Clinical Policy: Opioid Analgesics

Reference Number: CP.HNCA.03
Effective Date: 4.1.21
Last Review Date: 3.8.24 Revision Log
Line of Business: Commercial - HNCA

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 therapy (both preferred and non-preferred agents) that does not abide by this criterion will require prior authorization.

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

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Health Net of California that opioid analgesics are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cancer, Sickle Cell Disease, Palliative care, Hospice, or End-of-life 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, Palliative care, Hospice, or End-of-life 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, if available.
3. Request does not exceed Health Net formulary quantity limits.

Approval duration: 12 months

B. Short Term Therapy

Prior authorization will NOT be required for opioid use meeting all of the following criteria:

1. Prescribed for the treatment of non-cancer/non-malignant pain outside of cancer, sickle cell disease, Palliative care, Hospice, or End-of-life Care.
2. Member has received <7-day supply of an opioid in the last 90 days as evidenced in claims history;
3. Request is for ≤ 7-day supply;

4. Member is on no more than two different opioid analgesics concurrently;
5. Request is for an immediate release opioid;
6. 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
7. Total opioid dose does NOT exceed 90 morphine milligram equivalents (MME)/day or Health Net formulary quantity limits.

Approval duration: One fill or up to 7-day supply

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

A. Long Term Therapy (defined as a claims history of ≥ 7-day supply of an opioid within a 90-day period or request for an extended- release opioid) (must meet all)**:**

1. Previously received short term opioid therapy via Health Net benefit;
2. Prescribed for the treatment of non-cancer/non-malignant pain outside of cancer, sickle cell disease, Palliative care, Hospice, or End-of-life Care.
3. If request is for an extended release agent, a documented failure of an immediate release opioid is required.
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 effects are experienced or all are contraindicated;
   b. Member has had 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, if available;
6. 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
7. Member will be maintained on no more than two opioid analgesics concurrently;
   **If member requires therapy with two opioid analgesics, regimen must consist of one immediate-release and one extended-release analgesic*
8. Total opioid dose does not exceed 90 MME/day *or* for member who is stable on doses ≥ 90 MME/day for more than seven days of therapy, one of the following is met:
   1. Provider submits documentation that a dose taper will be attempted;
   2. Provider submits documentation that a dose taper has been attempted within the past six months and notes the reason(s) for taper failure;

   **Provider will be advised that doses higher than the current dose will not be approved in the future*
9. Provider agrees to continuously assess the member's pain management regimen for possible discontinuation of opioid therapy;
10. Provider has reviewed the Prescription Drug Monitoring Program (PDMP) to identify concurrently prescribed controlled substances.
    **California's controlled substance monitoring program (CURES) is an online system used by prescribers to review prescriptions for controlled substances.*

Approval duration: 3 months

B. Other diagnoses/indications- Not applicable

III. Continued Therapy

A. Cancer, Sickle Cell Disease, Palliative care, Hospice, or End-of-life 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 medication via health plan benefit or member has previously met initial approval criteria;
2. Request is for a preferred drug, unless member has previously failed, is intolerant to or has contraindications to two or more preferred drugs, if available;
3. Request does not exceed Health Net formulary quantity limits.

Approval duration: 12 months

B. Long Term Therapy (must meet all):

1. Currently receiving long term opioid therapy (defined as a history of chronic opioid use in the 3 months preceding the request) via Health Net benefit or member has previously met initial approval criteria;
2. Prescribed for the treatment of non-cancer/non-malignant pain outside of cancer, sickle cell disease, Palliative care, Hospice, or End-of-life Care;
3. Request is for a preferred drug, unless member has previously failed, is intolerant to or has contraindications to two or more preferred drugs, if available;
4. 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;
5. Prescriber provides documentation supporting continued need for opioids and inability to discontinue opioid therapy;
6. Member will not be maintained on more than two 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. Dose reduction has occurred since previous approval, if applicable;
   b. A dose taper has been attempted within the past three 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
   **MME calculator: https://agencymeddirectors.wa.gov/Calculator/DoseCalculator*
7. Provider has reviewed the PDMP to identify concurrently prescribed controlled substances.
   **California's controlled substance monitoring program (CURES) is an online system used by prescribers to review prescriptions for controlled substances.*

Approval duration: 6 months

4. **Other diagnoses/indications –** Not applicable

IV. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policies – CP.CPA.09 for commercial.

V. Appendices/General Information

Appendix A: Abbreviation Key
MME: morphine milligram equivalents
NSAID: non-steroidal anti-inflammatory drug
PDMP: Prescription Drug Monitoring Program
SNRI: serotonin-norepinephrine reuptake inhibitor
TCA: tricyclic antidepressant

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: 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.

Appendix D: General Information
The 2022 CDC Clinical Practice Guideline, which is intended for clinicians prescribing opioids for adult outpatients with pain — in situations other than those of sickle cell disease, cancer-related pain, palliative care, and end-of-life care — expands guidance for acute (<1 month's duration) and subacute (1 to 3 months' duration) pain to help primary care and other clinicians (e.g., surgeons, oral health practitioners, and emergency clinicians) weigh benefits and risks of opioids and other pain treatments for outpatients or patients being discharged from hospitals, emergency departments, or other facilities. The 2022 guideline recommends that when opioids are needed for acute pain, they should be prescribed at the lowest effective dose and for no longer than the expected duration of pain severe enough to warrant opioids. Tapering is recommended when opioid treatment is discontinued after being used continuously for more than a few days. For patients receiving opioids for 1 to 3 months (the timeframe for subacute pain), the 2022 guideline recommends that clinicians avoid continuing opioid treatment without carefully reassessing treatment goals, benefits, and risks in order to prevent unintentional initiation of long-term opioid therapy. If benefits do not outweigh risks of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually taper to lower dosages or, if warranted based on the individual circumstances of the patient, appropriately taper and discontinue opioids.

Opioid Morphine Equivalent Conversion Factors

Type of Opioid	MME Conversion Factor
Codeine	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
Hydrocodone (mg)	1
Hydromorphone (mg)	4
Levorphanol tartrate (mg)	11
Meperidine hydrochloride (mg)	0.1
Methadone (mg)	
> 0, ≤ 20 mg/day	4
> 20, ≤ 40 mg/day	8
> 40, ≤ 60 mg/day	10
> 60 mg/day	12
Morphine (mg)	1
Oxycodone (mg)	1.5
Oxymorphone (mg)	3
Tapentadol (mg)	0.4
Tramadol (mg)	0.1

VI. Dosage and Administration

There are numerous narcotic analgesics, please refer to the package insert of your drug of interest for information on appropriate dosage and administration.

VII. Product Availability

There are numerous narcotic analgesics, please refer to the package insert of your drug of interest for product availability information.

VIII. 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. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder - 2020-Focused Update. https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/guidelines/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2. Accesses March 2024.
3. SAMHSA TIP 63: Medications for Opioid Use Disorder – Updated 2021. https://store.samhsa.gov/sites/default/files/pep21-02-01-003.pdf. Accessed March 2024.
4. 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.
5. Newsom G, Varghese R, Lawson KD. Guidelines for Prescribing Controlled Substances for Pain. Medical Board of California. July 2023.

https://www.mbc.ca.gov/Download/Publications/pain-guidelines.pdf. Accessed March 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy.	01/4/2021	
4Q 2021 annual review: the following 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"; New Health Net logo added; Non-FDA approved indication section updated to include CP.CPA.09; references reviewed and updated.	10/5/2021	10.21
2Q 2024 review: added "Prescribed for the treatment of non-cancer/non-malignant pain outside of cancer, sickle cell disease, Palliative care, Hospice, or End-of-life Care" in the short term and longer therapy section; added CURES to the California version of Prescription Drug Monitoring Program (PDMP); updated Appendix D with 2022 CDC clinical practice guideline on opioid; references reviewed and updated.	03/8/2024	4/9/2024

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.