Clinical Policy: Oxycodone SR (Oxycontin)
Reference Number: CP.PPA.04
Effective Date: 09/06
Last Review Date: 02/17
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description
Oxycodone (Oxycontin®) is an opioid agonist.

FDA approved indication
Oxycontin is indicated for 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.

Limitation 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 formulations, 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 (including 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 Oxycontin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of chronic pain;
2. Member must meet one of the following (a or b):
   a. Age ≥ 18 years;
   b. Age ≥ 11 years already receiving and tolerant to a minimum daily opioid dose of at least 20 mg immediate-release oxycodone or equivalent;
3. Failure of 2 PDL long acting narcotic analgesics (e.g., MS Contin, fentanyl patches), in combination with short-acting narcotic analgesics for break-through pain, unless member experiences clinically significant adverse effects or has contraindication(s) to all PDL long acting narcotic analgesics;
4. Request does not exceed 2 tablets per day.

Approval duration: 6 months

B. Other diagnoses/indications – Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Request does not exceed 2 tablets per day;
3. Responding positively to therapy.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

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.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
FDA: Food and Drug Administration
PDL: preferred drug list
PRN: as needed

V. Dosage and Administration

Population	Recommended Initial Dose
Adults	10 mg tablets orally every 12 hours
Pediatric patients ≥ 11 years	20 mg total daily dose
Geriatric patients	1/3 to 1/2 the recommended starting dosage
Patients with hepatic impairment	1/3 to 1/2 the recommended staring dosage

VI. Product Availability

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

VII. Workflow Document

Oxycontin WF.docx

VIII. References

1. Oxycontin Prescribing Information. Stamford, CT. Purdue Pharma L.P.; August 2015. Available at: http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o. Accessed December 2016.
2. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.

Reviews, Revisions, and Approvals	Date	Approval Date
Add 15mg, 30mg, 60mg strengths of oxycodone SR and omit the 160mg strength. Add "and" after "Criteria for Approval" item "a.". Delete "failure or intolerance to one long-acting analgesics on PDL" from item "b.". Add item "c." "Failure or intolerance to two long-acting analgesics on the PDL, and".	02/08	02/08
Delete 160mg strength.	05/08	05/08
Criteria changed to be consistent with the prior authorization criteria for fentanyl patches. Removed specialty prescribing (pain management, oncologist) requirement. Defined maximum dosing of MS Contin and methadone.	02/10	02/10
Updated reference section to reflect current literature search.	02/11	02/11
Added fentanyl patches as a PDL "trials and failures" option. Added anticonvulsants and antidepressants as options for ancillary pain treatment. Updated reference section to reflect current literature search.	02/12	02/12
Updated reference section to reflect current literature search.	02/13	02/13
Updated reference section to reflect current literature search.	02/14	02/14
Updated reference section to reflect current literature search.	02/15	02/15
Deleted documented severe, requiring around the clock analgesia. Deleted failure of or intolerance to, at maximum dose. Deleted minimum doses related to PDL agents. Deleted adjunctive non-opioid agent criteria. Deleted no PRN use.	05/15	05/15
Converted to new policy template; Added age limits per labeling; Updated references.	11/15	02/16
Converted to new integrated template; Removed continued approval for once daily or twice daily dosing because quantity limit is 2 tablets daily	12/16	02/17

Reviews, Revisions, and Approvals	Date	Approval Date
based on core PDL; added positive response to therapy requirement for re-authorization.		

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.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.