Clinical Policy: Opioid Analgesics*

Reference Number: ERX.NPA.57
Effective Date: 12.01.17
Last Review Date: 02.22
Line of Business: Commercial, 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, 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 (which may include office chart notes and lab results) 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 taking 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.

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, 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 a health plan affiliated with Envolve Pharmacy Solutions;
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 (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;
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 opioid dose 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):
   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. 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 that the provider has reviewed the Prescription Drug Monitoring Program (PDMP) to identify concurrently prescribed controlled substances.

Approval duration: 3 months

B. Other diagnoses/indications: Not applicable

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, 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. 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*
7. If total opioid dose exceeds 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. 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;
9. Documentation that the provider has reviewed the PDMP to identify concurrently prescribed controlled substances.

Approval duration: 3 months

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

V. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
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

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/hr)	2.4
Hydrocodone (mg)	1
Hydromorphone (mg)	4
Levorphanol tartrate (mg)	11
Meperidine hydrochloride (mg)	0.1
Methadone (mg)	
> 0, ≤ 20	4
> 20, ≤ 40	8

Opioid Oral MME Conversion Factors	
Type of Opioid (strength units)	**MME Conversion Factor**
> 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

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 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- and Opana ER-specific criteria adapted from ERX.ST.21 and ERX.ST.22, respectively, which will both be retired. Removed age restriction for OxyContin and Opana ER.	12.06.17	02.18
1Q 2019 annual review: 84/120-day past opioid history changed to 90/120 days; removed requirement for management of concomitant benzodiazepine use; added health plan quantity limit requirement; references reviewed and updated.	11.05.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.26.19	02.20
Added Butrans to the policy, upon retiring ERX.NPA.98 Buprenorphine (Butrans).	08.04.20	11.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	12.01.20	02.21
1Q 2022 annual review: no significant changes; 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.

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.

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