

Clinical Policy: Opioid Analgesics

Reference Number: GA.PMN.26

Effective Date: 10/19

Last Review Date: 10/2023

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 analgesics therapy (both preferred and non-preferred agents) that does not abide with this criteria will require prior authorization. (See Appendix B for safety edits and Appendix C for opioid definitions)

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 Peach State Health Plans affiliated with Centene Corporation® that opioid analgesics are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for Short Term Therapy (meets 1 or 2)

1. If opioid naïve (see appendix B), member must meet the following:
 - a. Condition in which more than a 7 day supply of opioids may be necessary (i.e., post-operational surgery or acute traumatic injury);
 - b. Request is for an immediate release or short-acting opioid;
 - c. Member will not be taking more than 2 different opioid analgesics concurrently;
 - d. Total cumulative opioid does NOT exceed 50 MME per day
2. If opioid-tolerant (see appendix B), member must meet the following:
 - a. Condition in which more than a 7 day supply of opioids may be necessary (i.e., post-operational surgery or acute traumatic injury);
 - b. Request is for preferred immediate release or short-acting opioid;
 - c. Member will not be taking more than 2 different opioid analgesics concurrently;
 - d. Total cumulative opioid does NOT exceed 90 MME per day

Approval duration: 14 days and does not exceed health plan quantity limit

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 an FDA approved preferred drug, unless member has previously failed, is intolerant to or has contraindications to two or more FDA approved preferred drugs;
3. 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;
**Long acting opioid therapy may require prior authorization.*
4. If request is for concurrent use of > 2 opioids, prescriber must submit medical justification for its use;
5. Member's overall opioid therapy should not exceed one long-acting and two short-acting opioids

Approval duration: 12 months and does not exceed health plan quantity limits

C. Request for Long Term Therapy (Chronic Non-Cancer Pain) (must meet all):

1. Previously received short term opioid therapy via Centene benefit;
2. If request is for an extended release/long-acting agent, documented prior use of an immediate release opioid;
3. 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;
4. Request is for an FDA approved preferred drug, unless member has previously failed, is intolerant to or has contraindications to two or more FDA approved preferred drugs;
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;
**Long acting opioid therapy may require prior authorization.*
6. 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.*
7. Total opioid dose does not exceed 90 MME per day or more, or for members who are stable (history of > 7 days of therapy) on doses \geq 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.*

8. Provider agrees to continuously assess the member's pain management regimen for possible discontinuation of opioid therapy;
9. Documentation that the provider has reviewed the Prescription Drug Monitoring Program (PDMP) to identify concurrently prescribed controlled substances.

Approval duration: 3 months and does not exceed health plan quantity limits

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 via Centene benefit;
2. Criteria for initial therapy was met;
3. Member continues to respond positively to therapy;
4. Current opioid regimen remains the same;
5. If member continues to receive > 2 opioid analgesics concurrently, updated clinical rationale justifying continued use of > 2 opioid analgesics concurrently is provided.

Approval duration: 12 months and does not exceed health plan quantity limits

B. Long Term Therapy (Chronic Non-Cancer Pain) (must meet all):

1. Currently receiving long term therapy for pain via Centene benefit;
2. Criteria for initial therapy was met;
3. Member continues to respond positively to therapy;
4. Current opioid regimen remains the same;
5. If total opioid dose \geq 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;
6. Documentation that the provider has reviewed the PDMP to identify concurrently prescribed controlled substances.

Approval duration: 6 months and does not exceed health plan quantity limits

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

SAO: Short-acting opioid

LAO: Long-acting opioid

PDL: Preferred drug list

PDMP: Prescription Drug Monitoring Program

Appendix B: Opioid Edits

- Drug Interactions
 - Opioid/Antipsychotic soft message
 - Opioid/Benzodiazepine soft message
- Med Limits (Does not apply to Cancer, Sickle Cell, or Palliative Care)
 - Max 2 opioid medicines per 30 days
 - Max 50MME for total (SAO) dose for treatment-naïve
 - Max 90MME for total (SAO and LAO) dose for treatment-experienced
 - Max 7 days' supply for short-acting opioids for treatment-naïve
 - Requirement of short-acting/immediate release opioid use before long-acting opioid therapy

Appendix C: Definitions

- Opioid naïve is defined as not receiving a fill for any opioid product in the last 180 days.
- Opioid-tolerant or treatment experienced is defined as a claims history of at least one fill for any opioid product within a 180 days period or request for an extended-release opioid.

Appendix D: Therapeutic Alternatives

Not applicable

Appendix E: Contraindications/Boxed Warnings

- Contraindications: 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 warnings: 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, Ragan KR, Jones CM, Baldwin GT, and Chou R. CDC clinical practice guideline for prescribing opioids for pain – United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1-95.
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
New policy created, split from CP.PMN.97 Opioid Analgesics in order to have Georgia specific criteria for compliance with Department of Community Health opioid restrictions/edits. Added appendices for opioid edits and definitions. Also cleaned up some policy verbiage for less confusion.	10/19	10/19
Interim Review. Added the omitted phrase “must meet all” under Initial Approval Criteria, Section C (Request for Long Term Therapy – Chronic Non-cancer Pain) as was initially intended.	11/19	11/19
Annual review. Replaced Centene Logo with Peach State Health Plan Logo.	10/2020	10/2020
4Q 2021 annual review. No changes made.	10/2021	10/2021
For consistency with Corporate language, added *Requests for transmucosal immediate-release fentanyl products (TIRFs) should be evaluated using the Fentanyl IR (Abstral, Actiq, Fentora, Lazanda, Subsys) policy – CP.PMN.127. 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. Changed “Medical justification” language to “Member must use”.	04/2022	04/2022
4Q 2022 annual review. No changes made.	10/2022	10/2022
No significant changes. References reviewed and updated.	04/2023	04/2023
4Q 2023 annual review. No changes made.	10/2023	10/2023

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.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior

CLINICAL POLICY
Opioid Analgesics



written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.