Clinical Policy: Opioid Analgesics*

Reference Number: MDN.CP.PMN.97
Effective Date: 04.01.22
Last Review Date: 04.22
Line of Business: Illinois 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.

FDA Approved Indication(s)
Opioid analgesics are indicated for the management and treatment of moderate to severe pain.

Policy/Criteria
Provider must submit documentation (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. Opioid-Naïve Members, Duration > 7 Days (Opioid-naïve member is defined as a member with no utilization of opioids within the last 90 days. Prior authorization will NOT be required for ≤ 7 day supply of a preferred immediate release opioid within quantity limits. If request is for cancer, sickle cell, or palliative care, refer to Section I.B)**:**

1. Member is taking no more than 2 different opioid analgesics concurrently;
2. If request is for a non-preferred immediate release opioid, member has previously failed, is intolerant to, or has contraindications to two or more preferred immediate release opioids;
3. Member must meet one of the following (a or b):
   a. Post-operative pain requiring acute opioid therapy with rationale that pain is expected to last longer than 7 days;
   b. Other indications must meet criteria in Extended Use Therapy (Section I.C)
4. Extended-release opioids must meet criteria in Extended Use Therapy (Section I.C);
5. Request does not exceed health plan quantity limit.

Approval Duration:

Post-operative pain: Duration of request or up to 1 month of total treatment, whichever is less

Other indications: Refer to Extended Use Therapy (Section I.C)

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. If request is for concurrent use of > 2 opioids, prescriber must submit a documented clinical rationale supporting that upward titration of existing opioid analgesics is inappropriate or contraindicated;
3. Request does not exceed health plan quantity limit.
4. If request is for a non-preferred immediate release opioid, member has previously failed, is intolerant to, or has contraindications to two or more preferred immediate release opioids;
5. If request is for a non-preferred extended-release opioid, member has previously failed, is intolerant to, or has contraindications to morphine sulfate extended-release tablets.

Approval duration: 12 months

C. Extended Use Therapy (must meet all)**:**

1. Prescribed for the treatment of non-cancer/non-malignant pain outside of active cancer treatment, sickle cell disease treatment and palliative care;
2. Documentation that the provider has recently reviewed the Prescription Drug Monitoring Program (PDMP) to identify concurrently prescribed controlled substances.
3. 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.*
4. 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;
5. If request is for a non-preferred immediate release opioid, member has previously failed, is intolerant to, or has contraindications to two or more preferred immediate release opioids;
6. If request is for an extended-release opioid, documented failure of an immediate release opioid;
7. If request is for a non-preferred extended-release opioid, member has previously failed, is intolerant to, or has contraindications to morphine sulfate extended-release tablets;
8. Provider agrees to continuously assess the member's pain management regimen for possible discontinuation of opioid therapy;
9. Total opioid dose is under 200 MME per day unless one of the following is met (a or b):
    a. Prescribed by or in consultation with a board-certified Pain Management specialist or Anesthesiology;
    b. For patients already taking ≥ 200 MME per day, submission of a taper plan to under 200 MME or a referral to pain management is required;

Approval duration: 3 months

D. Other diagnoses/indications – Not applicable

II. Continued Therapy

A. Opioid-Naïve Members, Duration > 7 Days – Not applicable

B. 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 a non-preferred immediate release opioid, member has previously failed, is intolerant to, or has contraindications to two or more preferred short-acting opioids;
3. If request is for a non-preferred extended-release opioid, member has previously failed, is intolerant to, or has contraindications to morphine sulfate extended-release tablets;
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 upward titration of existing opioid analgesics is inappropriate or contraindicated;
5. Request does not exceed health plan quantity limit.

Approval duration: 12 months

C. Extended Use Therapy (must meet all)**:**

1. Currently receiving extended use (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 has received opioids in last 90 days;
2. Documentation that the provider has recently reviewed the Prescription Drug Monitoring Program (PDMP) to identify concurrently prescribed controlled substances.
3. Provider agrees to continuously assess the member's pain management regimen for possible discontinuation of opioid therapy;
4. If request is for an extended-release agent, documented failure of an immediate release opioid;
5. If request is for a non-preferred immediate release opioid, member has previously failed, is intolerant to, or has contraindications to two or more preferred immediate release opioids;
6. If request is for a non-preferred extended-release opioid, member has previously failed, is intolerant to, or has contraindications to morphine sulfate extended-release tablets;
7. Total opioid dose is under 200 MME per day unless one of the following is met (a or b):
   a. Prescribed by or in consultation with a board certified Pain Management specialist;
   b. Reduction in MME from prior approval, and plan to further taper to under 200 MME/day

Approval duration: 6 months

D. Other diagnoses/indications – Not applicable

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

IV. Appendices/General Information

Appendix A: Abbreviation Key

MME: morphine milligram equivalents
NSAID: non-steroidal anti-inflammatory drug
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.

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	Approval Date
Policy created, adapted from CP.PMN.97	3.17.22	04.22

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.