Clinical Policy: Opioid Analgesics*

Reference Number: CP.PMN.97
Effective Date: 02.01.11
Last Review Date: 02.22
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Requests for transmucosal immediate-release fentanyl products (TIRFs) should be evaluated using the Fentanyl IR (Abstral, Actiq, Fentora, Lazanda, Subsys) policy – CP.PMN.127.

Description
Opioid analgesics exert their analgesic effect through opiate receptors distributed in tissues throughout the body. All opioid analgesic therapies (both preferred and non-preferred agents) that do not abide with the short term therapy criteria (I.A) 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 ≤ 28 day supply of opioid in the last 90 days;
2. Request is for ≤ 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), member must use a generic non-ADF 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)**:**

**Requests for transmucosal immediate-release fentanyl products (TIRFs) should be evaluated using the Fentanyl IR (Abstral, Actiq, Fentora, Lazanda, Subsys) policy – CP.PMN.127.*

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, member must use a generic non-ADF of the same active ingredient as the requested opioid;
4. If request is for Oxycontin®, member is ≥ 11 years old and has failed two other preferred long acting opioids*, unless clinically significant adverse effects are experienced or all are contraindicated;
   **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 clinically significant adverse effect are experienced or all are contraindicated;
   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, member must use a generic non-ADF of the same active ingredient as the requested opioid;
7. If request is for Oxycontin, member is ≥ 11 years old and has failed two other preferred long acting opioids*, unless clinically significant adverse effects are experienced or all are contraindicated;
   **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;
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)**:**

**Requests for transmucosal immediate-release fentanyl products (TIRFs) should be evaluated using the Fentanyl IR (Abstral, Actiq, Fentora, Lazanda, Subsys) policy – CP.PMN.127.*

1. Currently receiving therapy for pain associated with cancer, sickle cell disease, or palliative care;
2. If request is for an ADF, member must use a generic non-ADF of the same active ingredient as the requested opioid;
3. If request is for Oxycontin, member is ≥ 11 years old and has failed two other preferred long acting opioids*, unless clinically significant adverse effects are experienced or all are contraindicated;
   **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, member must use a generic non-ADF of the same active ingredient as the requested drug;
4. If request is for Oxycontin, member is ≥ 11 years old and has failed two other preferred long acting opioids*, unless clinically significant adverse effects are experienced or all are contraindicated;
   **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 per 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; **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
MME: morphine milligram equivalents
NSAID: non-steroidal anti-inflammatory drug
PDL: Preferred drug list
PDMP: Prescription Drug Monitoring Program

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.

Appendix D: General Information

Opioid Oral MME Conversion Factors	
Type of Opioid (strength units)	**MME Conversion Factor**
Codeine (mg)	0.15
Dihydrocodeine (mg)	0.25
Fentanyl buccal or SL tablets, or lozenge/troche (mcg)	0.13
Fentanyl film or oral spray (mcg)	0.18
Fentanyl nasal spray (mcg)	0.16
Fentanyl patch (mcg)	7.2

Opioid Oral MME Conversion Factors	
Hydrocodone (mg)	1
Hydromorphone (mg)	4
Levorphanol tartrate (mg)	11
Meperidine hydrochloride (mg)	0.1
Methadone (mg)	
> 0, ≤ 20	4
> 20, ≤ 40	8
> 40, ≤ 60	10
> 60	12
Morphine (mg)	1
Opium (mg)	1
Oxycodone (mg)	1.5
Oxymorphone (mg)	3
Pentazocine (mg)	0.37
Tapentadol (mg)	0.4
Tramadol (mg)	0.1

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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
1Q 2021 annual review: no significant changes; references reviewed and updated.	12.01.20	02.21
1Q 2022 annual review: no significant changes; changed "Medical justification" language to "Member must use"; references reviewed and updated.	11.23.21	02.22

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 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.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.