Clinical Policy: Opioid Analgesics

Reference Number: IL.ERX.NPA.57
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois 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.

**Requests for transmucosal immediate-release fentanyl (TIRF) products (Abstral®, Actiq®, Fentora®, Lazanda®, Subsys®) cannot be approved using these criteria; refer to the Fentanyl IR policy, IL.ERX.NPA.66.*

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 > 7-day supply of opioid within a 90 day period 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 < 7-day supply of an opioid in the last 90 days;
2. Request is for ≤ 7-day supply;
3. Member is on no more than 2 different opioid analgesics concurrently;
4. Request is for an immediate-release opioid;
5. Total opioid dose does NOT exceed 90 morphine milligram equivalents (MME) per day;
6. Request does not exceed health plan quantity limit.

B. Cancer, Sickle Cell Disease, or Palliative Care** (must meet all)**:**

***Requests for transmucosal immediate-release fentanyl (TIRF) products (Abstral, Actiq, Fentora, Lazanda, Subsys) cannot be approved using these criteria; refer to the Fentanyl IR policy, IL.ERX.NPA.66.*

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. Request does not exceed health plan quantity limit.

Approval duration: 12 months

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 opioid within a 90 day period or request for an extended-release opioid) (must meet all)**:**

1. Previously received short term opioid therapy via Envolve Pharmacy Solutions 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, a documented failure of an immediate release opioid has occurred;
4. If request is for Butrans, OxyContin or Opana ER, failure of 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. For Butrans requests, at least one of the aforementioned trials occurred in the past 6 months, unless clinically significant adverse effects are experienced or all are contraindicated;
6. Member meets one of the following (a or b):
   a. Failure of at least 2 non-opioid ancillary treatments (such as non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, anticonvulsants, antidepressants, etc.), unless clinically significant adverse effect are experienced or all are contraindicated;
   b. Member has had a total of 90 cumulative days of opioid therapy in the last 120 days;
7. Request is for a preferred drug, unless member has previously failed, is intolerant to, or has contraindications to 2 or more preferred drugs;
8. Member will be maintained on no more than 2 opioid analgesics concurrently;
   **If member requires therapy with 2 opioid analgesics, regimen must consist of one immediate-release and one extended-release analgesic*
9. If total dose of opioid exceeds 90 MME per day, member is stable (history of > 7 days of therapy) on current dose, and one of the following is met (a or b):
   1. Provider's attestation that a dose taper will be attempted;
   2. 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. Requests for opioid products containing acetaminophen, aspirin, or ibuprofen do not exceed 4 grams of acetaminophen or aspirin, and 3.2 grams of ibuprofen per day;
11. Provider agrees to continuously assess the member's pain management regimen for possible discontinuation of opioid therapy;
12. Documentation of treatment agreement outlining the joint responsibilities of the clinician and patient which should include:
    a. Treatment goals in terms of pain management, restoration of function and safety
    b. Patient's responsibility for safe medication use (not taking more than prescribed; combination with alcohol or other substances like benzodiazepines, unless closely monitored by the prescriber, etc.)
    c. Secure storage and safe disposal
    d. Patient's responsibility to obtain prescribed opioids from only one clinician or practice
    e. Patient's agreement to periodic drug testing
    f. Clinician's responsibility to be available or to have a covering clinician available to care for unforeseen problems and to prescribe scheduled refills.
13. Documentation or attestation of the following:
    a. Pain contract or an informed consent and treatment agreement for chronic opioid therapy;
    b. Urine Drug Screen results from within the last 12 months that are consistent with patient's prescribed regimen;
14. Documentation that the provider has reviewed the Prescription Drug Monitoring Program (PDMP) to identify concurrently prescribed controlled substances.

Approval duration: 3 months or as requested by physician*

Authorizations for patients not from board certified providers, as stated above, with a calculated MME of ≥ 200 will be subject to taper requirement for continuation of care requests post initial approval

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Continued Therapy

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

***Requests for transmucosal immediate-release fentanyl (TIRF) products (Abstral, Actiq, Fentora, Lazanda, Subsys) cannot be approved using these criteria; refer to the Fentanyl IR policy, IL.ERX.NPA.66.*

1. Currently receiving therapy for pain associated with cancer, sickle cell disease, or palliative care;
2. 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 a health plan affiliated with Envolve Pharmacy Solutions or documentation supports that member is currently receiving opioids and has received this medication for at least 7 days in the last 90 days;
2. Request is for a preferred drug, unless member has previously failed, is intolerant to, or has contraindications to 2 or more preferred drugs;
3. If request is for Butrans, OxyContin or Opana ER, failure of 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. For Butrans requests, at least one of the aforementioned trials occurred in the past 6 months, unless clinically significant adverse effects are experienced or all are contraindicated;
5. Prescriber provides documentation supporting inability to discontinue opioid therapy;
6. Physical, behavioral, and non-opioid therapies (e.g., physical therapy, exercise, cognitive behavioral therapy, NSAIDs, antidepressants, anticonvulsants) are used as indicated in combination with chronic opioid therapy;
7. Member will not be maintained on > 2 opioid analgesics concurrently;
   **If member requires therapy with 2 opioid analgesics, regimen must consist of one immediate-release and one extended-release analgesic*
8. For requests for doses higher than 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;
      **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;
9. Requests for opioid products containing acetaminophen, aspirin, or ibuprofen do not exceed 4 grams of acetaminophen or aspirin, and 3.2 grams of ibuprofen per day;
10. Documentation that the provider has reviewed the PDMP, within the past 3 months of the request, to identify concurrently prescribed controlled substances.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

V. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

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.

VI. Dosage and Administration

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

VII. Product Availability

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

VIII. References

1. Dowell, Deborah, Tamara M. Haegerich, and Roger Chou. "CDC guideline for prescribing opioids for chronic pain—United States, 2016." Jama 315.15 (2016): 1624-1645.
2. Centers for Disease Control and Prevention. National Center for Injury Prevention and Control. Quality Improvement and Care Coordination. "Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain." “https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIP-QualityImprovementAndCareCoordination-508.pdf” (2018).
3. Centers for Disease Control and Prevention. "Pocket guide: tapering opioids for chronic pain." (2017).
4. Chou, et al. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. J Pain.2009 February; 10(2): 113–130.
5. Von Korff M, Saunders K, Thomas Ray G, et al. De facto long-term opioid therapy for noncancer pain. Clin J Pain. 2008 Jul–Aug; 24(6):521–527 and Washington State interagency guideline on prescribing opioids for pain; 2015.
6. Centers for Disease Control and Prevention. "Calculating total daily dose of opioids for safer dosage." “https://www. cdc. gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf” (2017).
7. Centers for Medicare & Medicaid Services. "Opioid oral morphine milligram equivalent (MME) conversion factors." (2018).

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created (adopted from MRX M50.58)	04.28.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.