Prior Authorization Approval Criteria

Effective Date: 01/01/2024

Prior authorization criteria is 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. Contrave (naltrexone/bupropion)
7. Cosentyx (secukinumab)
8. Dupixent (dupilumab)
9. Emgality (galcanezumab)
10. Forteo (teriparatide)
11. Gilenya (fingolimod)
12. Gleevec (imatinib)
13. Hepatitis C Virus (HCV) Non-Preferred Medications (Mavyret, Zepatier)
14. Hepatitis C Virus (HCV) Preferred Medications (Epclusa, Harvoni)
15. Horizant (gabapentin enacarbil)
16. Ingrezza (valbenazine)
17. Jakafi (ruxolitinib)
18. Kalydeco (ivacaftor)
19. Kesimpta (ofatumumab)
20. Kineret (anakinra)
21. Lupron, Lupron Depot, Lupron Depot-Ped (leuprolide)
22. Nurtec ODT (rimegepant)
23. Orencia (abatacept)
24. Orkambi (lumacaftor/ivacaftor)
25. Otezla (apremilast)
26. Qsymia (phentermine/topiramate)
27. Reyvow (lasmiditan)
28. Rinvoq (upadacitinib)
29. Rubraca (rucaparib)
30. Saxenda (liraglutide)
31. Sensipar (cinalcalcet)
32. Simponi (golimumab)

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33. Somatropin
34. Stelara (ustekinumab)
35. Synagis (palivizumab)
36. Tasigna (nilotinib)
37. Tecfidera (dimethyl fumarate)
38. Tobi Podhaler (tobramycin inhalation powder)
39. Tolvaptan
40. Trikafta (elexacaftor/tezacaftor/ivacaftor)
41. Tymlos (abaloparatide)
42. Ubrelvy (ubrogepant)
43. Valchlor (mechlorethamine)
44. Wegovy (semaglutide)
45. Xeljanz (tofacitinib)
46. Xolair (omalizumab)
47. Xyrem (sodium oxybate)
48. Zejula (niraparib)

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, December 2023

Prior Authorization Approval Criteria

Austedo (deutetrabenazine)

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

FDA-approved uses:

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

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

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

Contrave (naltrexone/bupropion)

Generic name: naltrexone/bupropion
Brand name: Contrave
Medication class: Weight loss agent

FDA-approved uses:

- Obesity or overweight in the presence of at least one weight-related comorbidity

Usual dose range:

- Up to 16 mg/180 mg twice daily

Criteria for use:

Initiation Criteria

Obesity or overweight in the presence of at least one weight-related comorbidity

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Confirmation that the patient is enrolled in an exercise and caloric reduction program or a weight loss/behavioral modification program
- Documentation of baseline BMI of 30 kg/m^2 or greater
  - If BMI is 27 – 29.9 kg/m^2, then additional documentation of at least one weight-related comorbidity must be provided (such as hypertension, type 2 diabetes mellitus or hyperlipidemia)
- Failure to respond or intolerance to an adequate trial of both of the following:
  - Saxenda
  - Wegovy

Renewal Criteria

- Documentation that the patient has achieved or maintained at least 5% weight loss from baseline body weight

Additional considerations:

- Maximum dose of 16 mg/180 mg twice daily [maximum daily limit (MDL) of 4 tablets/day].
- Preferred weight loss agents are Saxenda and Wegovy.
- Non-preferred weight loss agents are Contrave and Qsymia. Trials of both Saxenda and Wegovy must be considered before either Contrave or Qsymia will be approved.

Approval time frames:

- Initial – 4 months with MDL of 4/day (120 tablets per 30 days)
- Renewal – 1 year with MDL of 4/day (120 tablets per 30 days)

References:

- Contrave Prescribing Information; Brentwood, TN; Currax Pharmaceuticals LLC; 2023.
- Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. Endocr Pract 2016;22:(3):1-203.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: May 2023
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
- Sinusitis with nasal polyps
- Eosinophilic esophagitis
- Prurigo nodularis

Usual dose range:

- Moderate to severe atopic dermatitis
  - 600 mg subcutaneously followed by 300 mg subcutaneously every other week
- Moderate to severe asthma
  - 400 mg subcutaneously followed by 200 mg subcutaneously every other week OR 600 mg subcutaneously followed by 300 mg subcutaneously every other week
- Sinusitis with nasal polyps
  - 300 mg subcutaneously every other week
- Eosinophilic esophagitis
  - 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 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 of the following:
  - A formulary inhaled corticosteroid (i.e. Alvesco, Flovent, Pulmicort, QVAR)
  - An additional formulary controller medication (i.e. Advair, Spiriva, Symbicort)

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 all of the following:
  - A formulary nasal corticosteroid spray (i.e. Flonase, flunisolide nasal spray)
  - A formulary oral corticosteroid

Eosinophilic esophagitis

Adolescents and adults

- FDA indicated diagnosis
- 12 years of age or older
- Prescribed by (or in consultation with) a gastroenterologist, allergist or immunologist
- Diagnosis has been confirmed by an esophagogastroduodenoscopy (EGD) with biopsy
- Failure to respond to a trial of dietary therapy
- Failure to respond, intolerance, or contraindication to an adequate trial of a proton pump inhibitor (e.g. esomeprazole, lansoprazole, omeprazole, pantoprazole)

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 one of the following:
  - A formulary topical corticosteroid
  - An intralesional corticosteroid
  - A topical calcineurin inhibitor (e.g. tacrolimus ointment)
  - A topical calcipotriol (e.g. 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

Approval time frames:

- Initial – based on diagnosis and strength prescribed as follows:
  - Moderate to severe atopic dermatitis – enter 2 separate approvals as follows:
    - Approve for 1 month as follows:
      - 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 5 months as follows beginning 1 week 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.)
  - Moderate to severe asthma – for 100 mg/0.67 mL strength, approve as follows:
    - Approve for 4 months with MDL 0.05/day (1.34 mL per 28 days.)
  - Moderate to severe asthma – for other strengths, enter 2 separate approvals as follows:
    - Approve for 1 month as follows:
      - 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 as follows beginning 1 week 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.)
  - 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 – for 300 mg/2 mL strength only, approve as follows:
    - Approve for 6 months with 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 beginning 1 week 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 –
        - 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.)
    - Moderate to severe asthma –
        - For 100 mg/0.67 mL: MDL 0.05/day (1.34 mL per 28 days.)
        - 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.)
    - 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 –
        - 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:

- Dupixent® (package insert); Tarrytown, NY; Regeneron Pharmaceuticals, Inc.; 2023.
- Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from www.ginasthma.org. Accessed December 29, 2022.
- 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.
- 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.

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

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

Mavyret, Zepatier

(Hepatitis C Virus Non-Preferred Medications)

Non-Preferred Formulary agents: Mavyret, 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: 3 tablets/day for Mavryet (Note: quantity of Mavyret pediatric pellet packets will be approved according to patient weight); 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, December 2022, November 2023

Prior Authorization Approval Criteria

Epclusa, Harvoni

(Hepatitis C Virus Preferred Medications)

Preferred Formulary agents: Epclusa, Harvoni

Criteria for use:

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

- □ 3 years of age or older
- □ 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 patient is willing to adhere to treatment requirements
- □ Confirmation that the patient does not have a limited life expectancy (less than 12 months) due to non-liver related comorbid conditions
- Confirmation of one of the following:
  - □ No cirrhosis
  - □ Compensated cirrhosis
- Confirmation of one of the following:
  - □ Treatment-naïve
  - □ Treatment-experienced
- Confirmation of Hepatitis C virus (HCV) infection with a genotype obtained within the last year by selecting one of the following and completing additional criteria:
  - □ **Genotype 1 (a or b)**
    - □ Please confirm each of the following:
      - YES / NO – The patient has HCV RNA level < 6 million copies
      - YES / NO – The patient is treatment-naïve
      - YES / NO – The patient has no evidence of cirrhosis
      - YES / NO – The patient is HIV negative
    - □ If ALL questions above are answered YES, then Harvoni for 8 weeks is preferred.
    - □ If one or more questions above is answered NO, then Epclusa for 12 weeks is preferred.

  - □ **Genotype 2**
    - □ Epclusa for 12 weeks is preferred

  - □ **Genotype 3**
    - □ Treatment-naïve
      - □ Without cirrhosis
        - □ Epclusa for 12 weeks is preferred
      - □ With compensated cirrhosis, then RAS testing for Y93 is required

- If RAS absent, then Epclusa for 12 weeks is preferred
- If RAS present, then Epclusa plus ribavirin for 12 weeks is preferred

- Treatment-experienced
  - Without cirrhosis, then RAS testing for Y93H is required
    - If RAS absent, then Epclusa for 12 weeks is preferred
    - If RAS present, then Epclusa plus ribavirin for 12 weeks is preferred
  - With compensated cirrhosis
    - Epclusa plus ribavirin for 12 weeks is preferred

- **Genotype 4, 5 or 6**
  - Epclusa for 12 weeks is preferred

Contraindications:

- Ribavirin is contraindicated in pregnancy and men whose female partners are pregnant

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:

- Preferred HCV medications may not be required when there are confirmed major drug-drug interactions that prevent their use and changing current medications is not appropriate
- Some preferred HCV medication regimens may require concomitant ribavirin
  - If contraindication to ribavirin is documented, then the preferred HCV medication regimen will not be required for use and other appropriate treatment regimens will be considered
- 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
- Maximum daily limit (MDL) is 1 tablet per day (Note: quantity of pediatric pellet packets will be approved according to patient weight)

Approval time frames:

- Harvoni: 8 weeks with MDL of 1/day (Note: quantity of Harvoni pediatric pellet packets will be approved according to patient weight)
- Epclusa: 12 weeks with MDL 1/day (Note: quantity of Epclusa pediatric pellet packets will be approved according to patient weight)

References:

- Epclusa Prescribing Information. Gilead Sciences, Foster City, CA: 2022.
- Harvoni Prescribing Information. Gilead Sciences, Foster City, CA: 2021.
- 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, 2021.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: October 2016
Revision: July 2017, September 2017, May 2018, July 2019, December 2019, December 2020, November 2021, December 2022, November 2023

DENVER HEALTH MEDICAL PLAN INC.

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:

DENVER HEALTH MEDICAL PLAN INC.

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 one 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

Adults

- 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

Adults

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

Palliative treatment of advanced prostate cancer

Adults

- 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

Additional considerations:

- Pediatric dosing is weight-based

Approval time frames:

- 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

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

Qsymia (phentermine/topiramate)

Generic name: phentermine/topiramate
Brand name: Qsymia
Medication class: Anorexiant/anticonvulsant

FDA-approved uses:

- Obesity or overweight in the presence of at least one weight-related comorbidity

Usual dose range:

- 3.75 mg/23 mg – 15 mg/92 mg once daily

Criteria for use:

Initiation Criteria

Obesity or overweight in the presence of at least one weight-related comorbidity

Adults

- FDA indicated diagnosis
- 12 years of age or older
- Confirmation that the patient is enrolled in an exercise and caloric reduction program or a weight loss/behavioral modification program
- If 12 to 17 years of age, then documentation of initial body mass index (BMI) at the 95th percentile or greater standardized for age and sex
- If 18 years of age or older, then documentation of baseline BMI of 30 kg/m^{2}or greater
  - If BMI is 27 – 29.9 kg/m^2, then additional documentation of at least one weight-related comorbidity must be provided (such as hypertension, type 2 diabetes mellitus or hyperlipidemia)
- Failure to respond or intolerance to an adequate trial of both of the following:
  - Saxenda
  - Wegovy
- Confirmation that the patient is not currently taking another GLP-1 receptor agonist (such as Bydureon, Byetta, Rybelsus, Ozempic, Trulicity or Victoza)

Renewal Criteria

- For Qsymia 7.5 mg/46 mg, documentation of effectiveness of therapy as evidenced by one of the following:
  - If 12 to 17 years of age, achieved or maintained at least 3% reduction from baseline BMI
  - If 18 years of age or older, achieved or maintained at least 3% weight loss from baseline body weight

- For Qsymia 15 mg/92 mg, documentation of effectiveness of therapy as evidenced by one of the following:
  - If 12 to 17 years of age, achieved or maintained at least 5% reduction from baseline BMI
  - If 18 years of age or older, achieved or maintained at least 5% weight loss from baseline body weight

Not approved if:

- Concomitant use of MAOIs
- Patients with glaucoma
- Patients with hyperthyroidism
- Patient is pregnant
- Patients with valvular heart disease

Additional considerations:

- Maximum dose of phentermine 15 mg/topiramate 92 mg per day
- Preferred weight loss agents are Saxenda and Wegovy.
- Non-preferred weight loss agents are Contrave and Qsymia. Trials of both Saxenda and Wegovy must be considered before either Contrave or Qsymia will be approved.

Approval time frames:

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

References:

- Qsymia Prescribing Information; Campbell, CA; Vivus, Inc.; 2022.
- Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. Endocr Pract 2016;22:(3):1-203.

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

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

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

Saxenda (liraglutide)

Generic name: liraglutide
Brand name: Saxenda
Medication class: GLP-1 receptor agonist for weight loss

FDA-approved uses:

- Obesity or overweight in the presence of at least one weight-related comorbidity

Usual dose range:

- 0.6 mg – 3 mg subcutaneously once daily

Criteria for use:

Initiation Criteria

Obesity or overweight in the presence of at least one weight-related comorbidity

Pediatric and Adult

- FDA indicated diagnosis
- 12 years of age or older
- Confirmation that the patient is enrolled in an exercise and caloric reduction program or a weight loss/behavioral modification program
- If 12 to 17 years of age, then documentation of both of the following:
  - Body weight greater than 60 kg
  - Initial body mass index (BMI) corresponds to 30 kg/m^2 or greater to that for adults
- If 18 years of age or older, then documentation of baseline BMI of 30 kg/m^2 or greater
  - If BMI is 27 – 29.9 kg/m^2, then additional documentation of at least one weight-related comorbidity must be provided (such as hypertension, type 2 diabetes mellitus or hyperlipidemia)
- Confirmation that the patient is not currently taking another GLP-1 receptor agonist (such as Bydureon, Byetta, Rybelsus, Ozempic, Trulicity or Victoza)

Renewal Criteria

- Documentation of effectiveness of therapy as evidenced by one of the following:
  - If 12 to 17 years of age, achieved or maintained at least 1% weight loss from baseline body weight
  - If 18 years of age or older, achieved or maintained at least 4% weight loss from baseline body weight

Additional considerations:

- Maximum dose of 3 mg per day [maximum daily limit (MDL) of 0.5 mL/day]
- Preferred weight loss agents are Saxenda and Wegovy.
- Non-preferred weight loss agents are Contrave and Qsymia. Trials of both Saxenda and Wegovy must be considered before either Contrave or Qsymia will be approved.

Approval time frames:

- Initial – 4 months with MDL of 0.5/day (15 mL per 30 days)
- Renewal – 1 year with MDL of 0.5/day (15 mL per 30 days)

References:

- Saxenda Prescribing Information; Plainsboro, NJ; Novo Nordisk Inc.; 2022.
- Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. Endocr Pract 2016;22:(3):1-203.

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

DENVER HEALTH MEDICAL PLAN INC.

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.
- Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency. Horm Res Paediatr 2016; 86:361.
- American Association of Clinical Endocrinologists. Medical Guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients-2009 Update. *Endocr Pract*. 2009;15(Suppl 2).
- American Association of Clinical Endocrinologists. Medical Guidelines for clinical practice for growth hormone use in adults and children-2003 Update. *Endocr Pract*. 2003;9(1).
- Deal CL, Tony M, Hoybye C, et al. Growth hormone research society workshop summary: consensus guidelines for recombinant human growth hormone therapy in prader-willi syndrome. *J Clin Endocrinol Metab*. 2013 Jun;98(6):E1072-87.
- Hardin DS. Treatment of short stature and growth hormone deficiency in children with somatropin (rDNA origin). *Biologics*. 2008 December; 2(4): 655–661
- Rogol AD, Geffner M, Hoppin AG. Diagnostic approach to short stature. In: UpToDate, Rose, BD (Ed), UpToDate, Waltham, MA, 2005.
- Yuksel B, Ozbek MN, Mungan NO, et al. Serum IGF-1 and IGFBP-3 levels in healthy children between 0 and 6 years of age. *J Clin Res Ped Endo.* 2011;3(2):84-88.

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.
- 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.
- Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol 2019; 114:384.

- 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.
- 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

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

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.
- Gold R, Kappos L, Arnold DL, et al. Placebo-controlled phase 3 study of oral BG-12 for relapsing multiple sclerosis. N Engl J Med. 2012;367(12):1098-107.
- 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(12):1087-97.
- 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; 2020.
- Samsca Prescribing Information; Rockville, MD; Otsuka America Pharmaceutical, Inc; 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

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

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

Wegovy (semaglutide)

Generic name: semaglutide
Brand name: Wegovy
Medication class: GLP-1 receptor agonist for weight loss

FDA-approved uses:

- Obesity or overweight in the presence of at least one weight-related comorbidity

Usual dose range:

- 0.25 mg – 2.4 mg once weekly

Criteria for use:

Initiation Criteria

Obesity or overweight in the presence of at least one weight-related comorbidity

Pediatric and Adult

- FDA indicated diagnosis
- 12 years of age or older
- Confirmation that the patient is enrolled in an exercise and caloric reduction program or a weight loss/behavioral modification program
- If 12 to 17 years of age, then documentation of initial body mass index (BMI) at the 95th percentile or greater standardized for age and sex
- If 18 years of age or older, then documentation of baseline BMI of 30 kg/m^{2}or greater
  - If BMI is 27 – 29.9 kg/m^2, then additional documentation of at least one weight-related comorbidity must be provided (such as hypertension, type 2 diabetes mellitus or hyperlipidemia)
- Confirmation that the patient is not currently taking another GLP-1 receptor agonist (such as Bydureon, Byetta, Rybelsus, Ozempic, Trulicity or Victoza)

Renewal Criteria

- Documentation of effectiveness of therapy as evidenced by one of the following:
  - If 12 to 17 years of age, achieved or maintained at least 5% reduction from baseline BMI
  - If 18 years of age or older, achieved or maintained at least 5% weight loss from baseline body weight

Additional considerations:

- Maximum dose of 2.4 mg/0.75 mL per week [maximum daily limit (MDL) of 0.11/day]
- Preferred weight loss agents are Saxenda and Wegovy.
- Non-preferred weight loss agents are Contrave and Qsymia. Trials of both Saxenda and Wegovy must be considered before either Contrave or Qsymia will be approved.

Approval time frames:

- Initial – 5 months with MDL of 0.11/day (1 injection per week)
- Renewal – 1 year with MDL of 0.11/day (1 injection per week)

References:

- Wegovy Prescribing Information; Plainsboro, NJ; Novo Nordisk Inc.; 2022.
- Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. Endocr Pract 2016;22:(3):1-203.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: April 2022
Revision: May 2022, May 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:

DENVER HEALTH MEDICAL PLAN INC.

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:

DENVER HEALTH MEDICAL PLAN INC.

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