



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Immediate-Release Opioid Analgesic Duration of Therapy and Quantity Limits Page: 1 of 4

Effective Date: 7/5/2023 Last Review Date: 03/2023

Applies to: Illinois Florida Florida Kids
 New Jersey Maryland Michigan
 Pennsylvania Kids Virginia Texas

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for immediate-release opioid analgesics for members 19 years of age and younger under the patient's prescription drug benefit.

Description:

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines for immediate-release opioid analgesics for members 19 years of age and younger. All immediate-release opioid analgesics are limited to a maximum 3-day supply and other quantity limits. The American Pain Society Opioid Treatment Guidelines state that a reasonable definition for high dose opioid therapy is greater than 200 mg daily of oral morphine (or equivalent). Requests to exceed these limits and those for any non-preferred product are subject to the criteria in this policy. Medications requested for more than 200 Morphine Milligram Equivalents (MME) per day will require a Medical Director Review.

Applicable Drug List:

Immediate-Release Opioid Analgesics

Codeine sulfate tablets
Hydromorphone hydrochloride oral solution, suppositories, tablets
Levorphanol tartrate tablets
Meperidine hydrochloride oral solution, tablets
Morphine sulfate oral solution, oral solution concentrate, suppositories, tablets
Oxycodone hydrochloride capsules, oral solution, oral solution concentrate, tablets
Oxymorphone hydrochloride tablets
Pentazocine/naloxone tablets
Tapentadol tablets
Tramadol hydrochloride oral solution, tablets

Acetaminophen/Aspirin/Ibuprofen Containing Opioid Analgesics

Acetaminophen and benzhydrocodone
Acetaminophen and codeine
Acetaminophen and hydrocodone
Acetaminophen and oxycodone
Acetaminophen and tramadol
Acetaminophen, caffeine, and dihydrocodeine



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Applies to:

<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
<input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Texas

Aspirin and oxycodone
Celecoxib and tramadol
Ibuprofen and hydrocodone

Policy/Guideline:

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care
AND
- If the request is for a non-preferred product, the patient is unable to take the 3 formulary alternatives for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

OR

- The patient can safely take the requested dose based on their history of opioid use. [Note: The lowest effective dosage should be prescribed for opioid naïve patients.]
AND
- The patient is 19 years of age and younger and has been evaluated and will be monitored regularly for the development of opioid use disorder

AND

- The requested drug is being prescribed for moderate to severe CHRONIC pain where use of an opioid analgesic is appropriate. [Note: Chronic pain is generally defined as pain that typically lasts greater than 3 months.]

AND

- The patient's pain will be reassessed in the first month after the initial prescription or any dose increase AND every 3 months thereafter to ensure that clinically meaningful improvement in pain and function outweigh risks to patient safety

OR

- The patient requires extended treatment beyond 3 days for moderate to severe ACUTE pain where use of an opioid analgesic is appropriate

AND

- If the request is for a non-preferred product, the patient is unable to take the 3 formulary alternatives for the given diagnosis due to a trial and inadequate treatment



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response or intolerance, or a contraindication. Documentation is required for approval.

Quantity Limits may apply.

Approval Duration and Quantity Restrictions:

For pain associated with cancer, sickle cell disease, a terminal condition, or pain being managed through hospice or palliative care: Approve: 12 months

For all other indications: Approve: 6 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Codeine Sulfate tablets [package insert]. Philadelphia, PA: Lannett Company, Inc.; November 2019.
2. Dilaudid oral solution, tablets [package insert]. Coventry, RI: Rhodes Pharmaceuticals L.P.; March 2021.
3. Hydromorphone HCl oral solution, tablets [package insert] Coventry, RI: Rhodes Pharmaceuticals L.P.; March 2021.
4. Hydromorphone HCl suppositories [package insert]. Minneapolis, MN: Perrigo; November 2020.
5. Levorphanol Tartrate [package insert]. Solana Beach, CA: Sentyln Therapeutics, Inc.; January 2021.
6. Meperidine Hydrochloride oral solution, tablets [package insert]. Eatontown, NJ: West-Ward Pharmaceuticals Corp.; March 2021.
7. Morphine Sulfate 10 mg/5 mL, 20 mg/5 mL, 100 mg/5 mL (20 mg/mL) oral solution [package insert]. Coventry, RI: Rhodes Pharmaceuticals L.P.; March 2021.
8. Morphine Sulfate suppositories [package insert]. Minneapolis, MN: Perrigo; March 2019.
9. Morphine Sulfate tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; June 2021.
10. Nucynta oral solution [package insert]. Stoughton, MA: Collegium Pharmaceutical, Inc.; March 2021.
11. Nucynta tablets [package insert]. Stoughton, MA: Collegium Pharmaceutical, Inc.; March 2021.
12. Oxaydo [package insert]. Wayne, PA: Zyla Life Sciences US Inc.; March 2021.
13. Oxycodone Hydrochloride tablets [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY LLC; April 2021.
14. Oxycodone Hydrochloride capsules [package insert]. Philadelphia, PA: Lannett Company, Inc.; November 2019.
15. Oxycodone Hydrochloride 5 mg/5 mL, 100 mg/5 mL (20 mg/mL) oral solution [package insert]. Allentown, PA: Genus Lifesciences Inc.; July 2021.
16. Oxymorphone [package insert]. Newtown, PA: KVK-Tech, Inc.; February 2021.
17. Pentazocine and Naloxone [package insert]. Parsippany, NJ: Actavis Pharma, Inc; July 2020.
18. Qdolo [package insert]. Athens, GA: Athena Bioscience, LLC; September 2021.
19. RoxyBond [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; March 2021.
20. Tramadol [package insert]. Tampa, FL: Trupharma, LLC; April 2019
21. Ultram [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; September 2021.
22. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed December 2021.



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23. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed December 2021.
24. Palliative Care. NCCN Guidelines version 2.2021. Available at: http://www.nccn.org/professionals/physician_gls/pdf/palliative.pdf. Accessed December 2021.
25. Adult Cancer Pain. NCCN Guidelines version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed December 2021.
26. Chou R, Fanciullo G, Fine P, et al. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. *The Journal of Pain*. 2009;10:113-130.
27. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. *MMWR Recomm Rep*. 2016;65:1–49. Available at: <http://dx.doi.org/10.15585/mmwr.rr6501e1>. Accessed December 2021.
28. Clinical Pharmacology [database online]. Tampa, FL: Elsevier/Gold Standard; <http://clinicalpharmacology.com/> [available with subscription]. Accessed December 2021.
29. National Heart, Lung, and Blood Institute. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. Available at: https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Accessed December 2021.
30. Gaither, JR, Shabanova V, Leventhal JM. US National Trends in Pediatric Deaths From Prescription and Illicit Opioids, 1999-2016. *JAMA Network Open*. 2018;1(8):e186558.doi:10.1001/jamanetworkopen.2018.6558.
31. Meich R, Johnston L, O'Malley PM, et al. Prescription Opioids in Adolescence and Future Opioid Misuse. *Pediatrics*. 2015 Nov;136(5):e1169-77. doi: 10.1542/peds.2015-1364.
32. Acetaminophen and Codeine Phosphate Solution [package insert]. Amityville, NY: Hi-Tech Pharmacal Co., Inc.; September 2019.
33. Acetaminophen and Codeine Phosphate Tablet [package insert]. Webster Grove, MO: SpecGx LLC; August 2020.
34. Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Tablet [package insert]. Canton, MS: Larken Laboratories, Inc.; July 2020.
35. Apadaz [package insert]. Newtown, PA: KVK-Tech, Inc.; March 2021.
36. Endocet [package insert]. Chestnut Ridge, NY: Par Pharmaceuticals; August 2020.
37. Hydrocodone Bitartrate and Acetaminophen Solution [package insert]. Princeton, NJ: Eywa Pharma Inc.; April 2021.
38. Hydrocodone Bitartrate and Acetaminophen Tablets [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY LLC; July 2020.
39. Hydrocodone Bitartrate and Ibuprofen Tablet [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY LLC; March 2021.
40. Lortab Elixir [package insert]. Atlanta, GA: Mikart, LLC; May 2021.
41. Nalocet [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; May 2021.
42. Oxycodone and Acetaminophen Tablet [package insert]. Philadelphia, PA: Lannett Company, Inc; August 2020.
43. Oxycodone and Aspirin [package insert]. Greenville, NC: Mayne Pharma; July 2020.
44. Oxycodone and Ibuprofen [package insert]. Elizabeth, NJ: Actavis Pharma, Inc.; August 2020.
45. Prolate Solution [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; June 2021.
46. Prolate Tablet [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; June 2021.
47. Roxicet Tablet and Solution [package insert]. Columbus, OH: Roxane Laboratories, Inc.; August 2016.
48. Seglentis [package insert]. Montgomery, AL: Kowa Pharmaceuticals Inc., Inc; October 2021.
49. Trezix [package insert]. Ridgeland, MS: WraSer Pharmaceuticals LLC; March 2019.
50. Ultracet [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; September 2021.
51. Vicodin [package insert]. North Chicago, IL: AbbVie Inc.; November 2018.
52. Zamicet [package insert]. Greenville, SC: Pharmaceutical Associates, INC; June 2016.