

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG (S)	<u>Long Acting Hydrocodones</u> Zohydro ER (hydrocodone bitartrate HCl extended-release capsules)
POLICY #	12115
INDICATIONS	Zohydro ER is an opioid agonist 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.
CRITERIA	<p>ConnectiCare considers Zohydro ER to be medically necessary, when prescribed by a Hematologist or Oncologist, in adult patients who meet the following criteria:</p> <ul style="list-style-type: none"> • Patient has a diagnosis of chronic pain and requires around-the-clock pain management <p>AND</p> <ul style="list-style-type: none"> • Patient has a trial of, or intolerance or contraindication to, at least one (1) long-acting opioid product, one of which must be extended release <p>For all other providers, in addition to the above criteria, Zohydro ER will be approved when the following criteria are met:</p> <ul style="list-style-type: none"> • Patient has a trial, intolerance, or contraindication to at least two (2) long-acting opioid products, one of which must be extended release • There is an opioid treatment agreement signed by the prescriber and member prior to the initiation of chronic opioid therapy, including: <ul style="list-style-type: none"> ○ Diagnosis or conditions that are contributing to the pain ○ Pain intensity (scales or ratings) ○ Current analgesic (opioid and adjuvant) regimen ○ Plans for monitoring misuse including regular urine screening ○ No documentation of abuse of current opioids
LIMITATIONS	<p>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 opioid formulations, reserve Zohydro ER 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.</p> <p>If criteria is met, initial authorization will be for 3 months. Additional authorization (for up to 6 months) shall be reviewed to confirm that current medical necessity criteria are met, that the</p>

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	<p>medication is effective for chronic severe pain, and the patient is compliant with the treatment plan. The member must demonstrate measurable progress towards treatment goals after the initiation of the chronic opioid therapy. The prescriber must have accurate medication records for member.</p> <p>Zohydro ER is not indicated as as-needed (prn) analgesics.</p>
REFERENCES	<ol style="list-style-type: none">1. Zohydro ER extended release tablets [package insert]. Zogenix Inc, Gainesville, GA
P&T REVIEW HISTORY	2/14, 10/14, 11/15, 11/16, 5/17, 5/18
REVISION RECORD	1/15, 9/15, 6/16, 5/18