Clinical Policy: Abuse-Deterrent Opioid Formulations

Reference Number: CP.CPA.178
Effective Date: 03.01.19
Last Review Date: 02.20
Line of Business: Commercial

Revision Log

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

Description

The following are abuse-deterrent formulations (ADFs) of opioid agonist products requiring prior authorization: immediate-release oxycodone (Oxaydo®, Roxybond™).

FDA Approved Indication(s)

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

Limitation(s) 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 Oxaydo and Roxybond for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or non-opioid combination products)

- have not been tolerated, or are not expected to be tolerated, or
- have not provided adequate analgesia or are not expected to provide adequate analgesia.

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 ADFs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of chronic pain;
2. Age ≥ 18 years;
3. Medical justification supports inability to use a generic non-abuse-deterrent formulation of the same active ingredient as the requested opioid;
4. A treatment plan is required, including all of the following:
   a. Diagnosis or conditions that are contributing to the pain;
   b. Pain intensity (scales or ratings);
   c. Functional status (physical and psychosocial);
   d. Patient's goal of therapy (level of pain acceptable and/or functional status);
   e. Current analgesic (opioid and adjuvant) regimen;
   f. Current non-pharmacological treatment;

g. Opioid-related side effects;
h. Indications of medical misuse;
i. Action plan if analgesic failure occurs.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: 3 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 3 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

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.CPA.09 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ADF: abuse-deterrent formulation
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
oxycodone immediate-release capsules, tablets, or oral solution	Opioid naïve patients: 5-15 mg PO Q4-6 hours as needed for pain; titrate based on pain severity and patient response For chronic pain: Oral tablets may be administered around-the-clock rather than as needed.	Varies

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.

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

- Although Oxaydo and Roxybond have language in their labeling describing reduced abuse potential via specific routes (intranasal for Oxaydo and intranasal/injection for Roxybond), the Prescribing Information (PI) documents for both still contain black box warnings and Limitations of Use re: abuse potential. The Oxaydo PI says "The clinical significance of the difference in drug liking and difference in response to taking the drug again reported in this study has not yet been established. There is no evidence that Oxaydo has a reduced abuse liability compared to immediate-release oxycodone." The Roxybond PI says "However, abuse by the intranasal, oral, and intravenous route is still possible".
- Per the 2016 CDC treatment guidelines for opioid prescribing, "As indicated in FDA guidance for industry on evaluation and labeling of abuse-deterrent opioids, although abuse-deterrent technologies are expected to make manipulation of opioids more difficult or less rewarding, they do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes. The "abuse-deterrent" label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations."

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Oxaydo, Roxybond (immediate-release oxycodone, ADF)	5-15 mg PO Q4-6 hours as needed for pain; titrate based on pain severity and patient response	Not applicable

VI. Product Availability

Drug	Availability
Oxycodone immediate-release tablets (Oxaydo)	Immediate-release tablets: 5 mg, 7.5 mg
Oxycodone immediate-release tablets (Roxybond)	Immediate-release tablets: 5 mg, 15 mg, 30 mg

VII. References

1. Oxaydo Prescribing Information. Wayne, PA: Egalet US, Inc.; October 2019. Available at www.oxaydo.com. Accessed on November 26, 2019.
2. Roxybond Prescribing Information. Valley Cottage, NY: Inspirion Delivery Sciences, LLC; October 2019. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209777lbl.pdf. Accessed on November 26, 2019.
3. 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 Policy created.	11.07.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.26.19	02.20

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.

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