



AETNA BETTER HEALTH®
Coverage Policy/Guideline

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

Effective Date: 6/26/2024 Last Review Date: 6/6/2024

Applies to:	<input checked="" 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 type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> 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 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. All immediate-release opioid analgesics are limited to a maximum 5-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
- Aspirin and oxycodone
- Celecoxib and tramadol
- Ibuprofen and hydrocodone



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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 2 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 has been evaluated and the patient will be monitored regularly for the development of opioid use disorder

AND

- The requested drug is being prescribed for CHRONIC pain severe enough to require an opioid analgesic. [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 5 days for ACUTE pain severe enough to require an opioid analgesic. [NOTE: Many acute pain conditions (e.g., the pain that occurs with a number of surgical procedures or acute musculoskeletal injuries) require no more than a few days of an opioid analgesic.]

AND

- If the request is for a non-preferred product, the patient is unable to take 2 formulary alternatives for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Quantity Limits may apply.



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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

Chronic Pain: Approve 6 months

Acute pain: Approve 1 month

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

References:

1. Acetaminophen and Codeine Phosphate Solution [package insert]. Gurnee, IL: Akorn Operating Company LLC; August 2022.
2. Acetaminophen and Codeine Phosphate Tablet [package insert]. Webster Groves, MO: SpecGx LLC; November 2023.
3. Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate Tablet [package insert]. Canton, MS: Larken Laboratories, Inc.; January 2021.
4. Apadaz [package insert]. Celebration, FL: Zevra Therapeutics, Inc.; December 2023.
5. Hydrocodone Bitartrate and Acetaminophen Solution [package insert]. Princeton, NJ: Eywa Pharma Inc.; October 2022.
6. Hydrocodone Bitartrate and Acetaminophen Tablets 5/300 mg, 7.5/300 mg, 10/300 mg, 5/325 mg, 7.5/325 mg, 10/325 mg [package insert]. Newtown, PA: KVK-Tech, Inc.; November 2023.
7. Hydrocodone Bitartrate and Ibuprofen Tablet [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY, LLC; December 2023.
8. Lortab Elixir [package insert]. Atlanta, GA: Mikart, LLC; May 2021.
9. Nalocet [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; May 2021.
10. Oxycodone and Acetaminophen Tablet [package insert]. Newtown, PA: KVK-Tech, Inc.; December 2023.
11. Oxycodone and Acetaminophen Oral Solution 5 mg/325 mg [package insert]. Newtown, PA: KVK-Tec, Inc.; September 2023.
12. Oxycodone and Acetaminophen Oral Solution 10 mg/300 mg [package insert]. Las Vegas, NV: FH2 Pharma LLC; June 2023.
13. Oxycodone and Aspirin [package insert]. Laurelton, NY: Epic Pharma, LLC; July 2020.
14. Percocet [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; August 2020.
15. Prolate Solution [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; May 2021.
16. Prolate Tablet [package insert]. Las Vegas, NV: Forte Bio-Pharma LLC; June 2021.
17. Seglantis [package insert]. Montgomery, AL: Kowa Pharmaceuticals America, Inc; December 2023.
18. Trezix [package insert]. Ridgeland, MS: WraSer Pharmaceuticals; July 2017.
19. Ultracet [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; September 2021.
20. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed November 7, 2023.
21. Codeine Sulfate Tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; December 2023.
22. Dilaudid oral solution, tablets [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.
23. Hydromorphone HCl suppositories [package insert]. Minneapolis, MN: Perrigo; November 2020.



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24. Levorphanol Tartrate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; October 2023.
25. Meperidine Hydrochloride oral solution, tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; September 2023.
26. Morphine Sulfate 10 mg/5 mL, 20 mg/5 mL, 100 mg/5 mL (20 mg/mL) oral solution [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; December 2023.
27. Morphine Sulfate suppositories [package insert]. Minneapolis, MN: Perrigo; March 2019.
28. Morphine Sulfate tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; December 2023.
29. Nucynta tablets [package insert]. Stoughton, MA: Collegium Pharmaceutical, Inc.; July 2023.
30. Oxaydo [package insert]. Lake Forest, IL: Zyla Life Sciences US LLC.; December 2023.
31. Oxycodone Hydrochloride tablets [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY, LLC; December 2021.
32. Oxycodone Hydrochloride capsules [package insert]. Allentown, PA: Genus Lifesciences Inc.; December 2023.
33. Oxycodone Hydrochloride 5 mg/5 mL, 100 mg/5 mL (20 mg/mL) oral solution [package insert]. Webster Groves, MO: SpecGx LLC; November 2022.
34. Oxymorphone [package insert]. Laurelton, NY: Epic Pharma, LLC; December 2023.
35. Pentazocine and Naloxone [package insert]. Somerset, NJ: Novel Laboratories, Inc; December 2023.
36. Qdolo [package insert]. Athens, GA: Athena Bioscience, LLC; December 2023.
37. RoxyBond [package insert]. Princeton, NJ: Protega Pharmaceuticals Inc., LLC; December 2023.
38. Tramadol [package insert]. Plainsboro, NJ: Advagen Pharma Ltd.; August 2023.
39. Tramadol Oral Solution [package insert]. Tampa FL: TruPharma, LLC; November 2022.
40. Ultram [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; September 2021.
41. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed November 7, 2023.
42. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/07/2023).
43. Palliative Care. NCCN Guidelines version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/palliative.pdf. Accessed November 7, 2023.
44. Adult Cancer Pain. NCCN Guidelines version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed November 7, 2023.
45. 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.
46. Dowell D, Ragan, KR, Jones, CM, et al; CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022. MMWR Recomm Rep. 2022;71:1–95. Available at: <http://dx.doi.org/10.15585/mmwr.rr7103a1>. Accessed November 7, 2023.
47. Clinical Pharmacology [database online]. Tampa, FL: Elsevier/Gold Standard; <https://www.clinicalkey.com/pharmacology/> [available with subscription]. Accessed November 7, 2023.
48. 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%2020816_0.pdf. Accessed November 7, 2023.
49. U.S. Food & Drug Administration. FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use. April 13, 2023. Available at: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-prescribing-information-all-opioid-pain-medicines-provide-additional-guidance-safe-use>. Accessed January 4, 2024.