BlueCross BlueShield of Kansas City

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Long-Acting Opioid Step Therapy

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Last Review: 09/2014
Next Review: 10/2015

Policy

BCBSKC will provide coverage for long-acting opioids when it is determined that the below outlined step therapy has been met. Affected drugs are listed below.

DRUGS AFFECTED:

- Avinza® (morphine sulfate extended-release capsules – Ligand, generics)
- Embeda® (morphine sulfate and naltrexone hydrochloride extended-release capsules – King Pharmaceuticals)
- Exalgo® (hydromorphone HCl extended-release tablets – Alza/Covidien, generics)
- Kadian® (morphine sulfate extended-release capsules – Alpharma, generics)
- MS Contin® (morphine sulfate controlled-release tablets – Purdue Frederick; generics)
- Nucynta® ER (tapentadol extended-release tablets – Janssen)
- Opana® ER (oxymorphone extended-release tablets – Endo, generics [to the old formulation])
- Oramorph SR™ (morphine sulfate sustained-release tablets – Roxane) [discontinued]
- OxyContin® (oxycodone controlled-release tablets – Purdue Frederick)
- Zohydro™ ER (hydrocodone extended-release – Zogenix)

When Policy Topic is covered:

The use of long-acting opioids may be considered **medically necessary** when the following criteria are met.

Step 1: hydromorphone HCl extended-release tablets, morphine sulfate controlled-release tablets, morphine sulfate extended-release capsules (generics to Kadian and Avinza), oxymorphone extended-release tablets

Step 2: Avinza, Embeda, Exalgo, Kadian, MS Contin, Nucynta ER, Opana ER, Oramorph SR, OxyContin, Zohydro ER

CRITERIA

1. If a patient has tried a Step 1 product, then authorization for a Step 2 product may be given.

2. Authorization may be given for OxyContin, Nucynta ER, or Zohydro ER if the patient is unable to tolerate or has a drug allergy noted with morphine sulfate.

3. Authorization may be given for OxyContin, Nucynta ER, or Zohydro ER if the patient has renal insufficiency. Due to metabolite accumulation, which contributes significantly to the adverse effects, morphine may not be the ideal agent or may require more intensive monitoring in renally impaired patients. Oxymorphone and hydromorphone also may accumulate in renally-impaired patients.

4. Authorization may be given for OxyContin if the patient is pregnant. All of the long-acting morphine products are pregnancy category C, while OxyContin is pregnancy category B.

5. No other exceptions are recommended.

When Policy Topic is not covered:

The use of long-acting opioids is considered **investigational** for all other indications.

Considerations

Long-acting opioids require prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Hayes Medical Technology Directory, Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Opioid analgesics have a central role in the management of moderate to severe pain.[1-2] These medications produce most of their effects by binding to μ, κ, and δ receptors in the central nervous system (CNS). However, Nucynta ER has a unique dual mechanism of action. It demonstrates μ-opioid agonist activity and inhibition of norephinephrine reuptake.[3] Sustained-release opioid dosage forms offer a long duration of effect, reduce severity of end-of-dose pain, and allow many patients to sleep through the night.[1-2] long-acting products should be prescribed with an immediate-release dosage form, to be used as needed for breakthrough pain.

Morphine sulfate, oxycodone, oxymorphone, hydromorphone, tapentadol, and hydrocodone are the currently available oral long-acting opioids. All of the long-acting oral opioids are 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. Nucynta ER is the only product also indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults. Morphine sulfate is available in long-acting forms as sustained-release capsules (Avinza [generics] or Kadian [generics]) and controlled-release tablets (MS Contin, generics). Previously sustained-release tablets (Oramorph SR) were also available; however this product has been discontinued. MS Contin, Kadian, and Avinza are available generically. Morphine sulfate is also available as an extended-release capsule with a sequestered core of naltrexone hydrochloride, an opioid receptor antagonist (Embeda). When taken as directed, the sequestered naltrexone in Embeda is not consistently absorbed into systemic circulation. However, tampering with Embeda by crushing or chewing the pellets results in the rapid release and absorption of both morphine and naltrexone similar to an oral solution; thus, the naltrexone reduces the effects of the morphine. Embeda is bioequivalent to Kadian. Oxycodone is available in a long-acting form as a controlled-release tablet (OxyContin). All strengths of OxyContin were available generically; however, due to patent settlements, generics to OxyContin were eliminated from the market the end of 2007. A "tamper resistant" formulation of OxyContin was approved in 2010.[4] This formulation is bioequivalent to the previous formulation of OxyContin and is intended to prevent the tablet from being cut, broken, chewed, crushed, or dissolved. It contain**s** polyethylene oxide[5] and, in the presence of water, the new formulation will form a viscous liquid which will make it more difficult to draw the medication up in a syringe.[4-6] Patients who accidentally crush or chew the tablets will be provided enhanced protection against dose-dumping with the new formulation over the previously available OxyContin tablets.[5] A new "crush resistant" formulation of Opana ER was approved in 2011, and the original formulation of brand Opana ER was discontinued by the manufacturer.[13] The new formulation of Opana ER is bioequivalent to the previous formulation. Generic oxymorphone extended-release tablets are available in all strengths to the old formulation of Opana ER. Hydromorphone is available as an extended-release tablet (Exalgo) which is

only indicated for opioid tolerant patients.[14] Tapentadol is available as an extended-release tablet (Nucynta ER).[3]

Rationale

Various treatment guidelines on the management of pain are currently available, most of which have incorporated tapentadol. Treatment guidelines for cancer pain and other pain conditions do not differentiate between the long-acting (modified-release) opioid products and generally note that pain relief and tolerability is similar at equipotent doses. A specific long-acting (modified-release product) is not preferred in the guidelines.[1-2,26-30] Twelve- and 24-hour morphine preparations appear to have similar effectiveness and acceptability in comparative trials.[1] However, even with controlled-release preparations, some patients report decreased effectiveness during the last few hours of the recommended dosing interval.[1-2,26] Some patients appear to tolerate analgesic doses of one opioid better than another, and it is often useful to try a different opioid if the first is poorly tolerated. In 2007, a joint clinical practice guideline regarding the diagnosis and treatment of low back pain was published from the American College of Physicians and the American Pain Society.[28] The guideline cites that opioid analgesics or tramadol are an option for patients with acute or chronic low back pain that is severe, disabling and not controlled with acetaminophen or NSAIDs. Evidence is not sufficient to recommend one opioid over another. Guidelines for the American Pain Society from 2009 on the use of chronic opioid therapy in chronic noncancer pain note that there is insufficient evidence to conclude that any long-acting opioid (sustained-release formulation or transdermal fentanyl) is more beneficial or less harmful than others.[29]

The American Academy of Neurology (AAN) evidence-based guidelines for the treatment of painful diabetic neuropathy, published in 2011, state that agents which may be considered for the treatment of diabetic neuropathic pain include: pregabalin, gabapentin, sodium valproate, amitriptyline, venlafaxine, duloxetine, dextromethorphan, morphine, tramadol, oxycodone, capsaicin 0.075%, and Lidoderm® (lidocaine 5% patch).[31] Pregabalin is Level A evidence, Lidoderm is Level C evidence, and all the other agents are Level B evidence.

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Other References Utilized

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Billing Coding/Physician Documentation Information

N/A Long-acting opioids are considered a pharmacy benefit.

Additional Policy Key Words

Policy Number**:** 5.02.19

Related Topics

N/A

Policy Implementation/Update Information

09/2013 New Policy titled Long-acting opioids