Clinical Policy: Oxycodone/Acetaminophen ER (Xartemis XR)

Reference Number: CP.CPA.118
Effective Date: 11.16.16
Last Review Date: 08.22
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, and misuse 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 ≥ 18 years;
3. Failure of TWO of the following formulary short acting narcotic analgesics, unless clinically significant adverse effects are experienced or all are contraindicated:
   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 (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

A. Pain Management (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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
REMS: Risk Evaluation and Mitigation Strategy

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
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, hypersensitivity to oxycodone, acetaminophen
- Boxed warning(s): addiction, abuse, and misuse, risk evaluation and mitigation strategy (REMS), 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; September 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204031s004s005lbl.pdf. Accessed April 22, 2022.
2. Micromedex [Internet database]. Greenwood Village, CO: Truven Health Analytics. Available at www.micromedex.com/. Accessed April 22, 2022.
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
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
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.20.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.11.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	05.12.21	08.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	04.22.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.22.22	

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. 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.