Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Zohydro ER (hydrocodone bitartrate extended release)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***April 2014 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Zohydro ER (hydrocodone bitartrate extended release)

Zohydro ER (hydrocodone bitartrate extended release), a mu opioid agonist, 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.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002

Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Zohydro ER (hydrocodone bitartrate extended release), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be age 18 years or older
- Must be prescribed by or in consultation with a pain management specialist
- Must have a diagnosis of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
    - Not covered as an as-needed (prn) analgesic
- Must submit documentation of pain that is caused by a medical condition and severe, as documented by a pain assessment tool measurement (e.g. a numeric or visual analog scale)
- Must submit documentation of the treatment plan.
- Must submit documentation of the following:
    - The patient and members of the same household do not have a diagnosis of or history of substance dependency/abuse (including alcohol)
    - A recent quarterly urine drug screen (including testing for licit and illicit drugs with the potential for abuse) which is consistent for prescribed controlled substances
- Must submit documentation of acknowledgement of understanding of the Risk Evaluation and Mitigation Strategy (REMS) program for this medication
- Must not have any of the following contraindications:
    - Significant respiratory depression
    - Acute or severe bronchial asthma or hypercarbia
    - Confirmed or suspected paralytic ileus
- Must submit chart documentation showing the member has tried four of the five following medications for at least one month each with an inadequate response or significant side effects unless there is a documented contraindication:
    - Fentanyl patch
    - Morphine sulfate extended-release
    - Oxymorphone ER

- Methadone
- Oxycontin

Reauthorization Criteria:

All prior authorization renewals are reviewed every 6 months basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month intervals based upon chart documentation from the prescriber that the member's condition has improved as a result of treatment and documentation of a recent quarterly urine drug screen (including testing for licit and illicit drugs with the potential for abuse) which is consistent for prescribed controlled substances.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 6 months
Quantity Level Limit	
Zohydro ER	60 capsules per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Zohydro ER [package insert]. San Diego, CA: Zogenix Inc.; October 2013.
2. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Zohydro ER Summary Review NDA 202880, October 25, 2013. Retrieved March 12, 2014, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/202880Orig1s000SumR.pdf.
3. Duragesic Patch [package insert]. Raritan, NJ: PriCara, Inc.; July 2012.
4. MS Contin [package insert]. Stamford, CT: Purdue Pharma L.P.; March 2009.
5. Opana ER [package insert]. Horsham, PA: Endo Pharmaceuticals Inc.; July 2012.
6. Dolphine [package insert]. Columbus, OH: Roxane Laboratories Inc.; October 2006.
7. American Society of Interventional Pain Physicians. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: part 2-Guidance. *Pain Physician.* 2012; (15): S67-S116.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*