

Drug Policy

Policy:	Oxaydo (oxycodone)	Annual Review Date: 07/18/2024
		Last Revised Date: 07/18/2024

OVERVIEW

Oxycodone is a full opioid agonist. Oxaydo is indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Oxycodone is contraindicated in significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting, known or suspected gastrointestinal obstruction, including paralytic ileus, or hypersensitivity to oxycodone. Oxaydo has a boxed warning for addiction, abuse, and misuse. Continuing assessment and monitoring of patients using Oxaydo is recommended.

POLICY STATEMENT

This policy involves the use of Oxaydo. Prior authorization is recommended for pharmacy benefit coverage of Oxaydo. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Oxaydo as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Oxaydo be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Oxaydo is recommended in those who meet the following criteria:

1. **Hospice, Cancer, or Terminal Illness**

Criteria. *Approve.*

2. **Severe Chronic Pain**

Criteria. *Patient must meet the following criteria*

- A. The patient is 18 years of age or older; AND
- B. The patient's pain has been evaluated by one or more physicians who specialize in treatment of the area where the perceived pain located or a pain specialist; AND

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- C. If the patient is taking over 80 Morphine Equivalent Dosage of the opioid requested, provider must verify the dose has been titrated and the lowest appropriate dose is being used; AND
- D. The prescriber attests that they have reviewed controlled substance medication history by running an Ohio Automated Rx Reporting System (OARRS) report (or respective prescription monitoring program in the prescriber's state of practice if available) and they will continue to check OARRS (or respective prescription monitoring program in the prescriber's state of practice) at a minimum every 3 months, as recommended by the CDC's Prescribing Opioids for Chronic Pain Guidelines; AND
- E. The prescriber provides a treatment plan including the use of non-opioid analgesics and/or non-pharmacological interventions and expected opioid treatment duration; AND
- F. The prescribing physician must have a pain management contract with the patient; AND
- G. If the patient is using a benzodiazepine or muscle relaxant concurrently, the prescriber is aware of the risk versus benefit of the combination and attests that continuation of combination therapy is clinically necessary; AND
- H. The patient has been thoroughly evaluated and assessed on a regular basis by the provider to determine pain levels, quality of life, medication effectiveness, and an evaluation of possible addiction [**provider must supply information such as patient charts and documentation upon first fill**]; AND
- I. Realistic benefits and known risks (e.g. addiction, overdose) of opioid therapy have been discussed with the patient and expected benefits for pain and function are anticipated to outweigh risks to the patient: AND
- J. The patient has been counseled on safe storage and disposal of opioids by prescriber; AND
- K. The patient has been counseled on the dangers of combining opioids with alcohol or other CNS depressants; AND
- L. The prescriber verifies no concurrent substance abuse treatments are being prescribed (examples including but not limited to: Suboxone, Vivitrol, oral naloxone, buprenorphine)
- M. The patient has previously tried alternative treatments, including EACH of the following on separate occasions:
 - a. A non-opioid analgesic
 - b. Generic oxycodone IR (tablets, capsules, or solution)
 - c. Brand Roxycodone, AND
- N. Alternative treatments have provided inadequate analgesia

Initial Approval/ Extended Approval.

- A) *Initial Approval:* indefinitely for terminal illness/cancer related pain indications
1 year for all other chronic pain indications
- B) *Extended Approval:* 1 year for all other chronic pain indications

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Oxaydo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

- 1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Oxycodone hydrochloride. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 15 July 2024. Accessed on 17 July 2024.
2. Oxaydo [prescribing information]. Zyla Life Sciences US Inc; Wayne, PA. March 2021.
3. 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>.