

Opioids

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Opioids are a class of drugs naturally found in the opium poppy plant. Some prescription opioids are made from the plant directly, and others are made by scientists in labs using the same chemical structure. Opioids are often used as medicines because they contain chemicals that relax the body and can relieve pain. Prescription opioids are used mostly to treat moderate to severe pain. The Centers for Medicare and Medicaid Services (CMS) has issued guidance regarding reducing opioid misuse in response to the opioid epidemic. This is to be done by promoting safe and responsible pain management, making sure patients can access treatment for opioid use disorder, and using data to target prevention and treatment.

This policy addresses criteria for both immediate-acting opioid analgesics (such as tramadol, hydrocodone/acetaminophen, hydromorphone, and oxycodone) and extended-release opioid analgesics (such as Fentanyl, morphine extended release, oxymorphone extended release, and

oxycodone extended release). This policy applies to any opioid analgesic on the Plan's Formulary that requires a prior authorization:

- The first fill for members without claims history of prior opioid use for immediate-acting opioid analgesics is limited to:
 - 3-days for members 19 and younger; **or**
 - 7-days for members above the age of 19.
- Immediate-acting opioid analgesic use is required before prescribing extended-release opioid analgesics. A prior authorization is required if claims history has no prior use of an immediate-acting opioid or if a member is not already stable on an extended-release opioid analgesic.
- A prior authorization is also required if the member has exceeded a 90 mg per day MME (morphine milligram equivalent) limit (or 80 mg per day MME limit for Ohio).
- Non-formulary opioid analgesics will go through the non-formulary exception process. Members who meet the non-formulary exception process will then need to also meet the opioid requirements outlined below.
- Members being treated for pain associated with cancer, sickle cell, a terminal condition, or pain being managed through hospice or palliative care will be approved for an indefinite period of time.

Definitions

"Acute pain" is defined as having a duration less than one (1) month.

"Subacute pain" is defined as having a duration of one (1) to three (3) months.

"Chronic pain" is defined as having a duration of greater than (>) three (3) months.

"Opioid Naive" is a member who has not received opioids in the last 90 days.

"Opioid Experienced" is a member who has received opioids in the last 90 days.

Immediate Acting Opioid Analgesics:

Medical Necessity Criteria for Initial Authorization

The Plan considers Immediate Acting Opioid Analgesics medically necessary when **BOTH** of the following criteria is met:

1. The member is being treated for **ONE** of the following:
 - a. pain associated with cancer, sickle cell, a terminal condition, or pain being managed through hospice or palliative care; **OR**
 - b. acute or subacute pain and **BOTH** of the following criteria are met:
 - i. Prescriber attestation that initial treatment regimen beyond the following is medically necessary:
 1. 3-days for members 19 and younger; **or**
 2. 7-days for members above the age of 19; **and**
 - ii. The member's pain is related to **ONE** of the following:
 1. severe traumatic injuries (including crush injuries and burns); **or**
 2. invasive surgeries typically associated with moderate to severe postoperative pain; **or**
 3. other severe pain when NSAIDs and other therapies are contraindicated or likely to be ineffective; **OR**
 - c. chronic pain and **ALL** of the following criteria are met:
 - i. The member is unable to use, or has tried and failed **ONE** non-pharmacologic intervention (e.g., ice, heat, elevation, rest, immobilization, or exercise); **and**
 - ii. The member is unable to use, or has tried and failed **THREE** non-opioid pharmacologic therapies intended to treat pain, such as:
 1. Acetaminophen; **and/or**
 2. Anticonvulsants such as pregabalin/gabapentin; **and/or**
 3. Oral NSAIDs; **and/or**
 4. Serotonin and norepinephrine reuptake inhibitor (SNRI) antidepressants; **and/or**
 5. Topical nonsteroidal anti-inflammatory drugs (NSAIDs); **and/or**
 6. Tricyclic and tetracyclic antidepressants; **and**
 - iii. Documentation is submitted showing **BOTH** of the following:
 1. recent urine drug screen, to assess for prescribed medications as well as other prescribed and non-prescribed controlled substances; **and**
 2. the member's treatment plan (i.e., specific functional goals, how opioids will be prescribed and monitored, plan for initiating, increasing, tapering, or discontinuing opioids); **and**

- iv. Prescriber attestation is provided indicating **BOTH** of the following:
 1. That opioids will be prescribed in accordance with current clinical practice guidelines **AND** an assessment of risks, harms, and goals consistent with an opioid agreement (or similar agreement) has been undertaken; **and**
 2. The member has been assessed for concurrent use of opioid pain medication and benzodiazepines **AND** the prescriber has determined **ONE** of the following:
 - a. opioid pain medications and benzodiazepines will **NOT** be used concomitantly; **or**
 - b. benefits outweigh risks of continuing therapy with opioids and benzodiazepines or stopping benzodiazepines can be destabilizing; **AND**
2. Clinical chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

If the above prior authorization criteria is met for:

- **Management of pain related to sickle cell disease, cancer-related pain, palliative care, or end-of-life care, the requested medication will be approved indefinitely.**
- **Acute and subacute pain, the requested medication will be approved for 3 months.**
- **Chronic pain, the requested medication will be approved for 6 months or 12 months (if the prescriber is a pain management specialist).**

Medical Necessity Criteria for Reauthorization

The Plan considers **Immediate Release Opioid Analgesics** medically necessary when **BOTH** of the following criteria are met:

1. Clinical chart documentation is submitted showing **ALL** of the following:
 - a. The member has experienced benefit in pain or function from opioid therapy; **and**
 - b. recent urine drug screen, to assess for prescribed medications as well as other prescribed and non-prescribed controlled substances; **and**
 - c. the member's treatment plan (i.e., specific functional goals, how opioids will be prescribed and monitored, plan for initiating, increasing, tapering, or discontinuing opioids); **AND**
2. Prescriber attestation is provided indicating **BOTH** of the following:

- a. That opioids will be prescribed in accordance with current clinical practice guidelines **AND** an assessment of risks, harms, and goals consistent with an opioid agreement (or similar agreement) has been undertaken; **and**
- b. The member has been assessed for concurrent use of opioid pain medication and benzodiazepines **AND** the prescriber has determined **ONE** of the following:
 - i. opioid pain medications and benzodiazepines will **NOT** be used concomitantly; **or**
 - ii. benefits outweigh risks of continuing therapy with opioids and benzodiazepines or stopping benzodiazepines can be destabilizing

If the above prior authorization criteria is met for chronic pain, the requested medication will be approved for 6 months or 12 months (if the prescriber is a pain management specialist).

Extended Release Opioid Analgesics:

Medical Necessity Criteria for Initial Authorization

The Plan considers **Extended Release Opioid Analgesics** medically necessary when **BOTH** of the following criteria are met:

1. The member is being treated for **ONE** of the following:
 - a. pain associated with cancer, sickle cell, a terminal condition, or pain being managed through hospice or palliative care; **or**
 - b. pain severe enough to require daily, around-the-clock, long-term treatment in a member who has been taking an opioid and **BOTH** of the following criteria are met:
 - i. Clinical chart documentation is submitted showing **ALL** of the following:
 1. the member's prior therapies and outcomes with **ALL** of the following:
 - a. non-pharmacologic interventions (e.g., ice, heat, elevation, rest, immobilization, or exercise); **and**
 - b. non-opioid pharmacologic therapies (such as acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), and selected antidepressants and anticonvulsants); **and**
 - c. immediate release opioid therapies (such as acetaminophen w/ codeine, morphine sulfate, oxycodone); **and**
 2. recent urine drug screen, to assess for prescribed medications as well as other prescribed and non-prescribed controlled substances; **and**

3. the member's treatment plan (i.e., specific functional goals, how opioids will be prescribed and monitored, plan for initiating, increasing, tapering, or discontinuing opioids); **and**
- ii. Prescriber attestation is provided indicating **BOTH** of the following:
 1. That opioids will be prescribed in accordance with current clinical practice guidelines **AND** an assessment of risks, harms, and goals consistent with an opioid agreement (or similar agreement) has been undertaken; **and**
 2. The member has been assessed for concurrent use of opioid pain medication and benzodiazepines **AND** the prescriber has determined **ONE** of the following:
 - a. opioid pain medications and benzodiazepines will **NOT** be used concomitantly; **or**
 - b. benefits outweigh risks of continuing therapy with opioids and benzodiazepines or stopping benzodiazepines can be destabilizing; **AND**
 2. Clinical chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

If the above prior authorization criteria is met for:

- **Management of pain related to sickle cell disease, cancer-related pain, palliative care, or end-of-life care, the requested medication will be approved indefinitely.**
- **Chronic pain, the requested medication will be approved for 6 months or 12 months (if the prescriber is a pain management specialist).**

Medical Necessity Criteria for Reauthorization

Authorization may be granted for continuation of therapy when all criteria for initial authorization are met.

If the above prior authorization criteria is met for chronic pain, the requested medication will be approved for 6 months or 12 months (if the prescriber is a pain management specialist).

Experimental or Investigational / Not Medically Necessary

Opioid Analgesics for any other indication are considered not medically necessary by the Plan, as this is deemed to be experimental, investigational, or unproven.

References

1. Avery, N., McNeillage, A. G., Stanaway, F., Ashton-James, C. E., Blyth, F. M., Martin, R., ... & Glare, P. (2022). Efficacy of interventions to reduce long term opioid treatment for chronic non-cancer pain: systematic review and meta-analysis. *bmj*, 377.
2. Bolen, J. A Legal Interpretation of the CDC Opioid Prescribing Guidelines in Opioid Prescribing and Monitoring-(Second Edition), Chapter 2: Legal Ramifications (Last updated on: April 29, 2019). Available at: <https://www.practicalpainmanagement.com/resource-centers/opioid-monitoring-2nd-ed/legal-Interpretation-cdc-opioid-prescribing-guidelines>. Accessed April 26, 2021.
3. Centers for Disease Control and Prevention (CDC). Common elements in guidelines for prescribing opioids for chronic pain. https://www.cdc.gov/drugoverdose/pdf/common_elements_in_guidelines_for_prescribing_opioids-a.pdf. Published 2015. Accessed May 2022.
4. CMS. Reducing Opioid Misuse. Centers for Medicare and Medicaid Services. <https://www.cms.gov/About-CMS/Story-Page/Reducing-Opioid-Misuse>. Accessed May 26, 2020.
5. Currie, J. M., Schnell, M. K., Schwandt, H., & Zhang, J. (2021). Prescribing of opioid analgesics and buprenorphine for opioid use disorder during the COVID-19 pandemic. *JAMA network open*, 4(4), e216147-e216147.
6. DailyMed. Package Inserts. U.S. National Library of Medicine, a National Institutes of Health (NIH) website. Accessed May, 2022. <https://dailymed.nlm.nih.gov/dailymed/index.cfm>.
7. Daoust, R., Paquet, J., Marquis, M., Chauny, J. M., Williamson, D., Huard, V., ... & Cournoyer, A. (2022). Evaluation of Interventions to Reduce Opioid Prescribing for Patients Discharged From the Emergency Department: A Systematic Review and Meta-analysis. *JAMA network open*, 5(1), e2143425-e2143425.
8. Department of Health and Human Services. Pain management best practices inter-agency task force report: updates, gaps, inconsistencies, and recommendations. May 6, 2019 (<https://www.hhs.gov/sites/default/files/pain-mgmt-best-practices-draft-final-report-05062019.pdf>).
9. Dowell D, Haegerich T, Chou R. No shortcuts to safer opioid prescribing. *N Engl J Med* 2019;380:2285-2287.
10. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain—United States, 2016. *MMWR Recomm Rep*. 2016;65(1):1-49. doi:10.15585/mmwr.rr6501e1[PubMed 26987082]
11. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC clinical practice guideline for prescribing opioids for pain — United States, 2022. *MMWR Recomm Rep* 2022;71:1-95.
12. Feldman, C. A., Fredericks-Younger, J., Lu, S. E., Desjardins, P. J., Malmstrom, H., Miloro, M., ... & Fine, D. (2022). The Opioid Analgesic Reduction Study (OARS)—a comparison of opioid vs. non-opioid combination analgesics for management of post-surgical pain: a double-blind randomized clinical trial. *Trials*, 23(1), 1-20.

13. Friedhelm Sandbrink, Jennifer L. Murphy, Melanie Johansson, et al. The Use of Opioids in the Management of Chronic Pain: Synopsis of the 2022 Updated U.S. Department of Veterans Affairs and U.S. Department of Defense Clinical Practice Guideline. *Ann Intern Med.* 2023;176:388-397. [Epub 14 February 2023]. doi:10.7326/M22-2917
14. Goldstick JE, Guy GP, Losby JL, Baldwin GT, Myers MG, Bohnert ASB. Patterns in nonopioid pain medication prescribing after the release of the 2016 guideline for prescribing opioids for chronic pain. *JAMA Netw Open* 2022;5(6):e2216475-e2216475.
15. Hwang, C. S., Kang, E. M., Ding, Y., Ocran-Appiah, J., McAninch, J. K., Staffa, J. A., ... & Meyer, T. E. (2018). Patterns of immediate-release and extended-release opioid analgesic use in the management of chronic pain, 2003-2014. *JAMA network open*, 1(2), e180216-e180216.
16. Kelley-Quon LI, Kirkpatrick MG, Ricca RL, et al. Guidelines for Opioid Prescribing in Children and Adolescents After Surgery: An Expert Panel Opinion. *JAMA Surg.* 2021;156(1):76–90. doi:10.1001/jamasurg.2020.5045
17. Lawal, O. D., Gold, J., Murthy, A., Ruchi, R., Bavry, E., Hume, A. L., ... & Wen, X. (2020). Rate and risk factors associated with prolonged opioid use after surgery: a systematic review and meta-analysis. *JAMA network open*, 3(6), e207367-e207367.
18. Lefkowitz C, Buss MK, Ramzan AA, Fischer S, Urban RR, Fisher CM, Duska LR. Opioid use in gynecologic oncology in the age of the opioid epidemic: Part I - Effective opioid use across clinical settings, a society of gynecologic oncology evidence-based review. *Gynecol Oncol.* 2018 May;149(2):394-400. doi: 10.1016/j.ygyno.2018.01.027. Epub 2018 Feb 20. PMID: 29472016.
19. Manchikanti L, Kaye AM, Knezevic NN, et al. Comprehensive, Evidence-Based, Consensus Guidelines for Prescription of Opioids for Chronic Non-Cancer Pain from the American Society of Interventional Pain Physicians (ASIPP). *Pain Physician.* 2023 Dec;26(7S):S7-S126. PMID: 38117465.
20. Manchikanti L, Abdi S, Atluri S, et al. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 2 – Guidance, *Pain Physician*, July 2012; 15(3 Suppl): S67-116.
21. National Institute on Drug Abuse. Prescription Opioids. National Institute on Drug Abuse. <https://www.drugabuse.gov/publications/drugfacts/prescription-opioids>. Published May 2020. Accessed May 26, 2020.
22. Owen GT, Burton AW, Schade CM, Passik SA. Urine Drug Testing: Current Recommendations and Best Practices. *Pain Physician*, 2012; 15: ES119-ES133.
23. Roxycodone (oxycodone) [prescribing information]. Webster Groves, MO: SpecGx LLC; January 2023.
24. Scott E. Hadland, Rita Agarwal, Sudha R. Raman, Michael J. Smith, Amy Bryl, Jeremy Michel, Lorraine I. Kelley-Quon, Mehul V. Raval, Madeline H. Renny, Beth Larson-Steckler, Scott Wexelblatt, Robert T. Wilder, Susan K. Flinn; Opioid Prescribing for Acute Pain Management in Children and Adolescents in Outpatient Settings: Clinical Practice Guideline. *Pediatrics* November 2024; 154 (5): e2024068752. 10.1542/peds.2024-068752
25. US Department of Health and Human Services (HHS). HHS guide for clinicians on the appropriate dosage reduction or discontinuation of long-term opioid analgesics. https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf. Updated October 2019. Accessed May 2022.
26. US Food and Drug Administration (FDA). FDA drug safety communication: FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use. <https://www-fda-gov.libproxy.unm.edu/drugs/drug-safety-and-availability/fda-updates->

prescribing-information-all-opioid-pain-medicines-provide-additional-guidance-safe-use.
Published April 13, 2023.

27. Webster LR. Risk Factors for Opioid-Use Disorder and Overdose. *Anesth Analg*. 2017 Nov;125(5):1741-1748.
28. WHO Guidelines for the Pharmacological and Radiotherapeutic Management of Cancer Pain in Adults and Adolescents. Geneva: World Health Organization; 2018
29. Winhusen, T., Walley, A., Fanucchi, L. C., Hunt, T., Lyons, M., Lofwall, M., ... & Chandler, R. K. (2020). The opioid-overdose reduction continuum of care approach (ORCCA): evidence-based practices in the HEALing communities study. *Drug and Alcohol Dependence*, 217, 108325.

Clinical Guideline Revision / History Information

Original Date: 08/06/2020

Reviewed/Revised: 06/24/2021, 12/01/2021, 06/23/2022, 12/08/2022, 12/14/2023, 12/19/2024