AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Immediate-Release Opioid Analgesic Duration of Therapy and Quantity Limits	Page:	1 of 4
Effective Date:	12/10/2024	Last Review Date:	11/19/2024
Applies to:	☒Illinois		

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

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.

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 quanitity level limits

References:

1. Codeine Sulfate Tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; December 2023.
2. Dilaudid oral solution, tablets [package insert]. Stamford, CT: Purdue Pharma L.P.; December 2023.
3. Hydromorphone HCl suppositories [package insert]. Minneapolis, MN: Perrigo; November 2020.
4. Levorphanol Tartrate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; October 2023.
5. Meperidine Hydrochloride oral solution, tablets [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; September 2023.
6. 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.
7. Morphine Sulfate suppositories [package insert]. Minneapolis, MN: Perrigo; March 2019.
8. Morphine Sulfate tablets [package insert]. Berkely Heights, NJ: Hikma Pharmaceuticals USA Inc.; December 2023.
9. Nucynta tablets [package insert]. Stoughton, MA: Collegium Pharmaceutical, Inc.; July 2023.
10. Oxaydo [package insert]. Lake Forest, IL: Zyla Life Sciences US LLC.; December 2023.
11. Oxycodone Hydrochloride tablets [package insert]. Brookhaven, NY: Amneal Pharmaceuticals of NY, LLC; December 2021.
12. Oxycodone Hydrochloride capsules [package insert]. Allentown, PA: Genus Lifesciences Inc.; December 2023.
13. Oxycodone Hydrochloride 5 mg/5 mL, 100 mg/5 mL (20 mg/mL) oral solution [package insert]. Webster Groves, MO: SpecGx LLC; November 2022.
14. Oxymorphone [package insert]. Laurelton, NY: Epic Pharma, LLC; December 2023.
15. Pentazocine and Naloxone [package insert]. Somerset, NJ: Novel Laboratories, Inc; December 2023.
16. Qdolo [package insert]. Athens, GA: Athena Bioscience, LLC; December 2023.
17. RoxyBond [package insert]. Princeton, NJ: Protega Pharmaceuticals Inc., LLC; May 2024.
18. Tramadol [package insert]. Plainsboro, NJ: Advagen Pharma Ltd.; August 2023.
19. Tramadol Oral Solution [package insert]. Tampa FL: TruPharma, LLC; November 2022.
20. Ultram [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; September 2021.
21. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed November 7, 2023.
22. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed November 7, 2023.
23. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 11/07/2023).
24. Palliative Care. NCCN Guidelines version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/palliative.pdf. Accessed November 7, 2023.

25. Adult Cancer Pain. NCCN Guidelines version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf. Accessed November 7, 2023.
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, 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.
28. Clinical Pharmacology [database online]. Tampa, FL: Elsevier/Gold Standard; https://www.clinicalkey.com/pharmacology/ [available with subscription]. Accessed November 7, 2023.
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 November 7, 2023.
30. U.S. Food & Drug Administration. FDA updates prescribing information for all opioid pian 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.