



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 type="checkbox"/> Illinois <input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> New Jersey <input type="checkbox"/> Virginia	<input type="checkbox"/> Maryland <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 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
- Aspirin and oxycodone
- Celecoxib and tramadol
- Ibuprofen and hydrocodone



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Immediate-Release Opioid Analgesic Duration of Therapy and Quantity Limits Page: 2 of 4

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

Applies to: Illinois New Jersey Maryland
 Pennsylvania Kids Virginia Texas

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 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 3 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 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.

Quantity Limits may apply.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Immediate-Release Opioid Analgesic Duration of Therapy and Quantity Limits	Page:	3 of 4
Effective Date:	6/26/2024	Last Review Date:	6/6/2024
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> New Jersey <input type="checkbox"/> Virginia	<input type="checkbox"/> Maryland <input type="checkbox"/> Texas

Approval Duration and Quantity Restrictions:

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: 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.
24. Levorphanol Tartrate [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; October 2023.



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Immediate-Release Opioid Analgesic Duration of Therapy and Quantity Limits	Page:	4 of 4
Effective Date:	6/26/2024	Last Review Date:	6/6/2024
Applies to:	<input type="checkbox"/> Illinois <input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> New Jersey <input type="checkbox"/> Virginia	<input type="checkbox"/> Maryland <input type="checkbox"/> Texas

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%20020816_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.