Hysingla ER (hydrocodone bitartrate extended release)

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 year</td>
</tr>
<tr>
<td>Step Therapy</td>
<td></td>
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<tr>
<td>Quantity Limit</td>
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<tr>
<th>Medications</th>
<th>Quantity Limit</th>
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</thead>
<tbody>
<tr>
<td>Hysingla ER (hydrocodone bitartrate extended release) 20mg, 30mg, 40mg, 60mg, 80mg, 100mg, 120mg</td>
<td>1 tablet per day</td>
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**APPROVAL CRITERIA**

Requests for Hysingla ER (hydrocodone bitartrate extended release) may be approved for individuals who meet the following criteria:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of pain severe enough to require daily, around-the-clock, long term opioid treatment; **AND**
III. Individual has one of the following:
   a. An inadequate response to alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids; **OR**
   b. Alternative treatment options would otherwise be inadequate to provide sufficient management of pain.

**AND**

IV. Individual has had a trial of **any two** of the following generic long acting agents in the previous 180 days **OR** individual has completed titration and is already maintained on a stable dose of Hysingla ER (hydrocodone bitartrate extended release):
   a. Fentanyl Patch
   b. Levorphanol
   c. Methadone
   d. Methadose
   e. Morphine Sulfate ER (MS Contin)
   f. Tramadol ER (Ultram ER)
   g. Oxymorphone ER (Opana ER)
   h. Hydromorphone ER

Hysingla ER (hydrocodone bitartrate extended-release) may **not** be approved for the following:

I. Individual is requesting or using as an as-needed analgesic; **OR**
II. Individual has one of the following conditions:
   a. Significant respiratory depression; **OR**
b. Acute or severe bronchial asthma or hypercarbia; OR

c. Known or suspected paralytic ileus.

Note: Hysingla ER (hydrocodone bitartrate extended-release) has black box warnings for Addiction, abuse, and misuse; Life-threatening respiratory depression; Accidental exposure; Neonatal opioid withdrawal syndrome; Interaction with alcohol; and cytochrome P450 3A4 interaction. Hysingla ER is an opioid agonist. Each individual’s risk for opioid abuse or addiction should be assessed prior to prescribing. Routinely monitor for signs of misuse, abuse, and addiction during therapy. Serious, life-threatening, or fatal respiratory depression may occur with use. Individuals should be instructed to swallow capsule whole. Monitor for respiratory depression, especially during initiation or following a dose increase. Accidental exposure, especially in children, can result in a fatal overdose. Infants exposed to opioids during pregnancy may require treatment for neonatal opioid withdrawal syndrome. Prolonged maternal use during pregnancy can result in life-threatening neonatal opioid withdrawal syndrome. Individuals should not consume alcohol or any products containing alcohol during treatment due to a risk of fatal plasma hydrocodone levels. Concomitant use of Hysingla ER with all cytochrome P450 3A4 inhibitors may result in increased hydrocodone concentrations; in addition, discontinuation of a cytochrome P450 3A4 inducer may also result in an increase in hydrocodone concentration. Monitor individuals receiving Hysingla ER and any cytochrome P450 3A4 inhibitor or inducer.

Requests for increased quantity will be reviewed on a case by case basis.

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<tr>
<th>State Specific Mandates</th>
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<td>N/A</td>
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</tbody>
</table>

Key References:


DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2015; Updated periodically.