Clinical Policy: Oxycodone ER (Oxycontin)
Reference Number: ERX.ST.21
Effective Date: 09.01.17
Last Review Date: 08.17
Line of Business: Commercial [Prescription Drug Plan] Revision Log

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

Description
Oxycodone ER (Oxycontin®) is an opioid agonist.

FDA approved indication
Oxycontin is 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 in:
- Adults
- 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

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, reserve 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.
- Oxycontin is 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 Envolve Pharmacy Solutions™ that Oxycontin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria
A. Step Therapy for Oxycontin (must meet all)**:**
1. Age ≥ 11 years;
2. Previous use of an immediate-release (short-acting) narcotic analgesic in the past 6 months;
3. Previous use of fentanyl patch in the past 6 months, unless contraindicated or clinically significant adverse effects are experienced;
4. Previous use of morphine extended-release tablets/capsules in the past 6 months, unless contraindicated or clinically significant adverse effects are experienced;
5. Request does not exceed 2 tablets per day, unless both of the following are met (a and b):
   a. Dose cannot be adjusted within quantity limits using other dosage strengths;
   b. Prescribed by an oncologist or pain management specialist.

Approval duration: 3 months

II. Continued Therapy
A. Step Therapy for Oxycontin (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. If request is for a dose increase, request does not exceed 2 tablets per day, unless all of the following are met (a, b, and c):

a. Dose cannot be adjusted within quantity limits using other dosage strengths;
b. Prescribed by an oncologist or pain management specialist;
c. Pharmacy claims history reflects gradual dose titration.

Approval duration:
Requests within quantity limit: 6 months
Requests exceeding quantity limit: 3 months

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Immediate-release (short-acting) narcotic analgesics (e.g., hydrocodone/ acetaminophen, hydromorphone, morphine, oxycodone, etc.)*	Varies- refer to prescribing information	Varies- refer to prescribing information
Fentanyl transdermal patch (Duragesic®)	Dosing should be individualized based on the severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse, and misuse; each transdermal system is intended to be worn for 72 hours; however, some patients may require patch application at 48-hour intervals to maintain adequate analgesia	With appropriate dosage titration, there is no maximum dose
Morphine sulfate extended-release (tablets: Arymo® ER, MS Contin®, MorphaBond®; capsules: Avinza®, Kadian®)	Varies- refer to prescribing information	Varies- refer to prescribing information

**Examples of immediate-release (short-acting) narcotic analgesics provided, not an all-inclusive list*

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Pain management	Adults: For opioid-naïve and opioid non-tolerant patients, initiate with 10 mg tablets orally every 12 hours. See full prescribing information for instructions on conversion from opioids to Oxycontin, titration and maintenance of therapy. Pediatric patients ≥ 11 years already receiving and tolerating opioids for at least 5 consecutive days with a minimum of 20 mg per day of oxycodone or its equivalent for at least two days immediately preceding dosing with Oxycontin: See full prescribing information for instructions on conversion from opioids to Oxycontin, titration and maintenance of therapy.	With appropriate dosage titration, there is no maximum dose of Oxycontin

V. Product Availability

Extended-release tablets: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg

VI. References

1. Oxycontin Prescribing Information. Stamford, CT: Purdue Pharma L.P.; December 2016. Available at: https://www.oxycontin.com/. Accessed June 30, 2017.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from ERX.NSST.17 Extended-release oxycodone and oxymorphone (retired) and converted to new template. Added age restriction per PI. Added use of short-acting narcotic analgesic should have occurred within the past 6 months. Modified generic health plan approved daily QL statement to reflect specific QL/day. Updated references.	06/17	08/17

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.