

Clinical Policy: Opioid Analgesics

Reference Number: CP.PMN.97

Effective Date: 02.01.11

Last Review Date: 02.20

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Opioid analgesics exert their analgesic effect through opiate receptors distributed in tissues throughout the body. All opioid analgesics therapy (both preferred and non-preferred agents) that does not abide with this criteria will require prior authorization.

FDA Approved Indication(s)

Opioid analgesics are indicated for the management and treatment of moderate to severe pain.

Policy/Criteria

Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that opioid analgesics are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

- A. Short Term Therapy** (Prior authorization will NOT be required for opioid use meeting all of the following criteria. Requests for > 28 day supply of opioid or for extended release opioids will be evaluated using the Long Term Therapy criteria unless the request is for cancer, sickle cell disease or palliative care as presented in Section I.B.):
1. Member has received \leq 28 day supply of opioid in the last 90 days;
 2. Request is for \leq 7 day supply;
 3. Member is taking no more than 2 different opioid analgesics concurrently;
 4. Request is for an immediate release opioid;
 5. If request is for an abuse-deterrent formulation (ADF), medical justification supports inability to use a generic non-abuse-deterrent formulation of the same active ingredient as the requested opioid;
 6. Total opioid dose does NOT exceed 90 morphine milligram equivalents (MME) per day.
- B. Cancer, Sickle Cell Disease, or Palliative Care** (must meet all):
1. Prescribed for pain associated with cancer, sickle cell disease, or palliative care;
 2. Request is for a preferred drug, unless member has previously failed, is intolerant to or has contraindications to two or more preferred drugs;
 3. If request is for an ADF, medical justification supports inability to use a generic non-ADF of the same active ingredient as the requested opioid;

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4. If request is for Oxycontin, member is ≥ 11 years and has failed two other preferred long acting opioids*, unless contraindicated or clinically significant adverse effects are experienced;
**Long acting opioid therapy may require prior authorization.*
5. If request is for concurrent use of > 2 opioids, prescriber must submit a documented clinical rationale supporting the addition of an extended release opioid and that upward titration of existing opioid analgesics is inappropriate or contraindicated;
6. Request does not exceed health plan quantity limit.

Approval duration: 12 months

C. Members Transitioning from Short Term Therapy to Long Term Therapy

Long Term Therapy (defined as a claims history of > 28 -day supply of opioid within a 90 day period or request for an extended release opioid) (must meet all):

1. Previously received short term opioid therapy via Centene benefit;
2. Prescribed for the treatment of non-cancer/non-malignant pain outside of active cancer treatment, sickle cell disease treatment and palliative care;
3. If request is for an extended release agent, documented failure of an immediate release opioid;
4. Member meets one of the following (a or b):
 - a. Failure of at least 2 non-opioid ancillary treatments (e.g., non-steroidal anti-inflammatory drugs [NSAIDs], acetaminophen, anticonvulsants, antidepressants) unless contraindicated or clinically significant adverse effect are experienced;
 - b. Member has received a total of 90 cumulative days of opioid therapy in the last 120 days;
5. Request is for a preferred drug, unless member has previously failed, is intolerant to or has contraindications to two or more preferred drugs;
6. If request is for an ADF, medical justification supports inability to use a generic non-ADF of the same active ingredient as the requested opioid;
7. If request is for Oxycontin, member is ≥ 11 years and has failed two other preferred long acting opioids, unless contraindicated or clinically significant adverse effects are experienced;
**Long acting opioid therapy may require prior authorization.*
8. Member will be maintained on no more than 2 opioid analgesics concurrently;
**If member requires therapy with two opioid analgesics, regimen must consist of one immediate-release and one extended-release analgesic.*
9. Total opioid dose is not 90 MME per day or more, or for members who are stable (history of > 7 days of therapy) on doses ≥ 90 MME per day, one of the following is met (a or b):
 - a. Provider's attestation that a dose taper will be attempted;
 - b. Documentation that a dose taper has been attempted within the past 6 months, with the reasons for taper failure;
**Provider will be advised that doses higher than the current dose will not be approved in the future.*
10. Provider agrees to continuously assess the member's pain management regimen for possible discontinuation of opioid therapy;

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11. Documentation that the provider has reviewed the Prescription Drug Monitoring Program (PDMP) to identify concurrently prescribed controlled substances.

Approval duration: 3 months

D. Other diagnoses/indications – Not applicable

II. Continued Therapy**A. Cancer, Sickle Cell Disease, or Palliative Care** (must meet all):

1. Currently receiving therapy for pain associated with cancer, sickle cell disease, or palliative care;
2. If request is for an ADF, medical justification supports inability to use a generic non-ADF of the same active ingredient as the requested opioid;
3. If request is for Oxycontin, member is ≥ 11 years and has failed two other preferred long acting opioids, unless contraindicated or clinically significant adverse effects are experienced;
**Long acting opioid therapy may require prior authorization*
4. If member is receiving more than 2 opioid analgesics concurrently, at least one of the following requirements has been met (a or b):
 - a. Prescriber previously provided a documented clinical rationale for the use of > 2 opioid analgesics concurrently;
 - b. Prescriber provides a documented clinical rationale supporting that addition of an extended release agent or upward titration of existing opioid analgesics is inappropriate or contraindicated;
5. Request does not exceed health plan quantity limit.

Approval duration: 12 months

B. Long Term Therapy (must meet all):

1. Currently receiving long term (defined as a history of chronic opioid use in the 3 months preceding the request) opioid therapy via Centene benefit or documentation supports that member is currently receiving opioids and has received this medication for at least 28 days in last 90 days;
2. Request is for a preferred drug, unless member has previously failed, is intolerant to or has contraindications to two or more preferred drugs;
3. If request is for an ADF, medical justification supports inability to use a generic non-ADF of the same active ingredient as the requested drug;
4. If request is for Oxycontin, member is ≥ 11 years and has failed two other preferred long acting opioids*, unless contraindicated or clinically significant adverse effects are experienced;
**Long acting opioid therapy may require prior authorization*
5. Prescriber provides documentation supporting inability to discontinue opioid therapy;
6. Member will not be maintained on > 2 opioid analgesics concurrently;
If member requires therapy with two opioid analgesics, regimen must consist of one immediate-release and one extended-release analgesic
7. If total opioid dose ≥ 90 MME/day, one of the following is met (a, b, c or d):
 - a. Dose reduction has occurred since previous approval, if applicable;
 - b. A dose taper has been attempted within the past 6 months and was not successful;

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Reason(s) for taper failure must be provided.

- c. Medical justification why a taper should not be attempted or for any dose increase that has occurred since previous approval, if applicable;
- d. Prescribed by or in consultation with a pain management specialist;
- 8. Documentation that the provider has reviewed the PDMP to identify concurrently prescribed controlled substances.

Approval duration: 3 months

C. Other diagnoses/indications – Not applicable

III. Diagnoses/Indications for which coverage is NOT authorized: Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation Key

ADF: abuse-deterrent formulation

PDL: Preferred drug list

MME: morphine milligram equivalents

PDMP: Prescription Drug Monitoring Program

NSAID: non-steroidal anti-inflammatory drug

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): significant respiratory depression; acute or severe bronchial asthma; gastrointestinal obstruction, including paralytic ileus; hypersensitivity to the opioid active ingredient, salts, or any component of the product.
- Boxed warning(s): potential for addiction, abuse, and misuse; life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; cytochrome P450 3A4 interactions; risks from concomitant use with benzodiazepines or other CNS depressants.

V. Dosage and Administration

Please refer to the package insert of the requested drug for information on appropriate dosage and administration.

VI. Product Availability

Please refer to the package insert of the requested drug for product availability information.

VII. References

1. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain - United States, 2016. JAMA 2016 Apr 19; 315(15):1624-45.
2. Kampman K, Jarvis M. American Society of Addiction Medicine (ASAM) national practice guideline for the use of medications in the treatment of addiction involving opioid use. J Addict Med 2015 Sep-Oct; 9(5):358-67.

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Reviews, Revisions, and Approvals	Date	Approval Date
No changes	02.14	02.14
Updated references. Added tramadol as a narcotic.	02.15	02.15
Clarified item B under criteria for approval by specifying what the provider must supply as part of the request.	05.15	05.15
<p>Converted to new policy template.</p> <p>Removed Criteria B and C so guideline strictly addresses the restriction for narcotic analgesic. CP.PMN.16 addresses the use of PDL agents first prior to non-pdl agent:</p> <p>B- Available Preferred Drug List (PDL) agents must be used first-line. Non- PDL medications would only be eligible for authorization with the trial and failure of PDL medications. A trial and failure may include: insufficient response at maximum dose of PDL agents, adverse effects/intolerance, allergic reactions, or contraindications. The provider must provide the specific reason for the failure as part of the request.</p> <p>C- The minimum “Maximized doses” for extended release PDL medications are as follows: MS Contin, up to 400 mg/day; methadone, up to 60 mg/day, and fentanyl patches 100 mcg/hr. The provider may choose to exceed these doses (as there is no true maximum in the above opioid analgesics), but these are the minimum doses that must be trialed prior to deeming the medication a failure from suboptimal pain control.</p> <p>Added reference</p>	11.15	02.16
<p>Added levorphanol to opioid list and removed butalbital combination listing under background; Modified policy to delineate criteria for short and long term use of opioid analgesic to reflect CDC recommendation for opioid use in chronic pain; Added maximum allowable dose of 90 MME/day per CDC recommendation for chronic pain; Modified criteria for > 2 opioid analgesic concurrently to require</p> <ol style="list-style-type: none"> 1) Use for sickle cell pain, cancer pain or palliative care 2) Prescription by a pain/oncology specialist <p>Removed the PDL language within the policy and added that non preferred agent is subject to policy “CP.PMN.16 - Request for Medically Necessary Drug not on the PDL and this policy</p>	06.16	08.16
<ul style="list-style-type: none"> - Short term therapy without PA requirement modified to allow: a) no more than 28 day supply of opioid in the last 90 days, b) no more than 14 days supply dispensed at a time, c) immediate release agent to be used. - Long term therapy modified to require that: a) member has used ≥ 28 days of therapy in the last 90 days, b) member has been treated with ancillary treatment or received 84 cumulative days of therapy within a 120 day period, c) provider’s agreement to 	01.17	02.17

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Reviews, Revisions, and Approvals	Date	Approval Date
continuously assess the member’s pain management regimen for possible discontinuation of opioid therapy.		
<ul style="list-style-type: none"> - Short term therapy without PA requirement modified to allow no more than 7 days supply dispensed at a time. - Added Continuation of Care allowance to apply for requests for continuation of long-term therapy for chronic pain. - Added provider documentation that may be provided in order to allow approval of doses greater than 90 MME/day - Removed reference to CP.PMN.16 and redirected member to preferred agent within the criteria set 	10.31.17	11.17
1Q18 annual review: Added Oxycontin-specific criteria adapted from CP.PPA.04, which will be retired; Oxycontin is programmed with a QL of 2/day. Change name from CP.PPA.12 to CP.PMN.##. Change the requirement for approval for long term use to require 90 days of opioid use in 120 days from 84 in 120 days to align with edit programming. No significant changes. References reviewed.	12.06.17	02.18
1Q 2019 annual review: added ADF-specific criteria to require a prior trial of a generic non-ADF formulation of the same active ingredient; references reviewed and updated.	11.05.18	02.19
Updated > and ≤ symbols around the 28-day mark within the policy to more clearly define “short-term” vs. “long-term” opioid therapy. Clarification that the “Total opioid dose is not 90 MME per day or more” since CDC treatment guidelines recommend that prescribers should avoid increasing opioid dosages to ≥ 90 MME/day.	07.24.19	
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.26.19	02.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the

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administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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