per 28 days	One year

TRYVIO (aprocitentan)	**Tryvio** (aprocitentan) may be approved for members meeting the following criteria:
	• Member is 18 years of age or older AND
	• Member has a diagnosis of hypertension AND
	• Member has a blood pressure > 140/90 mmHg and meets both of the following:
	  ○ The requested product is being prescribed concurrently with a regimen containing at least three preferred antihypertensive agents from different drug classes AND
	  ○ Member has trialed and failed a trial of an antihypertensive regimen containing three preferred antihypertensive agents from different drug classes at maximally tolerated doses (failure is defined as lack of efficacy with 4-week trial, allergy, intolerable side effects, or significant drug-drug interaction)
	• AND
	• Member is not receiving a concurrent endothelin receptor antagonist, AND
	• Member does not have NYHA class III-IV heart failure AND
		Initial: 3 months
		
		Continued: One year

Drug Product(s)	Criteria	PA Approval Length
	• Prescriber attests that member's liver function tests are less than 3 times the upper limit of normal (ULN) prior to initiating Tryvio (aprocitentan) therapy, the member does not have moderate to severe hepatic impairment, and that liver function tests, complete blood count (CBC) and hemoglobin will be monitored during therapy AND • Prescriber attests that members who can become pregnant have been counseled regarding the potential for major birth defects and to use acceptable contraception prior to initiation of treatment, during treatment, and for one month after stopping Tryvio (aprocitentan) therapy. Dose limit: 12.5 mg/day Initial approval: 3 months Reauthorization: Tryvio (aprocitentan) may be approved for one year if, after 3 months of therapy, the member's blood pressure is within the goals established by national guidelines.	
TYBOST (cobicistat)	**Tybost** (cobicistat) may be approved for members meeting the following criteria: • Member has a diagnosis of HIV-1 AND • Member is currently being treated with atazanavir or darunavir only AND • Member is not taking cobicistat-containing drugs, or ritonavir-containing drugs AND • Member has failed treatment with ritonavir (failure defined as intolerable side effect, allergy, or lack of efficacy).	One year
TYSABRI (natalizumab)	**Tysabri** (natalizumab) may be approved if the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND** • Medication is not currently being used in combination with immunosuppresants (azathioprine, 6-mercaptopurine, methotrexate) or TNF-alpha inhibitors (adalimumab, certolizumab pegol, infliximab) **AND** • Member does not have anti-JC virus antibodies at baseline **AND** • <u>If prescribed for induction of remission of moderate to severe Crohn's disease</u>: o The patient is ≥ 18 years of age **AND** o Prescriber and member are enrolled in the CD TOUCH® REMS program **AND** o Member has tried and failed aminosalicylates **AND** o Member has tried and failed corticosteroids **AND** o Member has tried and failed immunomodulators **AND** o Member has tried and failed two TNF-alpha inhibitors (such as adalimumab, certolizumab pegol, or infliximab). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interactions **AND** o Tysabri (natalizumab) is prescribed by or in consultation with a gastroenterologist. • <u>If prescribed for relapsing remitting multiple sclerosis (RRMS)</u>: o The patient is ≥ 18 years of age; **AND**	One year

Drug Product(s)	Criteria	PA Approval Length
	○ Prescriber and member are enrolled in the MS TOUCH® REMS program **AND** ○ Tysabri is prescribed by or in consultation with a neurologist or a physician that specializes in the treatment of multiple sclerosis **AND** ○ Request meets <u>one</u> of the following: ▪ Member has had trial and failure* with any <u>two</u> high efficacy disease-modifying therapies (such as ofatumumab, ocrelizumab, fingolimod, rituximab, or alemtuzumab) **OR** ▪ Member has a diagnosis of highly active relapsing MS (based on measures of relapsing activity and MRI markers of disease activity such as numbers of galolinium-enhanced lesions) AND has had trial and failure* with any <u>one</u> high efficacy disease-modifying therapy (such as ofatumumab, fingolimod, rituximab, ocrelizumab, or alemtuzumab). <u>Exemption</u>: If member is currently receiving and stabilized on Tysabri (natalizumab), they may receive prior authorization approval to continue therapy. *Failure is defined as intolerable side effects, drug-drug interaction, contraindication, or lack of efficacy. Lack of efficacy is defined as one of the following: • On MRI, presence of any new spinal lesions, cerebellar or brainstem lesions, or change in brain atrophy **OR** • Signs and symptoms on clinical exam consistent with functional limitations that last one month or longer.	
TZIELD (teplizumab-mzwv)	**Tzield** (teplizumab-mzwv) may be approved if the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Member is ≥ 8 years of age AND • Member has a diagnosis of Stage 2 type 1 diabetes, AND • The member's clinical history does not suggest type 2 diabetes, AND • The requested medication is being prescribed in consultation with an endocrinologist AND • Prescriber attests that patient will be monitored for Cytokine Release Syndrome (CRS) AND • Prescriber attests that appropriate premedication will be administered prior to each Tzield (teplizumab-mzwv) infusion, AND • Prescriber attests that lymphocyte counts and liver function tests will be closely monitored during the treatment period, AND • Member has no serious infections at time of starting therapy AND • Member is not pregnant or planning to become pregnant. <u>Dosing limit:</u> Approval will be placed to allow for one 14-day course of treatment	One year
ULTOMIRIS (ravulizumab)	**Ultomiris** (ravulizumab) may be approved if the following criteria are met: • For requests for the <u>IV formulation,</u> prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND** • Member is diagnosed with either Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS), Neuromyelitis Optica Spectrum Disorder (NMOSD), or Generalized Myasthenia Gravis (gMG) **AND**	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member has been vaccinated for meningococcal disease according to current ACIP guidelines at least two weeks prior to Ultomiris initiation OR member is receiving 2 weeks of antibacterial drug prophylaxis if meningococcal vaccination cannot be administered at least 2 weeks prior to starting Ultomiris **AND** • Member does not have unresolved *Neisseria meningitidis* or any systemic infection **AND** • Prescriber is enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program **AND** • Medication is administered by or in consultation with a hematologist for PNH and by or in consultation with a hematologist or nephrologist for aHUS, by or in consultation with a neurologist for gMG, or by or in consultation with a neurologist or ophthalmologist for NMOSD **AND** • Member meets criteria listed below for specific diagnosis: o <u>Paroxysmal nocturnal hemoglobinuria (PNH):</u> ▪ Member is one month of age or older if prescribing the IV formulation OR is ≥ 18 years of age if prescribing the subcutaneous formulation **AND** ▪ Diagnosis of PNH must be accompanied by detection of PNH clones by flow cytometry diagnostic testing **AND** ▪ Baseline values are documented for the following: • Serum lactate dehydrogenase (LDH) • Hemoglobin levels • Packed RBC transfusion requirement **AND** ▪ Member has <u>one</u> of the following indications for therapy: • Presence of a thrombotic event • Presence of organ dysfunction secondary to chronic hemolysis • Member is transfusion dependent • Member has uncontrolled pain secondary to chronic hemolysis o A<u>typical hemolytic uremic syndrome (aHUS):</u> ▪ Member is one month of age or older if prescribing the IV formulation OR ≥ 18 years of age if prescribing the subcutaneous formulation **AND** ▪ Member does not have Shiga toxin E. coli related HUS (STEC-HUS) **AND** ▪ Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS13 level or a trial of plasma exchange did not result in clinical improvement **AND** ▪ Baseline values are documented for the following: • Serum LDH • Serum creatinine/eGFR • Platelet count • Dialysis requirement o <u>Generalized myasthenia gravis:</u> ▪ Member is 18 years of age or older **AND** ▪ Member has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies **AND**	

Drug Product(s)	Criteria	PA Approval Length
	▪ Member has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease **AND** ▪ Member has a MG-Activities of Daily Living (MG-ADL) total score of ≥ 6 **AND** ▪ Member has trial and failure of treatment over at least 1 year with at least 2 immunosuppressive therapies (such as azathioprine, cyclosporine, mycophenolate, etc.) OR has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG). o Neuromyelitis optica spectrum disorder (NMOSD): ▪ Member is 18 years of age or older **AND** ▪ Member has a positive test for anti-aquaporin-4 (AQP4) antibodies **AND** ▪ Exclusion of alternative diagnoses have been evaluated **AND** ▪ Member has at least one of the following clinical characteristics: • Optic neuritis • Acute myelitis • Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting) • Acute brainstem syndrome • Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions • Symptomatic cerebral syndrome with NMOSD-typical brain lesions. Maximum dose: 3.6 g every 8 weeks (IV formulation) 490 mg once weekly (subcutaneous formulation)	
UPLIZNA (inebilizumab)	**Uplizna** (inebilizumab) may be approved for members meeting the following criteria: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member is an adult (≥ 18 years of age) AND has a positive serologic test for anti-aquaporin-4 (AQP4) antibodies AND has a documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD) AND • Member has a past medical history of at least one of the following: o Optic neuritis o Acute myelitis o Area postrema syndrome; episode of otherwise unexplained hiccups or nausea and vomiting o Acute brainstem syndrome o Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions o Symptomatic cerebral syndrome with NMOSD-typical brain lesions AND • Member does not have active Hepatitis B infection, as confirmed by negative surface antigen [HBsAg] and anti-HBV tests AND • Provider has screened for immunizations the member is due to receive according to immunization guidelines AND any live or live-attenuated vaccines	One year

Drug Product(s)	Criteria	PA Approval Length
	will be administered at least 4 weeks prior to initiation of Uplizna (inebilizumab) AND • Member does not have active or untreated latent tuberculosis AND • For members of child-bearing potential, member is not pregnant or breastfeeding and has been counseled to use effective contraception while receiving Uplizna (inebilizumab) and for at least 6 months after the last dose AND • Uplizna (inebilizumab) is prescribed by, or in consultation with, a neurologist AND • Member will receive corticosteroid, antihistamine, and antipyretic premedication prior to each infusion. Maximum dose: Initial 300 mg IV infusion followed by 300mg IV infusion 2 weeks later, followed by 300mg IV infusion every 6 months (starting 6 months from the initial infusion).	
VACCINES	Pharmacies that have entered into a collaborative practice agreement with one or more physicians may receive reimbursement (with claim submission through the Health First Colorado medical benefit) for enrolled pharmacists to administer the following vaccines (claims for pharmacist administration of vaccines are not covered under the pharmacy benefit): • Covid-19 • Influenza • Pneumococcal • Rabies • Shingles • Tdap • Td All other vaccines must be billed on Colorado 1500 form as a medical expense unless administered in a long-term care facility. Pharmacy claims for vaccines administered in a long-term care facility may receive prior authorization approval with verification that the member is residing in a long-term care facility. Vivotif oral typhoid vaccine may be approved under the pharmacy benefit for out-patient administration. Vaccines are not qualified for emergency 3-day supply prior authorization. Additional information: • Pharmacist Services Billing Manual: https://hcpf.colorado.gov/pharm-serv • Immunizations Billing Manual: https://hcpf.colorado.gov/immunizations-billing-manual Vaccines for Children (VFC) Program Administrative Fee Reimbursement: Effective 8/6/23, pharmacies registered with the Vaccines for Children (VFC) program may bill the pharmacy benefit and receive reimbursement for the administration fee only when the claim is for a VFC acquired vaccine. Reimbursement by pharmacy claim submission for vaccine administration fees may only be received for children under 19 if the pharmacy is registered with the VFC program AND if the vaccine product included on the claim submission was provided at zero cost through the VFC program. For administration fee reimbursement that is not submitted as a pharmacy claim, providers may bill for reimbursement through medical. If assistance is needed for VFC program-	

Drug Product(s)	Criteria	PA Approval Length
	registered pharmacies processing pharmacy claims for vaccine administration fee reimbursement, please contact the Prime Therapeutics pharmacy help desk at 1-800-424-5725. Additional information: • VFC program: https://cdphe.colorado.gov/immunization/vaccines-for-children • Immunizations Billing Manual: https://hcpf.colorado.gov/immunizations-billing-manual	
VAFSEO (vadadustat)	**Vafseo** (vadadustat) may be approved if the following criteria are met: • Member is ≥ 18 years of age AND • Member has a diagnosis of anemia due to chronic kidney disease (CKD) and has been receiving dialysis for at least three months AND • Member does not have uncontrolled hypertension AND • Member does not have cirrhosis or acute, active liver disease AND • Member does not have any known active malignancies AND • Member has trialed and failed at least one month of treatment with an erythropoiesis-stimulating agent (ESA) AND • Laboratory tests to evaluate ALT, AST, alkaline phosphatase, total bilirubin, hemoglobin and iron status will be performed at baseline and during treatment with Vafseo (vadadustat), according to product labeling AND • Prescriber has counseled members who are taking an oral iron supplement, other products containing iron, or a phosphate binder that Vafseo (vadadustat) should be administered at least 1 hour before taking these products to avoid reducing the effectiveness of Vafseo (vadadustat) AND • Prescriber attests that member's medication profile has been reviewed for clinically significant drug interactions, including: o BCRP substrates (such as sulfasalazine, ciprofloxacin, acyclovir, nitrofurantoin, zidovudine): Monitor patients more frequently for adverse reactions and consider dose reduction of the BCRP substrate drug AND o OAT1 inhibitors (such as probenecid, rifampicin) AND o OAT3 inhibitors (such as gemfibrozil, probenecid, teriflunomide): Closely monitor for too large or too rapid an increase in hemoglobin response and for adverse reactions AND • Regarding concurrent statin therapy, provider attests that: o If member is concurrently taking simvastatin, the dose of simvastatin will be limited to 20 mg/day OR o If member is concurrently taking rosuvastatin, the dose of rosuvastatin will be limited to 5 mg/day AND • The requested medication is not being prescribed as a substitute for red blood cell transfusions in patients who require immediate correction of anemia AND • The requested medication is not being prescribed for treatment of anemia of chronic kidney disease in patients who are not on dialysis AND • Member has been counseled that Vafseo (vadadustat) tablets should not be cut, crushed or chewed. Maximum Dose: 600 mg/day	6 months

<table>
<tr><th>Drug Product(s)</th><th>Criteria</th><th>PA Approval Length</th></tr>
<tr><td></td><td>Initial Approval: 6 months

Reauthorization: Reauthorization for 6 months may be approved with documentation of lab results that indicate a clinically meaningful increase in hemoglobin level since initiation of treatment with Vafseo (vadadustat).

Note: Vafseo (vadadustat) should not be continued beyond 24 weeks of therapy if a clinically meaningful increase in hemoglobin level has not been achieved. Alternative explanations for an inadequate response should be sought and treated before re-starting therapy.</td><td></td></tr>
<tr><td>VALCYTE (valganciclovir hydrochloride)</td><td>Effective 10/15/19: Brand Valcyte solution is no longer covered as a favored product (see section “Brand Name Medications and Generic Mandate” for brand product coverage details).

Valcyte® will be approved for members with diagnosis of Cytomegalovirus (CMV) retinitis AND acquired immunodeficiency Syndrome (AIDS) per dosing guidelines below
OR
For members that require prophylactic treatment for CMV post kidney, heart, liver, or kidney-pancreas transplant per dosing guidelines below
OR
For members ≤ 16 years of age that are at high risk of CMV infection and need prophylactic treatment post heart, liver, or kidney transplant per dosing guidelines below.

<table>
<tr><th colspan="2">Adult Dosage</th></tr>
<tr><td>Treatment of CMV retinitis</td><td>Induction: 900 mg (two 450 mg tablets) twice a day for 21 days
Maintenance: 900 mg once a day</td></tr>
<tr><td>Prevention of CMV disease in heart or kidney-pancreas patients</td><td>900 mg once a day within 10 days of transplantation 100 days post-transplantation</td></tr>
<tr><td>Prevention of CMV disease in kidney transplant patients</td><td>900 mg once a day within 10 days of transplantation until 200 days post-transplantation</td></tr>
<tr><td>Prevention of CMV disease in liver transplant patients</td><td>900 mg once a day for 100 days after transplantation</td></tr>
<tr><th colspan="2">Pediatric Dosage</th></tr>
<tr><td>Prevention of CMV disease in kidney transplant patients 4 month to 16 years of age</td><td>Dose once daily within 10 days of transplantation until 200 days post-transplantation</td></tr>
<tr><td>Prevention of CMV disease in heart transplant patients 1 month to 16 years of age</td><td>Dose once a day within 10 days of transplantation until 100 days post-transplantation</td></tr>
<tr><td>Prevention of CMV disease in liver transplant for children</td><td>For patients < 15 kg: 15 mg/kg/dose PO once daily.
For patients > 15 kg: 500 mg/m^2/dose PO once daily).
Maximum dose: 900 mg/dose once daily for 3-6 months after transplantation.</td></tr>
</table>
</td><td>One year</td></tr>
</table>

Drug Product(s)	Criteria	PA Approval Length
VALTOCO (diazepam)	**Valtoco** (diazepam) may be approved for members meeting the following criteria: • Member is 6 years of age or older AND • Valtoco is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern and medical records are provided supporting this diagnosis AND • Member is stable on regimen of antiepileptic medications AND • Medication is being prescribed by or in conjunction with the same provider/provider team who manages the member's anti-epileptic regimen AND • Member is educated on appropriate identification of seizure cluster and Valtoco (diazepam) administration and not to exceed 2 doses per seizure cluster. Quantity Limits: 5mg and 10mg: 4 nasal spray units per year unless used / damaged / lost (limited to 2 units per fill) 15mg and 20mg: 8 nasal spray units per year unless used / damaged / lost (limited to 4 units per fill) Members are limited to one prior authorization approval on file for Valtoco (diazepam) and Nayzilam (midazolam). If member is currently receiving Valtoco (diazepam) intranasal, they may receive prior authorization approval to continue.	One year
VELTASSA (patiromer)	**Veltassa** (patiromer) prior authorization will be approved for members that meet the following criteria: • Documented diagnosis of hyperkalemia (serum potassium > 5 mEq/L) AND • Veltassa is not being used for emergent hyperkalemia AND • Member does not have severe gastrointestinal motility dysfunction AND • Member does not have hypomagnesemia (serum magnesium < 1.4 mg/dL).	One year
VEOZAH (fezolinetant)	Veozah (fezolinetant) may be approved if the following criteria are met: • Member is ≥ 18 years of age AND • Member has been diagnosed with moderate to severe vasomotor symptoms (such as hot flashes and sweating) associated with menopause AND • Member has tried and failed two alternate oral or transdermal estrogen-containing products. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction OR member has moderate to high risk for complications related to estrogen therapy AND • Member does not have known cirrhosis AND • Member does not have severe renal impairment (eGFR 15 to 29mL/min/1.73 m2) or end-stage renal disease (ESRD) AND • Member's baseline hepatic transaminases prior to starting fezolinetant therapy have been documented and are less than two times the upper limit of normal AND • Provider attests that hepatic transaminases will be closely monitored during fezolinetant therapy as described in the FDA product labeling AND	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member is not taking a medication that is a CYP1A2 inhibitor (fluvoxamine, mexiletine, cimetidine, and others). Maximum dose: One 45 mg tablet/day Quantity limit: 30 tablets/30 days	
VERIPRED (prednisolone)	A prior authorization will only be approved if a member has tried and failed on a generic prednisolone product (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions.)	One year
VERQUVO (vericiguat)	**Verquvo** (vericguat) may be approved if the following criteria are met: • Member is 18 years of age or older AND • Member is not pregnant AND • Member has a diagnosis of heart failure with reduced ejection fraction (LVEF <45%) AND • Member is not concurrently taking long-acting nitrates or nitric oxide donors (such as isosorbide dinitrate, isosorbide mononitrate, or transdermal nitroglycerin), riociguat, or PDE-5 inhibitors (such as vardenafil or tadalafil) AND • Member has a trial and failed ONE agent from EACH of the following drug classes (failure is defined as lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions): o ACE inhibitor (such as enalapril or lisinopril) OR ARB (such as valsartan or candesartan) OR angiotensin receptor-neprilysin inhibitor [ARNI] (such as sacubitril/valsartan) o Beta blocker (bisoprolol, carvedilol, metoprolol succinate) o Aldosterone antagonist (spironolactone or eplerenone) o SGLT-2 inhibitor: Farxiga (dapagliflozin), Jardiance (empagliflozin) or Invokana (canagliflozin). Maximum dose: 10 mg/day Quantity limits: • 2.5mg: 2 tablets/day • 5mg: 2 tablets/day • 10mg: 1 tablet/day	One year
VERSED (midazolam) Injection	*Effective 09/25/2019 prior authorization is no longer required for generic midazolam vial/syringe formulations.*	
VIJOICE (alpelisib)	**VIJOICE** (alpelisib) may be approved if the following criteria are met: • Member is ≥ 2 years of age **AND** • Member requires systemic therapy for severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) **AND** • Due to the risk of severe adverse reactions, provider confirms that VIJOICE (alpelisib) will not be used in the oncology setting **AND** • Prescriber confirms that potentially significant drug-drug interactions with strong CYP3A4 inducers (such rifampin, carbamazepine, phenytoin and St. John's Wort) will be carefully evaluated prior to initiating therapy with VIJOICE (alpelisib), based on the current product labeling **AND** • Prescriber attests that a pre-treatment pregnancy test will be performed for members of reproductive potential and that member will be advised to use	One year

Drug Product(s)	Criteria	PA Approval Length
	effective contraception (including condoms for male patients) during treatment and for 1 week after the final dose **AND** • Provider and patient or caregiver are aware that continued US FDA approval of VIJOICE (alpelisib) for PIK3CA-Related Overgrowth Spectrum may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Maximum Dose: 250 mg/day	
VILTEPSO (viltolarsen)	**Viltepso** (viltolarsen) may receive approval if meeting the following criteria: • Medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member must have genetic testing confirming mutation of the Duchenne muscular dystrophy (DMD) gene that is amenable to exon 53 skipping AND • Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e. neurologist, cardiologist, pulmonologist, or physical medicine and rehabilitation physician) AND • Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be measured before starting Viltepso (viltolarsen). Consider measurement of glomerular filtration rate prior to initiation of Viltepso (viltolarsen) AND • Members with known renal function impairment should be closely monitored during treatment with Viltepso (viltolarsen), as renal toxicity has occurred with similar drugs AND • If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a baseline Brooke Upper Extremity Function Scale score or Forced Vital Capacity (FVC) documented AND • Provider and patient or caregiver are aware that continued US FDA approval of Viltepso (viltolarsen) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in a confirmatory trial. Reauthorization: After 24 weeks of treatment with Viltepso (viltolarsen), member may receive approval to continue therapy for one year if the following criteria are met: • Member has shown no intolerable adverse effects related to Viltepso (viltolarsen) treatment at a dose of 80mg/kg IV once a week AND • Member has normal renal function or stable renal function if known impairment AND • Provider attests that treatment with Viltepso (viltolarsen) is necessary to help member improve or maintain functional capacity based on assessment of trajectory from baseline for ambulatory or upper extremity function or Forced Vital Capacity (FVC). Maximum dose: 80 mg/kg administered as an IV infusion once weekly (documentation of patient's current weight with the date the weight was obtained). Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.	Initial: 6 months Continuation: One year

Drug Product(s)	Criteria	PA Approval Length
VIMIZIM (elosulfase alfa)	**Vimizim** (elosulfase alfa) prior authorization may be approved for members meeting the following criteria: • Member is ≥ 5 years of age **AND** • Member has a confirmed diagnosis of mucopolysaccharidosis (MPS) Type IV A (Morquio A syndrome) **AND** • Medication is being administered by a healthcare provider in the member's home or in a long-term care facility (and meets approval criteria listed in "Physician Administered Drug" section of Appendix P) **AND** • Vimizim is prescribed by or in consultation with an endocrinologist **AND** • Prescriber acknowledges that Vimizim will be administered under close medical observation due to risk of life-threatening anaphylactic reactions.	One year
VITAMINS* (prescription vitamins)	**Coverage criteria outlined in this section apply to vitamin products available as prescription drugs. For over-the-counter product coverage, please see "OTC Products" section.* The following prescription vitamin products will be covered without prior authorization: • Vitamin D • Vitamin K **General prescription vitamin criteria: Prescription vitamin products will be approved for: • ESRD, CRF, renal insufficiency, diabetic neuropathy or renal transplant OR • Members under the age of 21 with a disease state or clinical diagnosis associated with prohibited nutritional absorption processes as a secondary effect OR • Members with Erythema Bullosum Hydroxocobalamin injection will be approved for: • Members meeting any general prescription vitamin criteria** OR • Methylmalonic acidemia (MMA) Cyanocobalamin will be approved for: • Members meeting any general prescription vitamin criteria** OR • Vitamin B12 deficiency Folic acid prescription products will be approved for: • Members meeting any general prescription vitamin criteria** OR • Folic acid 1mg will be approved for female members without a prior authorization OR • Members currently taking methotrexate or pemetrexed OR • Documented folic acid deficiency by the treating clinician (megaloblastic and macrocytic anemia are the most common. Some drugs or other conditions may cause deficiency as well) OR • Homocysteinemia OR • Sickle cell disease OR • Female members prescribed folic acid for the prevention of a neural tube defect during pregnancy or for the prevention of miscarriage Cyanocobalamin/folic acid/pyridoxine prescription products will be approved for: • Members meeting any general prescription vitamin criteria** OR • Members with homocysteinemia or homocystinuria OR • Members on dialysis OR	One year

Drug Product(s)	Criteria	PA Approval Length
	• Members with (or at risk for) cardiovascular disease For prescription iron-containing products see "Anti-anemia Medications" Metanx will be approved for members with non-healing diabetic wounds.	
VOWST (fecal microbiota spore, live-brpk)	**Vowst** (fecal microbiota spore, live-brpk) may be approved if the following criteria are met: • Member is ≥ 18 years of age AND • Member has had recent laboratory confirmation of a positive C. difficile stool sample AND • Member has a history of ≥ three episodes of C. difficile infection (CDI) within the past 12 months that were treated with appropriate antibiotic therapy and is receiving Vowst following completion of treatment for the third (or further) CDI episode AND • Treatment with the requested medication is following treatment of recurrent CDI with appropriate antibiotic therapy AND • Requested product is being prescribed by or in consultation with a gastroenterologist or infectious disease specialist AND • Antibacterial therapy for CDI has been discontinued 2 to 4 days prior to initiating Vowst therapy and concurrent antibacterial therapy will not be initiated during the 3-day course of Vowst therapy AND • Member has been evaluated to rule out dysphagia, known esophageal stricture, Zenker's diverticulum, gastroparesis, prior history of small bowel obstruction, prior colectomy or colostomy AND • Provider attests that member has (1) received instructions regarding the magnesium citrate (or polyethylene glycol electrolyte solution) pre-treatment regimen, and (2) has been advised to take nothing by mouth except water for at least 8 hours prior to taking the first dose of Vowst. Approval will be placed to allow for one treatment course. Quantity limit: 12 capsules	One treatment course
VOXZOGO (vosoritide)	**Voxzogo** (vosoritide) may be approved if the following criteria are met: • Member is ≥ 5 years of age AND • Member has a genetically-confirmed diagnosis of achondroplasia with open epiphyses AND • Prescriber acknowledges that in order to reduce the risk of low blood pressure the member should have adequate food intake and drink 240 to 300 mL of fluid in the hour prior to Voxzogo administration, AND • Prescriber agrees to monitor body weight, growth, and physical development every 3 to 6 months, and to permanently discontinue Voxzogo upon confirmation of no further growth potential, indicated by closure of epiphyses AND • Provider and patient or caregiver are aware that continued US FDA approval of Voxzogo (vosoritide) for achondroplasia with open epiphyses may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Maximum Dose: 0.8 mg/day	Initial: 6 months Continued: One year

Drug Product(s)	Criteria	PA Approval Length
	Quantity Limit: Three 10-packs of 0.4 mg, 0.56 mg, or 1.2 mg vials/30 days Initial Authorization: 6 months Reauthorization for Voxzogo (vosoritide) for 12 months may be approved if linear growth is improving and closure of epiphyses has not yet occurred.	
VOYDEYA (danicopan)	**Voydeya** (danicopan) may be approved if the following criteria are met: • Member is ≥18 years of age AND • Member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by high sensitivity flow cytometry AND • Voydeya (danicopan) is being prescribed to treat breakthrough hemolysis with symptomatic residual anemia as add-on therapy to current C5 inhibitor therapy with ravulizumab or eculizumab AND • Member does not have severe hepatic disease (Child-Pugh Class C) AND • Member does not have any active infections caused by an encapsulated bacteria (such as Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type b) AND • Member has received vaccination against encapsulated bacteria (such as Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type b) at least 2 weeks prior to initiation of Voydeya (danicopan) therapy AND • Member has residual anemia (hemoglobin < 9.5 g/dL) at baseline, with absolute reticulocyte count ≥ 120 × 109/L with or without transfusion support, and has been stable on ravulizumab or eculizumab therapy for at least 6 months AND • If urgent Voydeya (danicopan) therapy is indicated in a patient who is not up to date with vaccines, or the vaccines were administered within the last 2 weeks, prescriber attests that the member will receive appropriate antibacterial drug prophylaxis, and the vaccines will be administered as soon as possible AND • Requested product is being prescribed by or in consultation with a hematologist, immunologist or nephrologist AND • Prescriber attests that member's medication profile has been reviewed for clinically significant drug interactions, including: o BCRP substrates: Monitor patients more frequently for adverse reactions and consider dose reduction of the BCRP substrate drug (ciprofloxacin, atorvastatin, rosuvastatin, acyclovir, nitrofurantoin, zidovudine and others) AND o For concomitant rosuvastatin, the dose should not exceed 10 mg once daily AND o P-gp substrates: Dose adjustment might be necessary for P-gp substrates (apixaban, colchicine, cyclosporine, dabigatran, digoxin, edoxaban, rivaroxaban, tacrolimus) where minimal concentration changes may lead to serious adverse reactions. Quantity limit: 120 tablets/30 days Maximum dose: 600 mg/day Initial Approval: 6 months Reauthorization: Approval for 1 year may be given with prescriber attestation that member's hemoglobin has increased by ≥2 g/dL from baseline while on Voydeya (danicopan) therapy.	Initial: 6 months Continued: One year

Drug Product(s)	Criteria	PA Approval Length
VUSION OINTMENT (miconazole/zinc oxide/white petrolatum)	A prior authorization will only be approved if a member has failed on an OTC antifungal **and** a generic prescription antifungal. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)	One year
VYEPTI (eptinezumab)	**Vyepti** (eptinezumab) may be approved if the following criteria are met: • For claims billed through the pharmacy benefit, prescriber verifies that the medication is being administered by a healthcare professional in the member's home or in a long-term care facility **AND** • Member is 18 years of age or older **AND** • Member has a diagnosis of episodic (fewer than 15 headache days monthly) or chronic migraine (headaches occurring 15 days or more monthly, where at least 8 of these days per month for at least 3 months are migraine days with or without aura) **AND** • Member has tried and failed two oral preventive pharmacological agents listed as Level A per the most current American Headache Society/American Academy of Neurology guidelines (such as divalproex, topiramate, metoprolol, propranolol). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction AND • The requested medication is not being used in combination with another CGRP medication **AND** • Member has trial and failure of all preferred calcitonin gene-related peptide inhibitors (CGRPis) indicated for preventative therapy listed on the pharmacy benefit preferred drug list **AND** • Initial dose is no more than 100 mg every 3 months, and if Vyepti 300 mg is requested, prescriber verifies the member has tried and had an inadequate response (no less than 30% reduction in headache frequency in a 4-week period) to the 100 mg dosage **AND** • Initial authorization will be limited to 6 months. Continuation (12-month authorization) will require documentation of clinically relevant improvement with no less than 30% reduction in headache frequency in a 4-week period. <u>Maximum dose</u>: 300 mg IV every 3 months	Initial: 6 months Continued: One year
VYJUVEK (beremagene geperpavec-svdt)	**Vyjuvek** (beremagene geperpavec-svdt) may be approved if the following criteria are met: • For billing under the pharmacy benefit, medication is being administered in the member's home or in a long-term care facility (LTCF) by a healthcare professional AND • Member is ≥ 6 months of age, AND • Member has a documented diagnosis of dystrophic epidermolysis bullosa AND • Member must have undergone genetic testing confirming mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene AND • The requested medication is being prescribed by or in consultation with a provider who has expertise in treating dystrophic epidermolysis bullosa AND • Member has been counseled regarding use of highly effective contraceptive method(s) while receiving treatment. Quantity limit: one 1 mL vial of biological suspension plus one 1.5 mL excipient gel vial per week	One year

Drug Product(s)	Criteria	PA Approval Length
	Reauthorization: Prescribing provider attests that clinical condition is improving on Vyjevek (beremagene geperpavec-svdt) therapy.	
VYNDAMAX (tafamidis)	**Vyndamax** (tafamidis) may be approved for members meeting the following criteria: • Member is an adult ≥ 18 years of age AND • Member has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloid cardiomyopathy (ATTR-CM) AND • Member has a documented history of heart failure with NYHA functional class I-III Maximum dose: Vyndamax (tafamidis) 61mg daily	One year
VYNDAQEL (tafamidis meglumine)	**Vyndaqel** (tafamidis meglumine) may be approved for members meeting the following criteria: • Member is an adult ≥ 18 years of age AND • Member has a diagnosis of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloid cardiomyopathy (ATTR-CM) AND • Member has a documented history of heart failure with NYHA functional class I-III Maximum dose: Vyndaqel (tafamidis meglumine) 80mg daily	One year
VYONDYS 53 (golodirsen)	**Vyondys 53** (golodirsen) may be approved if all the following criteria are met: • For billing under the pharmacy benefit, medication is being administered in the member's home or in a long-term care facility by a healthcare professional AND • Member must have genetic testing confirming mutation of the Duchenne Muscular Dystrophy (DMD) gene that is amenable to exon 53 skipping AND • Medication is prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (i.e., neurologist, cardiologist, pulmonologist or physical medicine and rehabilitation physician) AND • The member must be on corticosteroids at baseline or has a contraindication to corticosteroids AND • If the member is ambulatory, functional level determination of baseline assessment of ambulatory function is required OR if not ambulatory, member must have a Brooke Upper Extremity Function Scale of five or less documented OR a Forced Vital Capacity of 30% or more. <u>Reauthorization</u>: Provider attests that treatment with Vyondys 53 (golodirsen) is necessary to help member improve or maintain functional capacity based on assessment of trajectory from baseline for ambulatory or upper extremity function or Forced Vital Capacity (FVC). <u>Maximum Dose</u>: 30 mg/kg per week *(documentation of patient's current weight with the date the weight was obtained*) *Above coverage standards will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options, and available peer-reviewed medical literature and clinical evidence.*	Initial: One year Continued: One year

Drug Product(s)	Criteria	PA Approval Length
VYVGART (efgartigimod alfa) **VYVGART HYTRULO (efgartigimod alfa/ hyaluronidase-qvfc)**	**Vyvgart** (efgartigimod alfa) or **Vyvgart Hytrulo** (efgartigimod alfa/ hyaluronidase-qvfc) may be approved if the following criteria are met: • The requested medication is being administered by a healthcare professional in the member's home or in a long-term care facility AND • Member is ≥ 18 years of age AND • The request meets the following criteria for the prescribed diagnosis: Generalized Myasthenia Gravis: o The requested medication is being prescribed for treatment of generalized myasthenia gravis (gMG) that is anti-acetylcholine receptor (AChR) antibody positive AND o The member meets the criteria for Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV AND o The requested medication is being prescribed by or in consultation with a neurologist AND o Provider will perform a myasthenia gravis functionality score (such as the MGADL or QMG) at baseline. Chronic Inflammatory Demyelinating Polyneuropathy (Vyvgart Hytrulo only): o The request meets FDA-labeled indication, age, dosing, and role in therapy as outlined in product package labeling. Maximum Dose: IV formulation: 1,200 mg weekly for 4 weeks Subcutaneous formulation: 1,008 mg weekly for 4 weeks (gMG); 1,008 mg weekly (CIDP) Quantity Limit: IV formulation: Twelve 400 mg/20 mL single-dose vials per 28 days Subcutaneous formulation: Four 1,008 mg/5.6 mL single-dose vials per 28 days (gMG and CIDP) Reauthorization: Additional one year approval may be granted with provider attestation that a follow-up myasthenia gravis functionality assessment indicates stable symptoms or clinical improvement.	One year
WINREVAIR (sotatercept-csrk)	**Winrevair** (sotatercept-csrk) may be approved if the following criteria are met: • Member is an adult ≥ 18 years of age AND • Member has a diagnosis of pulmonary arterial hypertension (PAH), WHO group 1 AND • Member is not currently experiencing serious bleeding AND • Member has been counseled and evaluated regarding signs and symptoms of blood loss AND • Member's pre-treatment platelet count is >50,000/mm3 AND • Member is not pregnant or planning to become pregnant AND • Member will not be breastfeeding during and within 4 months after last dose AND • Initial prescription for the requested product is being prescribed by or in consultation with a pulmonologist or cardiologist AND • Member has tried and failed‡ a preferred medication from one of the following categories: o Phosphodiesterase Inhibitors	One year

Drug Product(s)	Criteria	PA Approval Length
	○ Endothelin Receptor Antagonists ○ Prostacyclin Analogues and Receptor Agonists AND • Since Winrevair (sotatercept-csrk) is intended for use under the guidance of a healthcare professional, prescriber attests that the member self-administering the drug will be permitted to do so only when (1) it is considered appropriate, and (2) after they have received adequate initial training and administration technique assessment from a healthcare professional AND • Prescriber attests that hemoglobin (Hgb) and platelet counts will be assessed before each dose for the first 5 doses of Winrevair (or longer if lab values are unstable), and also monitored periodically thereafter to assess the need for dose adjustments. Maximum dose: 0.7 mg/kg every 3 weeks Continuation of therapy: Members who are currently stabilized on Winrevair (sotatercept-csrk) may receive approval to continue use of the product. ‡Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction	
XDEMVY (lotilaner)	**Xdemvy** (lotilaner) may be approved if the following criteria are met: • Member is ≥ 18 years of age AND • Member has a documented diagnosis of moderate to severe Demodex blepharitis confirmed through microscopic examination AND • Requested product is being prescribed by or in consultation with an ophthalmologist or optometrist AND • Member has failed to experience clinical improvement of Demodex blepharitis with regular lid hygiene practices including warm compresses, lid massage, eyelid washing for at least two months AND • Member has tried and failed† therapy with ivermectin OR clinical rationale is provided supporting why this medication cannot be trialed AND • Member has been advised that Xdemvy (lotilaner) solution may discolor soft contact lenses. Dosing limit: Approval will be given for one course of therapy (1 drop in each eye every 12 hours for 6 weeks) † Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction	See criteria
XERMELO (telotristat ethyl)	**Xermelo** (telotristat ethyl) prior authorization may be approved for members meeting the following criteria: • Member is at 18 years of age or older **AND** • Member has a diagnosis of carcinoid syndrome diarrhea **AND** • Member has trialed and failed three months of somatostatin analog therapy (such as octreotide). Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction **AND** • Xermelo is being used in combination with somatostatin analog therapy Maximum dose: 750 mg per day	One year
XIFAXAN (rifaximin)	**Xifaxan** (rifaximin) prior authorization will be approved for members meeting the following criteria:	See Criteria

Drug Product(s)	Criteria	PA Approval Length
	• For members prescribed Xifaxan for prophylaxis of hepatic encephalopathy (HE) in adults: o Member must be concomitantly taking lactulose or other non-absorbable disaccharide AND o Member must not have undergone transjugular intrahepatic portosystemic shunt (TIPS) procedure within the last 3 months AND o Xifaxan is being prescribed for secondary prophylaxis of HE (member has experienced previous episode of HE) AND o Maximum dosing regimen is 550mg twice daily o Members meeting criteria will receive approval for one year • For members prescribed Xifaxan for irritable bowel syndrome with diarrhea (IBS-D): o Maximum dosing regimen is 550mg three times daily for 14 days AND o Approval is limited to <u>two</u> 14-day treatment courses per 14 week time period • For members prescribed Xifaxan for traveler's diarrhea: o Member must be ≥ 12 years of age AND o Maximum dosing regimen is 200mg three times daily for 3 days o Members meeting criteria will receive approval for one year	
XOLREMDI (mavorixafor)	**Xolremdi** (mavorixafor) may be approved if the following criteria are met: • Member is ≥ 12 years of age AND • Member has a diagnosis of WHIM syndrome (warts, hypogammaglobulinemia, infections, myelokathexis) AND • Diagnosis of WHIM is based on a genotype-confirmed pathogenic variant in the CXCR4 gene AND • Member has a confirmed absolute neutrophil count of ≤ 400 cells/μL AND • The requested drug is being prescribed by a provider specializing in the treatment of WHIM (such as an immunologist, geneticist, hematologist, dermatologist, or infectious disease specialist) AND • Member has a recent creatinine clearance of 30 mL/min or greater AND • Member does not moderate to severe hepatic impairment AND • Provider attests that QTc interval will be assessed at baseline and monitored during treatment as clinically indicated AND • Prescriber attests that members of reproductive potential will be advised to use effective contraception while on Xolremdi (mavorixafor) therapy AND • Prescriber attests that members of reproductive potential will be advised that breastfeeding is not recommended during treatment and for 3 weeks after last dose of Xolremdi (mavorixaflor) AND • Due to the risk of adverse reactions that maybe be associated with significant increases in Xolremdi (mavorixafor) exposure, member is not concurrently taking a medication that is highly dependent on CYP2D6 for clearance (such as dextromethorphan, fluoxetine, nortriptyline, oxycodone, paroxetine, quinidine) OR a strong CYP3A4 inducer (such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, rifabutin, rifapentine, dexamethasone, efavirenz, etravirine, nevirapine, darunavir/ritonavir, ritonavir, St John's Wort) AND • Member's medication profile has been reviewed for other potential clinically significant drug interactions according to product labeling AND • Member is not being treated with any other CXCR4 antagonists AND	One year

Drug Product(s)	Criteria	PA Approval Length
	• Member has been counseled to take Xolremdi (mavorixaflor) on an empty stomach after an overnight fast, and at least 30 minutes before food and counseled that Xolremdi (mavorixaflor) capsules should not be cut, crushed or chewed. Maximum Dose: 400 mg/day Maximum Quantity: 120 capsules (100 mg strength)/30 days Reauthorization: Member may receive approval for one year with provider attestation to the efficacy of treatment based on a sustained increase in absolute neutrophil count with ongoing monitoring.	
XYREM (sodium oxybate)	**Xyrem** (sodium oxybate) may be approved for adults and children 7 to 17 years of age if all the following criteria are met: • Member has a diagnosis of cataplexy or excessive daytime sleepiness with narcolepsy (confirmed by one of the following): o Cataplexy episodes occurring three or more times per month OR o Hypocretin deficiency OR o Nocturnal sleep polysomnography showing rapid eye movement (REM) sleep latency less than or equal to 15 minutes, or a Multiple Sleep Latency Test (MSLT) showing a mean sleep latency less than or equal to 8 minutes and two or more sleep-onset REM periods AND • Baseline excessive daytime sleepiness is measured using the Epworth Sleepiness Scale or cataplexy episode count AND • Member has adequately trialed and failed therapy with 3 stimulants for narcolepsy (examples include methylphenidate and amphetamine salts) Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects, or significant drug-drug interactions. AND • Member must not have recent (within 1 year) history of substance abuse AND • Member is not taking opioids, benzodiazepines, sedative hypnotics (such as zolpidem, zaleplon, eszopiclone, chloral hydrate, etc.) or consuming alcohol concomitantly with Xyrem (sodium oxybate) AND • Prescriber is enrolled in corresponding REMS program AND • If member is an adult (age ≥ 18 years), they have had an adequate trial and failure of therapy with 3 sedative hypnotic medications (examples include zolpidem and eszopiclone). Failure is defined as: lack of efficacy with 2 week trial, allergy, intolerable side effects or significant drug-drug interactions. Initial and Continuation Prior Authorization Approval: Initial prior authorization approval will be for 30 days. For continuation approval for one year, the following information must be provided: • Verification of Epworth Sleepiness Scale score reduction on follow-up OR	Initial: 30 days Continued: One year

Drug Product(s)	Criteria	PA Approval Length
	• Verification of cataplexy episode count reduction on follow-up Maximum Dosing: 9 grams/day	

XYWAV (calcium, magnesium, potassium, sodium oxybates)	**Xywav** (calcium, magnesium, potassium, sodium oxybates) may be approved if the following criteria are met:
	• Member is ≥ 7 years of age AND
	• Member has a diagnosis of excessive daytime sleepiness with narcolepsy (confirmed by one of the following):
	  ○ Hypocretin deficiency OR
	  ○ Nocturnal sleep polysomnography showing rapid eye movement (REM) sleep latency less than or equal to 15 minutes, or a Multiple Sleep Latency Test (MSLT) showing a mean sleep latency less than or equal to 8 minutes and two or more sleep-onset REM periods
	AND
	• Baseline excessive daytime sleepiness is measured using the Epworth Sleepiness Scale or cataplexy episode count AND
	• Member has adequately trialed and failed therapy with 3 stimulants for narcolepsy (examples include methylphenidate and amphetamine salts) Failure is defined as: lack of efficacy with 2 week trial, contraindication to therapy, allergy, intolerable side effects, or significant drug-drug interactions AND
	• Member must not have recent (within 1 year) history of substance abuse AND
	• Member is not taking opioids, benzodiazepines, sedative hypnotics (such as zolpidem, zaleplon, eszopiclone, chloral hydrate, etc.) or consuming alcohol while receiving Xywav (calcium, magnesium, potassium, sodium oxybates) therapy AND
	• Prescriber is enrolled in corresponding REMS program AND
	• If member is an adult (≥ 18 years of age), they have had an adequate trial and failure of therapy with 3 sedative hypnotic medications (examples include zolpidem and eszopiclone). Failure is defined as: lack of efficacy with 2 week trial, contraindication to therapy, allergy, intolerable side effects or significant drug-drug interactions.
	
	Initial and Continuation Prior Authorization Approval:
	Initial prior authorization approval will be for 30 days. For continuation approval for one year, the following information must be provided:
	• Verification of Epworth Sleepiness Scale score reduction on follow-up OR
	• Verification of cataplexy episode count reduction on follow-up
	
	Maximum Dosing:
	9 grams/daily
		Initial:
		30 days
		
		Continued:
		One year

YCANTH (cantharidin)	**Ycanth** (cantharidin) may be approved if the following criteria are met: • For billing under the pharmacy benefit, medication is being administered in the member's home or in a long-term care facility (LTCF) by a healthcare professional AND • Member is ≥ 2 years of age AND	Five months

Drug Product(s)	Criteria	PA Approval Length
	• Member has a diagnosis of molluscum contagiosum AND • Requested product is being prescribed by or in consultation with a dermatologist AND • Member has tried and failed an adequate trial with topical podofilox. Failure is defined as lack of efficacy, allergy, intolerable side effects, or significant drug-drug interaction, AND • Member has undergone a surgical intervention (such as cryotherapy, surgical scraping, laser therapy) with inadequate resolution OR provider has determined that member is not a good candidate for any of these procedures. Quantity limit: 6 single-use applicators/9 weeks	
YOSPRALA (aspirin/omeprazole)	**Yosprala** (aspirin/omeprazole) will be approved for members who meet the following criteria: • Member requires aspirin for secondary prevention of cardiovascular or cerebrovascular events AND • Member is at risk of developing aspirin associated gastric ulcers (member is ≥ 55 years of age or has documented history of gastric ulcers) AND • Member has failed treatment with three preferred proton pump inhibitors in the last 6 months (Failure is defined as: lack of efficacy of a seven-day trial, allergy, intolerable side effects, or significant drug-drug interaction).	One year
ZILBRYSQ (zilucoplan)	**Zilbrysq** (zilucoplan) may be approved if the following criteria are met: • Member is ≥ 18 years of age AND • The requested medication is being prescribed for treatment of generalized myasthenia gravis that is anti-acetylcholine receptor (AChR) antibody positive AND • The member meets the criteria for Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV AND • The requested medication is being prescribed by or in consultation with a neurologist AND • Provider will perform a myasthenia gravis functionality score (such as the MGADL or QMG) at baseline. Maximum Dose: 32.4mg/day Quantity Limit 28 single-dose prefilled syringes/28 days Reauthorization: Additional one year approval may be granted with provider attestation that a follow-up myasthenia gravis functionality assessment indicates stable symptoms or clinical improvement.	One year
ZOKINVY (lonafarnib)	**Zokinvy** (lonafarnib) may be approved if the following criteria are met: 1. Member is one year of age or older AND 2. Member has a body surface area of 0.39 m^2 or greater AND 3. Member has one of the following diagnoses: a. Hutchinson-Gilford Progeria Syndrome (HGPS) confirmed by genetic testing for the pathogenic variant in the LMNA gene that results in production of progerin b. Processing-deficient progeroid laminopathy confirmed by genetic testing for heterozygous LMNA mutation with progerin-like protein	One year

Drug Product(s)	Criteria	PA Approval Length
	accumulation OR for homozygous or compound heterozygous ZMPSTE24 mutations AND 4. Member is not taking lovastatin, simvastatin, or atorvastatin AND 5. Member, parent, or legal guardian has been, or will be, counseled that Zokinvy (lonafarnib) may impact pubertal development and impair fertility AND 6. Zokinvy (lonafarnib) is being prescribed or in consultation with a specialist in the area of the patient's diagnosis (such as a cardiologist or geneticist). Maximum dose: 300 mg/day Quantity limit: 4 capsules/day	