

Clinical Policy: Oxycodone/Acetaminophen ER (Xartemis XR)

Reference Number: CP.CPA.118

Effective Date: 11.16.16

Last Review Date: 08.19

Line of Business: Commercial

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Oxycodone/acetaminophen ER (Xartemis™ XR) is a combination of an opioid agonist with a non-opioid analgesic.

FDA Approved Indication(s)

Xartemis XR is indicated for the management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate.

Limitation(s) of use: Because of the risks of addiction, abuse, misuse, overdose, and death with opioids, even at recommended doses, reserve Xartemis XR for use in patients for whom alternative treatment options (e.g., non-opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of 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.

It is the policy of health plans affiliated with Centene Corporation® that Xartemis XR is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Pain Management (must meet all):

1. Diagnosis of acute pain;
2. Age \geq 18 years;
3. Failure of TWO of the following formulary short acting narcotic analgesics, unless contraindicated or clinically significant adverse effects are experienced:
 - a. Hydrocodone/acetaminophen;
 - b. Immediate-release oxycodone/acetaminophen;
 - c. Oxycodone/aspirin;
 - d. Immediate-release oxycodone;
 - e. Immediate-release hydromorphone;
4. Dose does not exceed 4 tablets per day.

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;
3. If request is for a dose increase, new dose does not exceed 4 tablets per day.

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

FDA: Food and Drug Administration

ER: extended release

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Hydrocodone/acetaminophen (Norco®)	5-10 mg PO Q4-6H	The total daily dose of acetaminophen should be limited to ≤ 4 g/day
Immediate-release oxycodone/acetaminophen (Percocet®, Roxicet™)	2.5-10 mg PO 6H	The total daily dose of acetaminophen should be limited to ≤ 4 g/day
Oxycodone/aspirin (Percodan®)	4.8 mg PO Q6H	The total daily dose of aspirin should be limited to ≤ 4 g/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Immediate-release oxycodone (Roxicodone®)	5-15 mg PO Q4-6H	Reserve use of single doses > 40 mg or total daily doses > 80 mg for opioid-tolerant patients only
Immediate-release hydromorphone (Dilaudid®)	2-4 mg PO Q4-6H	Doses should be titrated to provide adequate pain relief

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 in an unmonitored setting or in absence of resuscitative equipment, known or suspected gastrointestinal obstruction, including paralytic ileus
- Boxed warning(s): addiction, abuse, and misuse, life-threatening respiratory depression, accidental ingestion, neonatal opioid withdrawal syndrome, cytochrome P450 3A4 interactions, hepatotoxicity, risks from concomitant use with benzodiazepines or other central nervous system depressants

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acute severe pain	Two tablets PO Q12H	4 tablets/day

VI. Product Availability

Extended-release tablet: 7.5 mg/325 mg (oxycodone hydrochloride/acetaminophen)

VII. References

1. Xartemis XR Prescribing Information. Hazelwood, MO: Mallinckrodt Pharmaceuticals; August 2018. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=efcb1e8b-c0be-47ee-b09e-7a6b41e64bdd>. Accessed May 20, 2019.
2. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 20, 2019.
3. Singla N, Barrett T, Sisk L, et al. A randomized, double-blind, placebo-controlled study of the efficacy and safety of MNK-795, a dual-layer, biphasic, immediate-release and extended-release combination analgesic for acute pain. *Curr Med Res Opin.* 2014; 30(3):349-59.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	01.30.17	11.17
3Q 2018 annual review: no significant changes; changed approval duration from length of benefit to 3 months; added age limit; References reviewed and updated.	05.22.18	08.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.20.19	08.19

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.

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