# CLINICAL GUIDELINES FOR HYSINGLA™ ER

**Description:** On November 20, 2014 the FDA announced the approval of Purdue Pharma's Hysingla ER (hydrocodone bitartrate). The FDA has determined that Hysingla ER has properties that are expected to reduce, but not totally prevent, abuse of the drug when chewed and then taken orally, or crushed and snorted or injected. Hysingla ER is difficult to crush, break or dissolve. It also forms a viscous hydrogel when exposed to an aqueous environment that resist passage through a hypodermic needle. Hysingla ER is administered once daily (every 24 hours). For opioid –naïve and opioid non-tolerant patients, initiate with 20mg tablets PO every 24 hours. Increase the dose of Hysingla ER in increments of 10mg to 20mg every 3 to 5 days as needed to achieve adequate analgesia. Available strengths Oral Tablet, Extended Release : 20mg, 30mg, 40mg, 60mg, 80mg, 100mg, and 120mg.

**Indication:** Hysingla ER 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. This product is not approved for as needed pain relief.

***Black box warning summary from MicroMedex***

- Prior to prescribing hydrocodone, assess each patient's risk for opioid addiction, abuse, and misuse and regularly monitor all patients for opioid addiction behaviors or conditions.
- Monitor for respiratory depression, which can be serious, life-threatening, or fatal, especially during initiation or following a dose increase, and instruct patients to swallow extended release capsules whole to avoid potentially fatal overdose.
- Fatal overdose can occur in children with accidental ingestion of just 1 dose of hydrocodone.
- If prolonged opioid use is necessary during pregnancy, advise the patient of the risk of life-threatening neonatal opioid withdrawal syndrome and arrange for appropriate treatment during and after delivery.
- Instruct patients to avoid alcoholic beverages or medications that contain alcohol to avoid a potentially fatal overdose.
- Concomitant use of a CYP3A4 inhibitor or discontinuation of a CYP3A4 inducer may increase or prolong adverse drug effects or cause potentially fatal respiratory depression.

Current Mississippi Medicaid Uniform Preferred Drug List (UPDL)

**ANALGESICS, NARCOTIC - LONG ACTING** SmartPA

| THERAPEUTIC DRUG CLASS | PREFERRED AGENTS | NON-PREFERRED AGENTS | PA CRITERIA |
|---|---|---|---|
| | fentanyl patches<br>methadone<br>morphine ER tablets<br>OPANA ER (oxymorphone) | AVINZA (morphine)<br>BUTRANS (buprenorphine)<br>CONZIP ER (tramadol)<br>DOLOPHINE (methadone)<br>DURAGESIC (fentanyl)<br>EMBEDA (morphine/naltrexone)<br>EXALGO (hydromorphone)<br>hydromorphone ER<br>HYSINGLA ER (hydrocodone)NH<br>KADIAN (morphine)<br>MS CONTIN (morphine)<br>morphine ER capsules<br>NUCYNTA ER (tapentadol)<br>oxycodone ER<br>OXYCONTIN (oxycodone)<br>oxymorphone ER<br>RYZOLT (tramadol)<br>tramadol ER<br>ULTRAM ER (tramadol)<br>XARTEMIS XR (oxycodone/APAP)<br>ZOHYDRO ER<br>(hydrocodone bitartrate) | **Minimum Age Limit**<br>• **18 years** – Xartemis XR, Zohydro ER<br><br>**Quantity Limits**<br>Applicable quantity limit per rolling days<br>• **31 tablets/31 days –** Avinza, Exalgo ER, Hysingla ER, Ultram ER, Ryzolt, Conzip ER<br>• **62 tablets/31 days –** Methadone, Kadian, Morphine ER, Embeda, oxycodone ER, Opana ER, Oxycontin, Zohydro ER<br>• **10 patches/31 days –** Duragesic<br>• **4 patches/31 days –** Butrans<br>• **40 tablets/10 days –** Xartemis XR<br><br>**Non-Preferred Criteria**<br>• Have tried 2 different preferred agents in the past 6 months **OR**<br>• Documented diagnosis of cancer **OR** Antineoplastic therapy **AND**<br>• 90 consecutive days on same agent in the past 105 days |

**Possible Criteria for Consideration by Board:**

The following potential criteria and areas for discussion have been identified by MS-DUR and DOM.

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|---|---|
| Age edit | Minimum age of 18 years |
| Quantity limit | Maximum 1 unit per day, |
| Diagnosis | Documented diagnosis of cancer |
| Step-therapy | Prior 30 days of therapy with 2 different preferred agents in the past 12 months<br>AND<br>Prior 30 days therapy with 2 different non-preferred agents in the past 12 months |

**Recommendation:**

The DUR Board recommends that DOM adopt the product specific PA criteria for use of Hysingla ER identified during the discussion.