Clinical Policy: Extended Release Opioids

Reference Number: CP.HNMC.02
Effective Date: 11.16.16
Last Review Date: 11.17
Line of Business: Medicaid – Medi-Cal

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The following are extended release opioid agonist products requiring prior authorization: Fentanyl transdermal system (Duragesic®), Tapentadol extended-release (Nucynta® ER), Oxymorphone extended-release (Opana® ER), Oxycodone controlled-release (OxyContin®).

Morphine sulfate/naltrexone hydrochloride extended-release (Embeda®) is a combination opioid agonist and opioid antagonist product.

FDA approved indication
Duragesic is indicated for:

- Management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
- Patients considered opioid-tolerant are those taking, for one week or longer, at least 60 mg oral morphine per day, 25 mcg transdermal fentanyl per hour, 30 mg oral oxycodone per day, 8 mg oral hydromorphone per day, 25 mg oral oxymorphone per day, 60 mg oral hydrocodone per day, or an equianalgesic dose of another opioid.

Opana ER is indicated for:

- Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Oxycontin is indicated for:

- Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate in:
  - Adults; and
  - Opioid-tolerant pediatric patients 11 years of age and older who are already receiving and tolerate a minimum daily opioid dose of at least 20 mg oxycodone orally or its equivalent.

Nucynta ER is indicated for:

- Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
- Management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Embeda is indicated for:

- Management of pain severe enough to require daily, around-the-clock, long term opioid treatment and for which alternative treatment options are inadequate.

Limitations of use:

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve Nucynta ER, Embeda, Duragesic, Opana ER, Oxycontin for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
- Nucynta ER, Embeda, Duragesic, Opana ER, Oxycontin are not indicated as an as-needed (prn) analgesic.

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 plans affiliated with Centene Corporation® that Duragesic, Nucynta ER, Opana ER, OxyContin, Embeda are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Pain Management (must meet all)**:**

1. Diagnosis of one of the following (a, b, or c):
   a. Cancer pain
   b. End-stage medical conditions accompanied by significant pain;
   c. Chronic pain for which there is a documented, objective etiology and one of the following: (i or ii)
      i. Documentation that the patient is being managed under a pain medication contract signed and dated within the year by both the provider and the patient individually;
      ii. Member resides in a Long Term Care (LTC) facility;
2. Failure of ONE of the following formulary controlled-release product unless contraindicated or clinically significant adverse effects are experienced: controlled-release morphine sulfate (MS Contin), morphine sulfate sustained-release beads (Avinza), or sustained-release morphine sulfate (Kadian).

Approval duration:
Cancer pain, End-stage medical condition, LTC residents: Length of Benefit
Pain medication contract: Up to 1 year

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. For members with chronic pain being managed under a pain medication contract, a new pain medication contract is required every year;
3. Member is responding positively to therapy (e.g., no significant toxicity).

Approval duration:
Cancer pain, End-stage medical condition, LTC residents: Length of Benefit
Pain medication contract: Up to 1 year

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

1. Currently receiving medication via a health plan affiliated with Centene Corporation and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. 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 – CP.PMN.53 or evidence of coverage documents;
B. Acute or intermittent pain;
C. Immediate post-surgical pain;
D. Use in patients who require opioid analgesia for a short period of time.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
LTC: long term care facility
ER: extended-release

Appendix B: General Information

- Avinza (45 mg, 60 mg, 75 mg, 90 mg and 120 mg), Kadian (100 mg and 200 mg), MS Contin (100 mg and 200 mg), OxyContin (60 mg and 80 mg, a single dose greater than 40mg, or a total daily dose greater than 80 mg), Duragesic, and Embeda (100 mg/4 mg) are for use only in opioid tolerant patients. Opioid tolerant patients are those receiving, for one week or longer, at least 60 mg PO morphine/day, 25 mcg/hr transdermal fentanyl, 30 mg PO oxycodone/day, 8 mg PO hydromorphone/day, 25 mg PO oxymorphone/day or an equianalgesic dose of another opioid.
- Avinza, Kadian, MS Contin, Oxycontin, Opana ER, Duragesic, and Embeda are not indicated as an as-needed (prn) analgesic.
- Because it may be difficult to determine analgesic need using a controlled-release product, it is recommended to initiate therapy with immediate-release products. The table below may be useful in determining the appropriate dosing of a variety of analgesic options.

Equianalgesic Opioid Chart

Analgesic	Parenteral IM, SC, IV (mg)	Oral/Rectal/Patch (mg)
Fentanyl	0.1 – 0.2	25 mcg/hr (patch)
Oxycodone	-	20
Methadone	10	20
Oxymorphone	1	10 (rectal)
Hydromorphone	1.5	7.5
Morphine*	10	30
Codeine	130	200
Levorphanol	2	4
Meperidine*	75	-

**Adjust dose in renal impairment*

- Due to the potency of OxyContin, it is recommended to use the conversion factor table when converting TO oral oxycodone to avoid overestimating the dose.
- Conversion back FROM prior opioid divides by the conversion factor shown in the table below.

Estimated Conversion Factor for Converting Prior Opioid Doses to Oral Oxycodone (mg/day prior opioid x factor = mg/day oral oxycodone)		
Prior Opioid	**Oral**	**Parenteral**
Oxycodone	1	--
Methadone	1.5	3
Oxymorphone	2	--
Hydromorphone	4	20
Morphine	0.5	1.5-3
Codeine	0.15	--
Hydrocodone	0.9	--
Levorphanol	7.55	15
Meperidine	0.1	0.4

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
MS Contin (morphine sulfate controlled-release tablet)	Opioid naïve patients: 15 mg PO Q12 hours Conversion to MS Contin: Dosing is individualized based on previous analgesic therapy. Administer at ½ the total daily requirement PO Q12 hours or 1/3 the total daily requirement PO Q8 hours	The 100 mg and 200 mg tablets are reserved only for opioid tolerant individuals who require morphine equivalent doses of 200 mg or more for the 100 mg tablet and 400 mg or more for the 200 mg tablet
Kadian (morphine sulfate sustained-release capsule)	Opioid naïve patients: 10mg or 20mg PO, may adjust dosage at 20mg increment QOD	Should not be given more frequently than every 12 hours

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
	Conversion to Kadian: Dosing is individualized based on previous analgesic therapy. Administer patient's total daily requirement PO Q24 hours or administer ½ patient's total daily requirement PO Q12 hours.	
Avinza (morphine sulfate beads sustained release)	Opioid naïve patients: 30 mg PO Q24 hours, with dosage adjustments of not > 30 mg every 4 days Conversion to Avinza: Dosing is individualized based on previous analgesic therapy Administer patient`s total daily morphine requirement PO Q24 hours	1600 mg/day Should not be given more frequently than every 24 hours

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Tapentadol extended-release (Nucynta ER)	The starting dose in patients currently not taking opioid analgesics is 50 mg PO BID (approximately Q12H). Individually titrate the dose within the therapeutic range of 100 mg to 250 mg BID.	Varies
Oxycodone extended-release (OxyContin)	One tablet PO BID; individualized dosing may require multiple tablets and TID dosing	Varies
Oxymorphone extended-release (Opana ER)	One tablet PO BID; individualized dosing may require multiple tablets dosing	Varies
Fentanyl transdermal system (Duragesic)	Dosing is individualized based on previous analgesic therapy. Initiate dose at one patch TD	Varies

	Q72H. May increase following 3 days of therapy. Some patients may require dosing Q48H	
Morphine sulfate/Naltrexone hydrochloride extended-release (Embeda)	For opioid naive and opioid non-tolerant: initiate with 20 mg/0.8 mg PO every 24 hours.	Varies

VI. Product Availability

Drug	Availability
Tapentadol extended-release (Nucynta ER)	Extended-release tablets: 50 mg, 100 mg, 150 mg, 200 mg, 250 mg
Oxymorphone extended-release (Opana ER)	Extended-release tablets: 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg
Oxycodone extended-release (OxyContin)	Extended-release tablets: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg
Fentanyl transdermal system (Duragesic)	Patches: 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr; available under generic name only: 37.5mcg, 62.5 mcg, 87.5 mcg/hr
Morphine sulfate/Naltrexone hydrochloride extended-release (Embeda)	Extended-release capsules: 20 mg/0.8 mg, 30 mg/1.2 mg, 50 mg/2 mg, 60 mg/2.4 mg, 80 mg/3.2 mg, 100 mg/4 mg

VII. References

1. Nucynta ER [Prescribing Information] Newark, CA: Depomed, Inc.; December 2016.
2. Opana ER [Prescribing Information] Malvern, PA: Endo Pharmaceuticals Inc.; December 2016.
3. OxyContin [Prescribing Information] Stamford, CT: Purdue Pharma L.P.; December 2016.
4. Duragesic [Prescribing Information] Titusville, NJ: Janssen Pharmaceuticals Inc.; December 2016.
5. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 31, 2017.
6. American Hospital Formulary Service Drug Information. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed May 31, 2017.
7. Embeda [Prescribing Information] New York, NY: Pfizer Inc.; December 2016.
8. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: http://www.clinicalpharmacology-ip.com/. Accessed May 31, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; minor changes to verbiage and grammar. References updated.	05.01.17	11.17

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.