Prior Authorization Approval Criteria

Effective Date: 07/01/2022

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.

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

1. Abilify Maintena (aripiprazole long-acting injectable)
2. Aimovig (erenumab)
3. Ajovy (fremanezumab)
4. Ampyra (dalfampridine)
5. Aubagio (teriflunomide)
6. Briviact (brivaracetam)
7. Cimzia (certolizumab)
8. Cosentyx (secukinumab)
9. Cuvposa (glycopyrrolate oral solution)
10. Daytrana (methylphenidate extended release transdermal system)
11. Dupixent (dupilumab)
12. Emgality (galcanezumab)
13. Epidiolex (cannibidiol)
14. Fanapt (iloperidone)
15. Forteo (teriparatide)
16. Gilenya (fingolimod)
17. Gleevec (imatinib)
18. Hepatitis C Virus (HCV) Non-Preferred Medications (Mavyret, Zepatier)
19. Hepatitis C Virus (HCV) Preferred Medications (Epclusa, Harvoni)
20. Horizant (gabapentin enacarbil)
21. Invega Sustenna (paliperidone palmitate)
22. Jakafi (ruxolitinib)
23. Kalydeco (ivacaftor)
24. Kapvay (clonidine extended release)
25. Lupron, Lupron Depot, Lupron Depot-Ped (leuprolide)
26. Nurtec ODT (rimegepant)
27. Opioid Benzodiazepine Concurrent Use [Applies to Medicaid Choice Only]
28. Opioid Morphine Equivalent Dose (MED) Limit [Applies to Medicaid Choice Only]
29. Opioid Naïve Day Supply Limit [Applies to Medicaid Choice Only]
30. Orencia (abatacept)
31. Orkambi (lumacaftor/ivacaftor)
32. Otezla (apremilast)
33. Reyvow (lasmiditan)

34. Rozerem (ramelteon)
35. Rubraca (rucaparib)
36. Saphris (asenapine)
37. Sensipar (cinalcalcet)
38. Simponi (golimumab)
39. Somatropin
40. Stelara (ustekinumab)
41. Synagis (palivizumab)
42. Tasigna (nilotinib)
43. Tecfidera (dimethyl fumarate)
44. Tobi Podhaler (tobramycin inhalation powder)
45. Tolvaptan
46. Trikafta (elexacaftor/tezacaftor/ivacaftor)
47. Tymlos (abaloparatide)
48. Ubrelvy (ubrogepant)
49. Valchlor (mechlorethamine)
50. Xyrem (sodium oxybate)
51. Zejula (niraparib)
52. Zyprexa Relprevv (olanzapine pamoate extended release injection)

Prior Authorization Approval Criteria

Abilify Maintena

(aripiprazole long-acting injectable)

Generic name: aripiprazole long-acting injectable
Brand name: Abilify Maintena
Medication class: Antipsychotic

FDA-approved uses:

- Treatment of bipolar I disorder
- Treatment of schizophrenia

Usual dose range:

- Bipolar I disorder/Schizophrenia – adults
  - 400mg monthly (may be reduced to 300 mg in patients with adverse reactions or who are known CYP2D6 poor metabolizers)

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

Initiation criteria

Bipolar I disorder/Schizophrenia:

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Documented tolerance to oral aripiprazole
- Patient has a history of noncompliance and/or refuses to utilize oral medication and documentation that patient education and other efforts to improve adherence have been attempted
- Either one of the following:
  - Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of Risperdal Consta (Step Therapy required: trial of oral risperidone)

  OR
  - Documented stabilization on oral aripiprazole (trial of 4-6 weeks), evidenced by coverage by the plan or confirmed coverage by the previous plan (e.g. pharmacy has been filling through the previous plan)

Renewal criteria

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

Additional considerations:

- In conjunction with first dose, give 14 consecutive days of concurrent oral aripiprazole (10 mg to 20 mg) or current oral antipsychotic then discontinue
- Dosage adjustments are required for missed doses
- Dosage adjustments for patients who are CYP2D6 poor metabolizers and patients taking CYP2D6 inhibitors, CYP3A4 inhibitors, or CYP3A4 inducers for greater than 14 days
- Maximum dose is 400 mg monthly

Approval time frames:

- Initial – 6 months with a quantity limit of 1 vial/syringe per month
- Renewal – 1 year with a quantity limit of 1 vial/syringe per month

References:

- Abilify Maintena Prescribing Information (2021). Otsuka Pharmaceutical CO, Tokyo, Japan.
- American Psychiatric Association (APA): Practice guideline for the treatment of patients with schizophrenia, third edition (2021). Available at: https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841. Accessed on December 20, 2021.
- Yatham LN, Kennedy SH, Parikh SV, et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) and International Society for Bipolar Disorders (ISBD) 2018 guidelines for the management of patients with bipolar disorder. Bipolar Disord. 2018;20:97–170. https://doi.org/10.1111/bdi.12609
- American Psychiatric Association. Five things physicians and patients should question [guideline on the internet]. Available at: http://www.choosingwisely.org/doctor-patient-lists/american-psychiatric-association. Accessed on December 20, 2021.
- Kane JM, Sanchez R, Perry PP, Jin N, Johnson BR, Forbes RA et al. Aripiprazole intramuscular depot as maintenance treatment in patients with schizophrenia: a 52-week, multicenter, randomized, double-blind, placebo-controlled study. J Clin Psychiatry 2012; 73(5):617-624.
- PL Detail-Document, Comparison of Atypical Antipsychotics. Pharmacist's Letter/Prescriber's Letter 2015; 31(9): 310909.
- Hasan A, Falkai P, Wobrock T, Lieberman J, Glenthøj B, Gattaz W et al. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Schizophrenia, Part 2: Update 2012 on the long-term treatment of schizophrenia and management of antipsychotic-induced side effects. World J Biol Psychiatry 2013; 14: 2-44.
- Dixon L, Perkins D, Calmes C. American Psychiatric Association. Guideline Watch (September 2009): practice guideline for the treatment of patients with schizophrenia. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia-watch.pdf. Accessed on December 20, 2021.
- American Psychiatric Association. Practice guideline for the treatment of patients with schizophrenia, second edition. Am J Psychiatry. 2004 Feb;161(2 Suppl):1-56.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: June 2013
Revision: June 2014, June 2015, June 2016, June 2017, June 2018, June 2019, October 2020, January 2022

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: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Migraine prophylaxis

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 **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)

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.; 2021.
- 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

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: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Migraine prophylaxis

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 **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)

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: 2021.
- 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

Prior Authorization Approval Criteria

Ampyra (dalfampridine)

Generic name: dalfampridine
Brand name: Ampyra
Medication class: Potassium Channel blocker

FDA-approved uses:

- Improvement of walking ability in multiple sclerosis (MS) patients

Usual dose range:

- Improvement of walking ability in MS patients - adults 10 mg twice daily

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

Initiation Criteria

Improvement of walking ability in MS patients:

Adults

- FDA indicated diagnosis
- Prescribed by (or in consultation with) a neurologist
- 18 – 70 years of age
- Complete the 25 foot walk test in 8-45 seconds
  OR
- If 25 foot walk test is < 8 seconds, the Expanded Disability Status Scale (EDSS) must be between 4.5-6.5

Renewal Criteria

- Provider attestation that the patient has experienced improvement in walking ability

Contraindications:

- History of seizure disorders
- Moderate to severe renal impairment (CrCL < 50mL/min)
- Hypersensitivity to Ampyra or 4-aminopyridine

Not approved if:

- Patient has any contraindications
- Patient is wheelchair bound

Additional considerations:

- Discontinue Ampyra if patient experiences a seizure

Approval time frames:

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

References:

- Ampyra ® [package insert], Ardsley, NY: Acorda; 2021.
- 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.
- Goodman A.D., Brown T.R. Edwards K.R. et al. A Phase 3 Trial of Extended Release Oral Dalfampridine in Multiple Sclerosis. Ann Neurol 2010; 68:494-502.
- Goodman AD, Brown TR, Krupp LB, Schapiro RT, Schwid SR, Cohen R et al. Sustained-release oral fampridine in multiple sclerosis: a randomised, double-blind, controlled trial. Lancet 2009; 373(9665):732-738.
- Goodman AD, Brown TR, Cohen JA, Krupp LB, Schapiro R, Schwid SR et al. Dose comparison trial of sustained-release fampridine in multiple sclerosis. Neurology 2008; 71(15):1134-1141.

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

Prior Authorization Approval Criteria

Aubagio (teriflunomide)

Generic name: teriflunomide
Brand name: Aubagio
Medication class: Pyrimidine synthesis inhibitor

FDA-approved uses:

- Relapsing forms of multiple sclerosis (MS)

Usual dose range:

- Relapsing forms of multiple sclerosis – adults 7-14 mg once daily

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

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
- 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:

- Severe hepatic impairment
- Women who are pregnant or of childbearing potential not using reliable contraception
- Current treatment with leflunomide

Not approved if:

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

Black box warning:

- Severe liver injury including fatal liver failure has been reported in patients treated with leflunomide. A similar risk would be expected for teriflunomide.
- Concomitant use of teriflunomide with other potentially hepatotoxic drugs may increase the risk of severe liver injury
- Teriflunomide may cause major birth defects if used during pregnancy. Pregnancy must be excluded before starting teriflunomide

Additional considerations:

- Female patients of child bearing age must use a reliable form of contraception

Approval time frames:

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

References:

- Aubagio ® [package insert], Cambridge, MA: Genzyme Corp.; 2021.
- 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.
- Confavreux C, O'connor P, Comi G, et al. Oral teriflunomide for patients with relapsing multiple sclerosis (TOWER): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Neurol. 2014;13(3):247-56.
- National Institute for Health and Care Excellence (2014) Multiple sclerosis in adults: management. Clinical Guideline CG186. London: National Institute for Health and Care Excellence.
- O'connor P, Wolinsky JS, Confavreux C, et al. Randomized trial of oral teriflunomide for relapsing multiple sclerosis. N Engl J Med. 2011;365(14):1293-303.
- O'connor PW, Li D, Freedman MS, et al. A Phase II study of the safety and efficacy of teriflunomide in multiple sclerosis with relapses. Neurology. 2006;66(6):894-900.
- 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

Prior Authorization Approval Criteria

Briviact (brivaracetam)

Generic name: brivaracetam
Brand name: Briviact
Medication class: Anticonvulsant

FDA-approved uses:

- Partial-onset seizure

Usual dose range:

- 0.5 mg/kg – 100 mg twice daily

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

Initiation Criteria

Partial-onset seizure

Pediatric and adult

- FDA indicated diagnosis
- 1 month of age or older
- Prescribed by or in consultation with a neurologist
- Failure to respond (or intolerance) to levetiracetam
- Failure to respond (or intolerance) to **two** of the following:
  - Carbamazepine
  - Felbamate
  - Gabapentin
  - Lamotrigine
  - Oxcarbazepine
  - Phenytoin
  - Pregabalin
  - Primidone
  - Topiramate
  - Valproate (valproic acid or divalproex)
  - Zonisamide

Renewal Criteria

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

Additional considerations:

- Maximum dose of 200 mg per day

Approval time frames:

- Initial – 6 months, MDL 2 tablets/day (oral solution is weight-based)
- Renewal – 1 year, MDL 2 tablets/day (oral solution is weight-based)

References:

- Briviact Prescribing Information. UCB, Inc., Smyrna, GA: 2021.
- Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy. Neurology 2018;91(2):74-81.
- Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy. Neurology 2018;91(2):82-90.

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

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/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 intolerance) to all of the following:
  - Humira
  - Enbrel
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

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 Humira
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

Plaque psoriasis

Adult

- FDA indicated diagnosis
- 12 years of age or older
- Prescribed by or in consultation with a dermatologist
- Failure to respond (or intolerance) to all of the following:
  - Methotrexate, calcipotriene, cyclosporine or acitretin
  - Humira or Enbrel
  - Otezla (PA required)
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

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 (i.e. methotrexate, leflunomide, sulfasalazine)
  - Humira or Enbrel
  - Otezla (PA required)
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

Rheumatoid 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 (i.e. methotrexate, leflunomide, sulfasalazine)
  - Humira
  - Enbrel
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

Renewal Criteria

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

Additional considerations:

- Maximum dose of 400 mg every 28 days (maintenance dosing)

Approval time frames:

- Initial – 6 months with MDL of 0.04/day (1 kit per 28 days)
  – 1 month loading dose; MDL 0.04/day (2 kits per 28 days)
- Renewal – 1 year with MDL of 0.04/day (1 kit per 28 days)

References:

- Cimzia Prescribing Information; Smyrna, GA; UCB, Inc.: 2021.
- 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

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 one of the following:
  - Humira
  - Enbrel
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

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 all of the following:
  - One oral DMARD: methotrexate, leflunomide or sulfasalazine
  - Humira or Enbrel

- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

Psoriatic arthritis

Pediatric

- FDA indicated diagnosis
- 2 years of age or older
- Prescribed by or in consultation with a rheumatologist
- If peripheral disease, then failure to respond to all of the following:
  - One oral DMARD: methotrexate, leflunomide or sulfasalazine
  - Humira or Enbrel
- If axial disease, then failure to respond to one of the following:
  - Humira
  - Enbrel
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a rheumatologist
- If peripheral disease, then failure to respond to all of the following:
  - One oral DMARD: methotrexate, leflunomide or sulfasalazine
  - Humira or Enbrel
  - Otezla (PA required)
- If axial disease, then failure to respond to one of the following:
  - Humira
  - Enbrel
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

Plaque psoriasis

Pediatric

- FDA indicated diagnosis
- 6 years of age or older
- Prescribed by or in consultation with a dermatologist
- Failure to respond to all of the following:
  - One conventional therapy: methotrexate, calcipotriene or cyclosporine
  - Humira or Enbrel
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

Adult

- FDA indicated diagnosis
- 18 years of age or older

- Prescribed by or in consultation with a dermatologist
- Failure to respond to all of the following:
  - One conventional therapy: methotrexate, calcipotriene, cyclosporine or acitretin
  - Otezla (PA required)
  - Humira or Enbrel
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

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: 2021.
- 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

Prior Authorization Approval Criteria

Cuvposa (glycopyrrolate oral solution)

Generic name: glycopyrrolate oral solution
Brand name: Cuvposa
Medication class: Anticholinergic agent

FDA-approved uses:

- Chronic severe drooling (sialorrhea) in neurologic conditions associated with problem drooling

Usual dose range:

- Up to 3 mg three times daily (weight-based dosing, max 0.1 mg/kg per dose)

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

Initiation Criteria

Chronic severe drooling in neurologic conditions associated with problem drooling

Pediatric

- FDA indicated diagnosis
- 3 years of age or older
- Prescribed by or in consultation with a neurologist
- Documentation of specific neurologic condition that is causing problem drooling (e.g. cerebral palsy)
- Confirmation of one of the following:
  - Failure to respond (or intolerance) to glycopyrrolate tablets
    - OR -
  - Patient is physically incapable of taking tablets

Renewal Criteria

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

Additional considerations:

- Maximum of 9 mg per day

Approval time frames:

- Initial – 6 months, MDL 45 mL/day (9 mg/day)
- Renewal – 1 year, MDL MDL 45 mL/day (9 mg/day)

References:

- Cuvposa Prescribing Information. Merz North America, Inc., Raleigh, NC: 2021.

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

Prior Authorization Approval Criteria

Daytrana (methylphenidate extended release transdermal system)

Generic name: methylphenidate extended release transdermal system
Brand name: Daytrana
Medication class: CNS Stimulant

FDA-approved uses:

- Attention Deficit Hyperactivity Disorder (ADHD) in children (ages 6-12) and adolescents (ages 13-17)

Usual dose range:

- ADHD – children and adolescent 10 mg – 30 mg /9 hours

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

Initiation Criteria

ADHD:

Children and Adolescents

- FDA indicated diagnosis
- Age 6 to 17 years of age
- Failure to respond (or intolerance) to each of the following
  - A formulary methylphenidate product
  - A formulary amphetamine product

OR

- Inability to take oral formulations

Renewal Criteria

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

Additional considerations:

- Maximum daily dose is 30 mg/9 hours.
- The patch should be applied 2 hours before an effect is needed and should be removed 9 hours after application.
- Dose should be titrated to effect. Dose titration, final dosage and wear time should be individualized according to the needs and response of the patient.

Approval time frames:

- Initial – 1 year with MDL of 1 patch/day

- Renewal – 1 year with MDL of 1 patch/day

References:

1. Daytrana Prescribing Information. Noven Pharmaceuticals, Inc., Miami, FL: 2021.
2. Wolraich ML, Hagan JF, Allan C, et al. AAP SUBCOMMITTEE ON CHILDREN AND ADOLESCENTS WITH ATTENTION-DEFICIT/HYPERACTIVE DISORDER. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528.
3. American Academy of Pediatrics Subcommittee on ADHD, Steering Committee on Quality Improvement and Management. ADHD: clinical practice guidelines for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics. 2011; 128:1007-1022.
4. Feldman HM, Reiff MI. Attention deficit-hyperactivity disorder in children and adolescents. N Engl J Med. 2014; 370:838-846.
5. Pelham WE, Burrows-MacLean L, Gnagy EM, Fabiano GA, Coles EK, Tresco KE et al: Transdermal methylphenidate, behavioral, and combined treatment for children with ADHD. Exp Clin Psychopharmacol. 2005; 13(2):111-126.
6. McGough JJ, Wigal SB, Abikoff H, Turnbow JM, Posner K, Moon E. A randomized, double-blind, placebo-controlled, laboratory classroom assessment of methylphenidate transdermal system in children with ADHD. J Atten Disord. 2006; 9(3):476-485.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/19/2013
Revision: July 2015, July 2016, July 2017, July 2018, July 2019, November 2020, January 2022

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

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

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 years 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 all of the following:
  - A formulary medium- or high-potency topical steroid
  - Topical tacrolimus (ST required)

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

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 – 6 months with MDL of 2 injections per 28 days; MDL is based on strength prescribed (Note: Initial loading dose requires 2 injections as a 14 day supply; MDL is based on strength prescribed)
- Renewal – 1 year with MDL of 2 injections per 28 days; MDL is based on strength prescribed)

References:

- Dupixent® (package insert); Tarrytown, NY; Regeneron Pharmaceuticals, Inc.; 2021.
- Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2021. Available from www.ginasthma.org. Accessed December 28, 2021.
- 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

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: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Migraine prophylaxis

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 **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)

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/pen)
  - Renewal: 1 year with MDL of up to 3 mL per 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

Prior Authorization Approval Criteria

Epidiolex (cannibidiol)

Generic name: cannibidiol
Brand name: Epidiolex
Medication class: Cannabinoid; anticonvulsant

FDA-approved uses:

- Dravet Syndrome
- Lennox-Gastaut Syndrome
- Tuberous Sclerosis Complex

Usual dose range:

- 2.5 – 12.5 mg/kg twice daily

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

Initiation Criteria

Dravet Syndrome/Tuberous Sclerosis Complex

Pediatric

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

Lennox-Gastaut Syndrome

Pediatric and adult

- FDA indicated diagnosis
- 1 years of age or older
- Prescribed by or in consultation with a neurologist
- Documentation of current patient weight in kg
- Failure to respond (or intolerance) to all of the following in order of Step Therapy requirements:
  - First, both lamotrigine **AND** topiramate must be tried
  - Second, clobazam must be tried
  - Third, rufinamide must be tried

Renewal Criteria

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

Additional considerations:

- Maximum dose of 25 mg/kg daily

Approval time frames:

- Initial – 6 months, MDL 25 mg/kg calculated to mL/day
- Renewal – 1 year, MDL 25 mg/kg calculated mL/day

References:

- Epidiolex Prescribing Information. Greenwich Biosciences, Inc., Carlsbad, CA: 2022.
- Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy. Neurology 2018;91(2):74-81.
- Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy. Neurology 2018;91(2):82-90.

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

Prior Authorization Approval Criteria

Fanapt (iloperidone)

Generic name: iloperidone
Brand name: Fanapt
Medication class: Antipsychotic

FDA-approved uses:

- Treatment of schizophrenia in adults

Usual dose range:

- Schizophrenia – adults
  - Starting dose — 1 mg twice a day
  - Target dose — 6-12 mg twice a day

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

Initiation criteria

Schizophrenia:

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of three formulary antipsychotics agents

Renewal criteria

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

Additional considerations:

- Fanapt must be titrated slowly from a low starting dose to avoid orthostatic hypotension.
- Maximum daily dose is 24 mg/day
- Dose should be reduced in patients taking CYP2D6 or CYP3A4 inhibitors

Approval time frames:

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

References:

- Fanapt Prescribing Information (2021). Novartis Pharmaceuticals Corporation East Hanover, NJ.
- American Psychiatric Association (APA): Practice guideline for the treatment of patients with schizophrenia, third edition (2021). Available at: https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841. Accessed on December 20, 2021.
- American Psychiatric Association. Five things physicians and patients should question [guideline on the internet]. Available from: http://www.choosingwisely.org/doctor-patient-lists/american-psychiatric-association. Accessed on December 20, 2021.
- PL Detail-Document, Comparison of Atypical Antipsychotics. Pharmacist's Letter/Prescriber's Letter 2015; 31(9): 310909. June 2015.
- Hasan A, Falkai P, Wobrock T, Lieberman J, Glenthøj B, Gattaz W et al. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Schizophrenia, Part 1: Update 2012 on the acute treatment of schizophrenia and the management of treatment resistance. World J Biol Psychiatry 2012; 13: 318-378.
- Hasan A, Falkai P, Wobrock T, Lieberman J, Glenthøj B, Gattaz W et al. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Schizophrenia, Part 2: Update 2012 on the long-term treatment of schizophrenia and management of antipsychotic-induced side effects. World J Biol Psychiatry 2013; 14: 2-44.
- Dixon L, Perkins D, Calmes C. American Psychiatric Association. Guideline Watch (September 2009): practice guideline for the treatment of patients with schizophrenia. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia-watch.pdf. Accessed December 20, 2021.
- Cutler AJ, Kalali AH, Weiden PJ, Hamilton J, Wolfgang CD. Four-week, double-blind, placebo- and ziprasidone-controlled trial of iloperidone in patients with acute exacerbations of schizophrenia. J Clin Psychopharmacol 2008; 28(2 Suppl 1):S20-S28.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: June 2013
Revision: June 2014, June 2015, June 2016, June 2017, June 2018, June 2019, October 2020, January 2022

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: (bullet points are all inclusive unless otherwise noted)

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)
- 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)

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 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

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: (bullet points are all inclusive unless otherwise noted)

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.; 2021.
- 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

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: (bullet points are all inclusive unless otherwise noted)

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; 2021.

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

Prior Authorization Approval Criteria

Mavyret, Zepatier

(Hepatitis C Virus Non-Preferred Medications)

Non-Preferred Formulary agents: Mavyret, Zepatier

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

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

- ☐ If requesting completion of therapy, then go to "Renewal Criteria" section below
- ☐ 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; 18 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: 2019.
- 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 October 27, 2021.

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

Prior Authorization Approval Criteria

Epclusa, Harvoni

(Hepatitis C Virus Preferred Medications)

Preferred Formulary agents: Epclusa, Harvoni

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

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

- ☐ If requesting completion of therapy, then go to "Renewal Criteria" section below
- ☐ 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: 2021.
- 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 October 27, 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

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: (bullet points are all inclusive unless otherwise noted)

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: 2021.
- 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

Prior Authorization Approval Criteria

Invega Sustenna (paliperidone palmitate)

Generic name: paliperidone palmitate
Brand name: Invega Sustenna
Medication class: Antipsychotic

FDA-approved uses:

- Treatment of schizophrenia
- Treatment of schizoaffective disorder as monotherapy and as adjunct to mood stabilizers or antidepressants

Usual dose range:

- Initial loading dose
  - Schizophrenia: 234 mg on day 1, 156 mg on day 8
  - Schizoaffective disorder: 234 mg on day 1, 156 mg on day 8
- Maintenance
  - Schizophrenia: 39-234 mg every month
  - Schizoaffective disorder: 78-234 mg every month

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

Initiation criteria

Schizophrenia/Schizoaffective disorder:

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Documented tolerance to oral paliperidone or risperidone
- Patient has a history of noncompliance and/or refuses to utilize oral medication and documentation that patient education and other efforts to improve adherence have been attempted
- Either one of the following:
  - Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of Risperdal Consta (Step Therapy required: trial of oral risperidone)

  OR
  - Documented stabilization on oral paliperidone (trial of 4-6 weeks), evidenced by previous prior authorization approval by the plan or confirmed coverage by the previous plan (e.g. pharmacy has been filling through the previous plan)

Renewal criteria

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

Additional considerations:

- To reduce the risk of hypersensitivity and first dose adverse effects patients should have a documented exposed to oral risperidone or paliperidone prior to initiation of paliperidone palmitate.
- Patients should not receive supplemental oral doses of antipsychotics after the first dose of IM paliperidone palmitate.
- Dose adjustments:
    - Moderate to severe renal impairment (CrCl < 50mL/min) – not recommended
    - Mild renal impairment (CrCl 50-80mL/min)
        - Initial loading dose – 156 mg on day 1 and 117 mg on day 7 then 78 mg monthly
- Maximum daily dose is 234 mg monthly

Approval time frames:

- Initial – 6 months with a quantity limit of 1 syringe/month
- Renewal – 1 year with a quantity limit of 1 syringe/month

References:

- Invega Sustenna Prescribing Information (2021). Janssen Pharmaceuticals, Inc. Titusville, NJ.
- American Psychiatric Association (APA): Practice guideline for the treatment of patients with schizophrenia, third edition (2021). Available at: https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841. Accessed on December 20, 2021.
- American Psychiatric Association. Five things physicians and patients should question [guideline on the internet]. Available from: http://www.choosingwisely.org/doctor-patient-lists/american-psychiatric-association/. Accessed on December 20, 2021.
- Hasan A, Falkai P, Wobrock T, Lieberman J, Glenthøj B, Gattaz W et al. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Schizophrenia, Part 1: Update 2012 on the acute treatment of schizophrenia and the management of treatment resistance. World J Biol Psychiatry 2012; 13: 318-378.
- Hasan A, Falkai P, Wobrock T, Lieberman J, Glenthøj B, Gattaz W et al. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Schizophrenia, Part 2: Update 2012 on the long-term treatment of schizophrenia and management of antipsychotic-induced side effects. World J Biol Psychiatry 2013; 14: 2-44.
- Dixon L, Perkins D, Calmes C. American Psychiatric Association. Guideline Watch (September 2009): practice guideline for the treatment of patients with schizophrenia. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia-watch.pdf. Accessed on December 20, 2021.
- Kramer M, Litman R, Hough D, Lane R, Lim P, Lin Y et al. Paliperidone palmitate, a potential long-acting treatment for patients with schizophrenia. Int J Neuropsychopharmacol 2010; 13(5):635-647.
- Pandina GJ, Lindenmayer J-P, Lull J, Lim P, Gopal S, Herben V et al. A randomized, placebo-controlled study to assess the efficacy and safety of 3 doses of paliperidone palmitate in adults with acutely exacerbated schizophrenia. J Clin Psychopharmacol 2010; 30(3): 235-244.
- Hough D, Lindenmayer J-P, Gopal S, Melkote R, Lim P, Herben V et al. Safety and tolerability of deltoid and gluteal injections of paliperidone palmitate in schizophrenia. Prog Neuropsychopharmacol Biol Psych 2009; 33(6):1022-1031.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: June 2013
Revision: June 2014, June 2015, June 2016, June 2017, June 2018, June 2019, October 2020, January 2022

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 intolerance to an adequate trial of hydroxyurea

Intermediate or high-risk myelofibrosis

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Confirmation that the patient is ineligible for allogeneic hematopoietic cell transplantation (HCT)
- 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: 2022.

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

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: 2020.

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

Prior Authorization Approval Criteria

Kapvay (clonidine extended-release)

Generic name: clonidine extended release
Brand name: Kapvay
Medication class: antiadrenergic agent, centrally acting

FDA-approved uses:

- Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications in children and adolescents

Usual dose range:

- ADHD – children and adolescents ages 6 to 17
  0.1 mg – 0.4 mg/daily (taken twice daily, divided equally or split with the higher dose given at bedtime)

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

Initiation Criteria

ADHD:

Children and adolescents

- FDA indicated diagnosis
- Age 6 to 17 years of age
- Failure to respond (or intolerance) to both of the following:
  - Guanfacine extended-release
  - Atomoxetine

Renewal Criteria

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

Additional considerations:

- Dose should be initiated with one 0.1 mg tablet at bedtime, and the daily dosage should be adjusted in increments of 0.1 mg/day at weekly intervals until the desired response is achieved. Doses should be taken twice daily, with either an equal or higher split dosage given at bedtime.
- Tablet should not be crushed, chewed, or broken before swallowing
- When discontinuing, the dosage should be tapered in decrements of no more than 0.1 mg every 3 to 7 days to avoid rebound hypertension
- Heart rate and blood pressure should be determined prior to initiation of therapy, following dosage increases, and periodically during therapy
- Maximum daily dose is 0.4 mg/day

Approval time frames:

- Initial – 1 year with MDL of 1-4/day (based on dose)
- Renewal – 1 year with MDL of 1-4/day (based on dose)

References:

1. Kapvay Prescribing Information. Shionogi Inc. Florham Park, NJ: 2021.
2. Wolraich ML, Hagan JF, Allan C, et al. AAP SUBCOMMITTEE ON CHILDREN AND ADOLESCENTS WITH ATTENTION-DEFICIT/HYPERACTIVE DISORDER. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528.
3. Feldman HM, Reiff MI. Attention deficit-hyperactivity disorder in children and adolescents. N Engl J Med. 2014; 370:838-846.
4. American Academy of Pediatrics Subcommittee on ADHD, Steering Committee on Quality Improvement and Management. ADHD: clinical practice guidelines for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics. 2011; 128:1007-1022.
5. Kollins SH, Jain R, Brams M, Segal S, Findling RL, Wigal SB et al. Clonidine extended-release tablets as add-on therapy to psychostimulants in children and adolescents with ADHD. Pediatrics. 2011; 127(6):e1406-e1413.
6. Jain R, Segal S, Kollins SH, Khayrallah M. Clonidine extended-release tablets for pediatric patients with attention-deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry. 2011; 50(2):171-179.
7. Palumbo DR, Sallee FR, Pelham WE, Bukstein OG, Daviss WB, McDermott MP. Clonidine for attention-deficit/hyperactivity disorder: I. Efficacy and tolerability outcomes. J Am Acad Child Adolesc Psychiatry. 2008; 47(2):180-188.
8. Hazell PL, Stuart JE: A randomized controlled trial of clonidine added to psychostimulant medication for hyperactive and aggressive children. J Am Acad Child Adolesc Psychiatry 2003; 42(8):886-894.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/19/2013
Revision: July 2015, July 2016, July 2017, July 2018, July 2019, November 2020, January 2022

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: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Central precocious puberty

Pediatrics

- FDA indicated diagnosis
- 2 years 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: 2021.
- Lupron Depot-Ped Prescribing Information; North Chicago, IL; AbbVie Inc: 2021.
- 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

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: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Migraine (acute treatment)

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an neurologist
- Failure to respond to an adequate trial of **two** the following:
  - Eletriptan
  - Sumatriptan
  - Rizatriptan
  - Zolmitriptan
- Failure to respond to an adequate trial of Cambia

Migraine prophylaxis

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 **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)

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; 2021.
- 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

Prior Authorization Approval Criteria

OPIOID-BENZODIAZEPINE CONCURRENT USE

Medication class: Opioids and Benzodiazepines

Criteria:

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

Exceptions:

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

Approval time frames:

- One year

References:

- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016; 65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.Available at http://www.cdc.gov/drugoverdose/prescribing/guideline.html. [Accessed September 15, 2017].
- Washington State Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf [Accessed September 15, 2017].
- Ballas SK. Pain Management of Sickle Cell Disease, 2005. Hematol Oncol Clin N Am 19 (2005) 785-802.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: October 2019
Reviewed: September 2020, September 2021

Prior Authorization Approval Criteria

Opioid Morphine Equivalent Dose (MED) Limit

Medication class: Opioids

Usual dose range:

- No prior authorization needed if < 200 MED per day

Criteria for use:

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

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

–OR—

- Intent to taper down to < 200 MED

Renewal Criteria:

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

Not approved if:

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

Approval time frames:

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

References:

- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016; 65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.Available at http://www.cdc.gov/drugoverdose/prescribing/guideline.html. [Accessed September 15, 2017].
- Washington State Interagency Guideline on Prescribing Opioids for Pain. June 2015. Available at http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf [Accessed September 15, 2017].
- Ballas SK. Pain Management of Sickle Cell Disease, 2005. Hematol Oncol Clin N Am 19 (2005) 785-802.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: December 2017
Revision: December 2021

Prior Authorization Approval Criteria

Opioid Naïve Day Supply Limit

Medication class: Opioids

Criteria:

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

Exceptions:

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

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

Approval time frame:

- One year

References:

- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016; 65(No. RR-1):1–49. doi: http://dx.doi.org/10.15585/mmwr.rr6501e1.
- Colorado Department of Regulatory Agencies. 2019. Guidelines for the Safe Prescribing and Dispensing of Opioids. [Online]. Accessed from https://www.colorado.gov/pacific/dora/opioid_guidelines

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

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 (i.e. methotrexate, leflunomide, sulfasalazine)
  - Humira or Enbrel
  - Otezla (PA required)
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

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 (i.e. methotrexate, leflunomide, sulfasalazine)
  - Humira or Enbrel
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

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

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:

- 100 mg/125 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
- 2 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 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: 2020.

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

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/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, intolerance, or contraindication to an adequate trial of one of the following:
  - A formulary DMARD (i.e. methotrexate, leflunomide, sulfasalazine)
  - A formulary TNF-inhibitor (i.e. Humira, Enbrel)

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, intolerance, or contraindication to an adequate trial of all 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 (First month override for titration starter pack 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.
- 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. Journal of the American Academy of Dermatology 2009;61:451-85.

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

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: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Migraine (acute treatment)

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an neurologist
- Failure to respond to an adequate trial of **two** the following:
  - Eletriptan
  - Sumatriptan
  - Rizatriptan
  - Zolmitriptan
- Failure to respond to an adequate trial of Cambia

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; 2020.
- 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

Prior Authorization Approval Criteria

Rozerem (ramelteon)

Generic name: ramelteon
Brand name: Rozerem
Medication class: Nonbenzodiazepine hypnotic

FDA-approved uses:

- Insomnia

Usual dose range:

- Insomnia - adult — 8 mg at bedtime

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

Initiation Criteria

Insomnia:

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial of two of the following:
  - Doxepin (generic Silenor)
  - Trazodone
  - Temazepam
  - Zolpidem or zolpidem extended-release
  - Eszopiclone

Renewal Criteria

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

Not approved if:

- Patient is currently taking other medications that can cause wakefulness (e.g. stimulants)
- Patient is currently taking fluvoxamine

Additional considerations:

- Do NOT take with meals
- Maximum daily dose is 8mg/day

Approval time frames:

- Initial – 1 year with MDL of 1/day

- Renewal – 1 year with MDL of 1/day

References:

- Rozerem Prescribing Information. Takeda Pharmaceuticals America, Inc., Deerfield, IL: 2021.
- Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(2):307–349.
- Wilson SJ, Nutt DJ, Alford C, Argyropoulos SV, Baldwin DS, Bateson AN et al. British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders. J Psychopharmacol. 2010;24(11):1577-1601.
- Mayer G, Wang-Weigand S, Roth-Schechter B, Lehmann R, Staner C, Partinen M. Efficacy and safety of 6-month nightly ramelteon administration in adults with chronic primary insomnia. Sleep. 2009;32(3):351-360.
- Erman M, Seiden D, Zammit G, Sainati S, Zhang J. An efficacy, safety, and dose-response study of ramelteon in patients with chronic primary insomnia. Sleep Med. 2006;7(1):17-24.
- Roth T, Stubbs C, Walsh JK. Ramelteon (TAK-375), a selective MT1/MT2-receptor agonist, reduces latency to persistent sleep in a model of transient insomnia related to a novel sleep environment. Sleep. 2005;28(3):303-307.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: 07/10/2013
Revision: 07/10/2014, July 2015, July 2016, July 2017, July 2018, July 2019, November 2020, January 2022

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) by an FDA-approved diagnostic test for Rubraca
- Documentation of one of the following:
  - Failure to respond to a trial of two previous chemotherapy regimens
    -OR-
  - 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

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: 2021.

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

Prior Authorization Approval Criteria
Saphris (asenapine)

Generic name: Saphris
Brand name: asenapine
Medication class: antipsychotic

FDA-approved uses:

- Treatment of schizophrenia
- Acute treatment of manic or mixed episodes associated with bipolar I disorder as monotherapy or adjunctive treatment to lithium or valproate

Usual dose range:

- Schizophrenia – adults — 5-10 mg twice a day sublingually
- Bipolar Mania – adults — 5-10 mg twice a day sublingually
- Bipolar Mania – pediatric patients (10-17 years) — 2.5-10 mg twice a day sublingually

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

Initiation criteria

Schizophrenia:

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of three formulary antipsychotics agents

OR

- Patient requires orally disintegrating formulation
- Failure to respond (or intolerance) to an adequate trial (at least 30 days) of each of the following:
  - Risperidone ODT
  - Olanzapine ODT

Bipolar I Disorder:

Pediatrics and Adults

- FDA indicated diagnosis
- 10 years of age or older
- Failure to respond (or intolerance) to an adequate trial (at least 30 days with adequate blood levels) of each of the following:
  - Lithium OR valproic acid
  - Two formulary antipsychotic agents

OR

- Patient requires orally disintegrating formulation
- Failure to respond (or intolerance) to an adequate trial (at least 30 days) of each of the following:
  - Risperidone ODT
  - Olanzapine ODT

Renewal criteria

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

Additional considerations:

- Maximum daily dose is 10 mg twice a day

Approval time frames:

- Initial – 6 month(s) with MDL of 2/day
- Renewal – 1 year(s) with MDL of 2/day
- Special approval notes – for renewals of patients requiring orally disintegrating formulation verify that they still need ODT formulation

References:

- Saphris Prescribing Information (2017). Merck & Co. Inc., Whitehouse Station, NJ.
- American Psychiatric Association (APA): Practice guideline for the treatment of patients with schizophrenia, third edition (2021). Available at: https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841. Accessed on December 20, 2021.
- Yatham LN, Kennedy SH, Parikh SV, et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) and International Society for Bipolar Disorders (ISBD) 2018 guidelines for the management of patients with bipolar disorder. Bipolar Disord. 2018;20:97–170. https://doi.org/10.1111/bdi.12609
- American Psychiatric Association. Five things physicians and patients should question [guideline on the internet]. Available from: http://www.choosingwisely.org/doctor-patient-lists/american-psychiatric-association/ Accessed on December 20, 2021.
- PL Detail-Document, Comparison of Atypical Antipsychotics. Pharmacist's Letter/Prescriber's Letter 2015; 31(9): 310909. June 2015.
- PL Detail-Document, Off-label Use of Atypical Antipsychotics in Adults. Pharmacist's Letter/Prescriber's Letter 2015; 31(7): 310701. June 2015.
- Hasan A, Falkai P, Wobrock T, Lieberman J, Glenthøj B, Gattaz W et al. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Schizophrenia, Part 1: Update 2012 on the acute treatment of schizophrenia and the management of treatment resistance. World J Biol Psychiatry 2012; 13: 318-378.
- Dixon L, Perkins D, Calmes C. American Psychiatric Association. Guideline Watch (September 2009): practice guideline for the treatment of patients with schizophrenia. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia-watch.pdf. Accessed on December 20, 2021.
- Potkin SG, Cohen M, Panagides J. Efficacy and tolerability of asenapine in acute schizophrenia: a placebo- and risperidone-controlled trial. J Clin Psychiatry 2007; 68:1492-1500.
- Kane JM, Cohen M, Zhao J, Alphs L, Panagides J. Efficacy and safety of asenapine in a placebo- and haloperidol-controlled trial in patients with acute exacerbation of schizophrenia. J Clin Psychopharmacol 2010; 30:106-115.
- Grunze H, Vieta E, Goodwin GM, Bowden C, Licht RW, Möller H-J et al. The World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for the Biological Treatment of Bipolar Disorders: Update 2009 on the treatment of acute mania. World J Biol Psychiatry 2009; 10: 85-116.
- McIntyre RS, Cohen M, Zhao J, Alphs L, Macek TA, Panagides J. Asenapine in the treatment of acute mania in bipolar I disorder: a randomized, double-blind, placebo-controlled trial. J Affect Disord 2010; 122(1-2): 27-38.

Formal Review as per Rx-DOP-3.0 Criteria Development and Maintenance Procedures:
Initial: June 2013
Revision: June 2014, June 2015, June 2016, June 2017, June 2018, June 2019, October 2020, January 2022

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: (bullet points are all inclusive unless otherwise noted)

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: 2019.
- 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

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 (or intolerance) to all of the following:
  - Humira
  - Enbrel
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

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 (i.e. methotrexate, leflunomide, sulfasalazine)
  - Humira or Enbrel
  - Otezla (PA required)

- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

Rheumatoid 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 (i.e. methotrexate, leflunomide, sulfasalazine)
  - Humira
  - Enbrel
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

Ulcerative colitis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a gastroenterologist
- Failure to respond to Humira
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

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, Gensler 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

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: (bullet points are all inclusive unless otherwise noted)

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)

- Height determination, documentation that epiphyseal is not closed, improved growth velocity
  - Therapy should be discontinued when:
    - When epiphyses have fused
    - 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

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 Humira
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

Plaque psoriasis

Adult

- FDA indicated diagnosis
- 12 years of age or older
- Prescribed by or in consultation with a dermatologist
- Failure to respond (or intolerance) to all of the following:
  - Methotrexate, calcipotriene, cyclosporine or acitretin
  - Humira or Enbrel
  - Otezla (PA required)

- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

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 (i.e. methotrexate, leflunomide, sulfasalazine)
  - Humira or Enbrel
  - Otezla (PA required)
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

Ulcerative colitis

Adult

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with a gastroenterologist
- Failure to respond to Humira
- Confirmation that the patient is not using another biologic medication concomitantly to treat the same diagnosis

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 0.018/day (1 mL syringe every 56 days)
  - Renewal: 1 year with MDL 0.018/day (1 mL syringe every 56 days)
- Plaque psoriasis/Psoriatic arthritis
  - Initial: 6 months with MDL 0.012/day (1 mL syringe every 84 days)
    - Loading dose: 1 month with MDL 0.08/day (2 x 1 mL syringes as a 28 day supply)
  - Renewal: 1 year with MDL 0.012/day (1 mL syringe every 84 days)

References:

- Stelara Prescribing Information; Horsham, PA; Janssen Biotech, Inc.: 2020.
- 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

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 subcutaneously once monthly for maximum of 5 doses

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

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.
- RSV season is generally from October/November through March/April, however, it varies from year to year. See "approval time frames" section for the current year's season range.

Approval time frames:

- Initial
  - 1 dose monthly within the RSV season of August 2021 through April 2022; maximum of 5 doses per RSV season
- Renewal
  - 1 dose monthly within the RSV season of August 2021 through April 2022; 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

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: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Philadelphia chromosome-positive chronic myelogenous leukemia

Pediatrics

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

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; 2021.
- National Comprehensive Cancer Network. Chronic Myeloid Leukemia 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf [Accessed January 6, 2022].

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

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: (bullet points are all inclusive unless otherwise noted)

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.; 2021.
- 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

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: 2020.
- 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

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: (bullet points are all inclusive unless otherwise noted)

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; 2021.
- 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

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 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: 2021.

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

Prior Authorization Approval Criteria

Tymlos (abaloparatide)

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

FDA-approved uses:

- Postmenopausal osteoporosis

Usual dose range:

- 80 mcg daily

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

Initiation Criteria

Postmenopausal osteoporosis

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)
- 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)

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 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; 2021.
- 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

Prior Authorization Approval Criteria

Ubrelvy (ubrogepant)

Generic name: ubrogepant
Brand name: Lupron Depot and Lupron Depot-Ped
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: (bullet points are all inclusive unless otherwise noted)

Initiation Criteria

Migraine (acute treatment)

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Prescribed by or in consultation with an neurologist
- Failure to respond to an adequate trial of **two** the following:
  - Eletriptan
  - Sumatriptan
  - Rizatriptan
  - Zolmitriptan
- Failure to respond to an adequate trial of Cambia

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; 2021.
- 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

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: 2021.

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

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
- 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: 2022.
- 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

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: (bullet points are all inclusive unless otherwise noted)

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: 2021.
- Rubraca Prescribing Information; Boulder, CO; Clovis Oncology, Inc: 2021.

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

Prior Authorization Approval Criteria

Zyprexa Relprevv

(olanzapine pamoate extended release injection)

Generic name: olanzapine pamoate extended release injection
Brand name: Zyprexa Relprevv
Medication class: Antipsychotic

FDA-approved uses:

- Treatment of schizophrenia

Usual dose range:

- Schizophrenia – adult
  - Dose is based on correspondence to oral olanzapine dose
  - Initial dose — 210 mg or 300 mg every 2 weeks or 405 mg every 4 weeks
  - Maintenance — 150 mg, 210 mg or 300 mg every 2 weeks or 300 mg or 405 mg every 4 weeks

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

Initiation criteria

Schizophrenia:

Adults

- FDA indicated diagnosis
- 18 years of age or older
- Documented tolerance to oral olanzapine
- Patient has a history of noncompliance and/or refuses to utilize oral medication and documentation that patient education and other efforts to improve adherence have been attempted
- Either one of the following:
  - Failure to respond (or intolerance) to an adequate trial (4-6 weeks) of Risperdal Consta (Step Therapy required: trial of oral risperidone)

  OR
  - Documented stabilization on oral olanzapine (trial of 4-6 weeks)

Renewal criteria

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

Additional considerations:

- Medication can only be administered in a registered healthcare facility with ready access to emergency response services, and the patient will be monitored for at least 3 hours after injection for delirium/sedation syndrome prior to release
- Establish tolerability with oral olanzapine prior to initiating treatment
- Plasma concentrations remain in the therapeutic effective range and oral supplementation is generally not necessary
- Maximum dose is 405mg every 4 weeks or 300mg every 2 weeks

Approval time frames:

- Initial
  - 6 months with the following quantity limits:
    - 2 vials/month for 150 mg, 210 mg, or 300 mg injection
    - 1 vial/month for 405 mg injection

- Renewal
  - 1 year with the following quantity limits:
    - 2 vials/month for 150 mg, 210 mg, or 300 mg injection
    - 1 vial/month for 405 mg injection

References:

- Zyprexa Relprevv Prescribing Information (2021). Lilly USA, LLC. Indianapolis, IN.
- American Psychiatric Association (APA): Practice guideline for the treatment of patients with schizophrenia, third edition (2021). Available at: https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890424841. Accessed on December 20, 2021.
- American Psychiatric Association. Five things physicians and patients should question [guideline on the internet]. Available at: http://www.choosingwisely.org/doctor-patient-lists/american-psychiatric-association/ Accessed on December 20, 2021.
- L Dixon, Perkins D, Calmes C. American Psychiatric Association. Guideline Watch (September 2009): practice guideline for the treatment of patients with schizophrenia. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/schizophrenia-watch.pdf. Accessed on December 20, 2021.
- Lauriello J, Lambert T, Andersen S, Lin D, Taylor CC, McDonnell D. An 8-week, double-blind, randomized, placebo-controlled study of olanzapine long-acting injection in acutely ill patients with schizophrenia. J Clin Psychiatry 2008; 69(5):790-799.
- Kane JM, Detke HC, Naber D, Sethuraman G, Lin DY, Bergstrom RF et al. Olanzapine long-acting injection: a 24-week, randomized, double-blind trial of maintenance treatment in patients with schizophrenia. Am J Psychiatry 2010; 167(2):181-189.

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