RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	oxycodone/acetaminophen ER
Policy Number:	RxA.319
Drug(s) Applied:	Xartemis™ XR
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Oxycodone/acetaminophen ER (Xartemis™ XR)	Acute severe pain	Two tablets PO every 12H	4 tablets/day

Dosage Forms

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

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

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

1. Diagnosis of acute pain;
2. Age 18 years of age or older;
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
Commercial :3 months
Medicaid : 3 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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
Commercial :3 months
Medicaid : 3 months

III. Appendices

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 every 4-6 hours	The total daily dose of acetaminophen should be limited to ≤ 4 g/day
Immediate-release oxycodone/ acetaminophen (Percocet®, Roxicet™)	2.5-10 mg PO 6 hours	The total daily dose of acetaminophen should be limited to ≤ 4 g/day
Oxycodone/aspirin (Percodan®)	4.8 mg PO every 6 hours	The total daily dose of aspirin should be limited to ≤ 4 g/day
Immediate-release oxycodone (Roxicodone®)	5-15 mg PO every 4-6 hours	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 every 4-6 hours	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 (e.g., anaphylaxis) to oxycodone, acetaminophen.

- 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.

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#page=34. Accessed July 13,2020.
2. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 13,2020.
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.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	02/07/2020
Policy was reviewed: 1) Policy description table was updated 2) Background, “limitations of use” was updated per latest prescribing information 3) Continuation therapy criteria II.A.1. was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…” 4) Initial therapy and continued therapy criteria approval duration for Medicaid was added 5) Appendix B, therapeutic alternatives, dosing regimen - “Q “replaced with ”every”; “H” was replaced with “hours” 6) Appendix Contraindications were	07/13/2020	09/14/2020

updated 7) References were updated		