Program Number: 2016 P 3053-3
Program: Step Therapy – Long Acting Opioids

Medication: Includes both brand and generic versions of the listed products unless otherwise noted: Avinza^ (morphine extended-release capsules), Embeda^ (morphine sulfate and naltrexone), Exalgo^ (hydromorphone extended-release), Hysingla ER^ (hydrocodone extended-release), Kadian^ (morphine sulfate sustained-release capsules), MS Contin brand only, OxyContin (oxycodone controlled-release^), oxymorphone hcl extended release^ (generic only), Zohydro ER (hydrocodone extended-release)

Generic MS Contin (morphine sulfate controlled release tablets is not included in this program.

P&T Approval Date: 2/2015, 10/2015
Effective Date: 1/1/2016

1. **Background:**
   Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. Long-acting opioid analgesics including Avinza, Embeda, Exalgo, hydromorphone ER, Hysingla ER, Kadian, MS Contin, Nucynta ER, Opana ER, oxycodone ER, OxyContin, oxymorphone ER and Zohydro ER are indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid is needed for an extended period of time and for which alternative treatment options are not appropriate. They are not intended for use as an as needed analgesic.

   Long-acting opioids are not indicated for pain in the immediate postoperative period (the first 12-24 hours following surgery), or if the pain is mild, or not expected to persist for an extended period of time. They are only indicated for postoperative use if the patient is already receiving the drug prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time. Physicians should individualize treatment, moving from parenteral to oral analgesics as appropriate.

   Long-acting opioids should not be used in treatment naïve patients. Physicians should individualize treatment in every case, initiating therapy at the appropriate point along a progression from non-opioid analgesics, such as non-steroidal anti-inflammatory drugs and acetaminophen to opioids in a plan of pain management such as those outlined by the World Health Organization, the Agency for Healthcare Research and Quality, the Federation of State Medical Boards Model Guidelines, or the American Pain Society.
This program requires a member to try three of the preferred agents (Nucynta ER, Opana ER, morphine sulfate controlled-release tablets (generic MS Contin), or fentanyl transdermal) before coverage for other long-acting opioids (Avinza, Embeda, Exalgo, hydromorphone ER, Hysingla ER, Kadian, MS Contin, OxyContin, oxymorphone ER and Zohydro ER) is approved. Members already established with a non-preferred long-acting opioid who are being treated for cancer pain will be grandfathered.

Currently there are two long-acting opioid products that are approved for use in children. Fentanyl transdermal is approved for children >2 years of age and OxyContin is approved for use in opioid-tolerant pediatric patients 11 years of age and older. OxyContin will not be subject to the step requirement for patients less than 18 years of age.

2. Coverage Criteria<sup>a,b</sup>:
(Refer to Section 3 for state of Maryland and Section 4 for state of Maine)

<table>
<thead>
<tr>
<th>A. Avinza&lt;sup&gt;a&lt;/sup&gt;, Embeda&lt;sup&gt;a&lt;/sup&gt;, Exalgo&lt;sup&gt;a&lt;/sup&gt;, Hysingla ER&lt;sup&gt;a&lt;/sup&gt;, Kadian&lt;sup&gt;a&lt;/sup&gt;, MS Contin (brand only), generic oxymorphone extended-release&lt;sup&gt;a&lt;/sup&gt; and Zohydro ER [Applies to all brand and generic versions of listed products except generic morphine sulfate controlled release tablets (generic MS Contin) and brand name Opana ER] will be approved based on the following criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. <strong>One</strong> of the following:</td>
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<tr>
<td>(1) The patient has a history of failure, contraindication or intolerance to a trial of at least <strong>three</strong> of the following:</td>
</tr>
<tr>
<td>(a) Nucynta ER</td>
</tr>
<tr>
<td>(b) Opana ER</td>
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<tr>
<td>(c) morphine sulfate controlled release tablets (specifically generic MS Contin)</td>
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<tr>
<td>(d) Fentanyl transdermal (generic only)</td>
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<tr>
<td><strong>-OR-</strong></td>
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<tr>
<td>(2) Patient is established on pain therapy with the requested medication for cancer-related pain, and the medication is not a new regimen for treatment of cancer-related pain.</td>
</tr>
<tr>
<td>B. OxyContin [Applies to all brand and generic versions of listed products] will be approved based on <strong>one</strong> of the following criteria:</td>
</tr>
<tr>
<td>a. The patient is less than 18 years of age</td>
</tr>
<tr>
<td><strong>-OR-</strong></td>
</tr>
</tbody>
</table>
b. **One** of the following:

(1) The patient has a history of failure, contraindication or intolerance to a trial of at least **three** of the following:

(a) Nucynta ER  
(b) Opana ER  
(c) morphine sulfate controlled release tablets (specifically generic MS Contin)  
(d) Fentanyl transdermal (generic only)

-OR-

(2) Patient is established on pain therapy with the requested medication for cancer-related pain, and the medication is not a new regimen for treatment of cancer-related pain.

**Authorization will be issued for 12 months.**

a. For Indiana (effective 7/1/16) and West Virginia (effective 1/1/17), step therapy requirements may be approved if the patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as a preceding prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event. For West Virginia (effective 1/1/17) members only, coverage may also be provided for continuation of therapy if the member is currently stabilized on the requested medication for the same medical condition.

b. Criteria is not applicable to groups situated in Arkansas when medication is being used for pain control in someone who is terminally ill (defined as no expectation of recovery and death as a result of the illness or disease is reasonably expected within six (6) months.)

3. **Coverage Criteria for State of Maryland**:

A. **Avinza**, Exalgo, Kadian, MS Contin (brand only), and **generic oxymorphone extended-release** [Applies to all brand and generic versions of listed products except generic morphine sulfate controlled release tablets (generic MS Contin) and brand name Opana ER] will be approved based on the following criteria:

a. **One** of the following:

(1) The patient has a history of failure, contraindication or intolerance to a
trial of at least **three** of the following:

(a) Nucynta ER  
(b) Opana ER  
(c) morphine sulfate controlled release tablets (specifically generic MS Contin)  
(d) Fentanyl transdermal (generic only)  
(e) Embeda  
(f) Hysingla ER  
(g) Zohydro ER

-OR-

(2) Patient is established on pain therapy with the requested medication for cancer-related pain, and the medication is not a new regimen for treatment of cancer-related pain.

B. **OxyContin** *[Applies to all brand and generic versions of listed products]*

will be approved based on **one** of the following criteria:

a. The patient is less than 18 years of age

-OR-

b. **One** of the following:

(1) The patient has a history of failure, contraindication or intolerance to a trial of at least **three** of the following:

(a) Nucynta ER  
(b) Opana ER  
(c) morphine sulfate controlled release tablets (specifically generic MS Contin)  
(d) Fentanyl transdermal (generic only)  
(e) Embeda  
(f) Hysingla ER  
(g) Zohydro ER

-OR-

(2) Patient is established on pain therapy with the requested medication for cancer-related pain, and the medication is not a new regimen for treatment of cancer-related pain.

**Authorization will be issued for 12 months.**
a. For Maryland, requests for continuation of therapy may also be approved if the provider confirms the patient has been on the medication in the past 180 days and that the medication is effective in treating the patient’s condition. Please see Maryland Continuation of Care guideline.

4. Coverage Criteria for State of Maine:

A. **Avinza**, **Exalgo**, **Hysingla ER**, **Kadian**, **MS Contin** (brand only), **generic oxymorphone extended-release** and **Zohydro ER** [Applies to all brand and generic versions of listed products except generic morphine sulfate controlled release tablets (generic MS Contin) and brand name Opana ER] will be approved based on the following criteria:

   a. **One** of the following:

      (1) The patient has a history of failure, contraindication or intolerance to a trial of at least **three** of the following:

      (a) Nucynta ER  
      (b) Opana ER  
      (c) morphine sulfate controlled release tablets (specifically generic MS Contin)  
      (d) Fentanyl transdermal (generic only)  
      (e) Embeda  

      -OR-  

      (2) Patient is established on pain therapy with the requested medication for cancer-related pain, and the medication is not a new regimen for treatment of cancer-related pain.

B. **OxyContin** [Applies to all brand and generic versions of listed products] will be approved based on **one** of the following criteria:

   a. The patient is less than 18 years of age  

   -OR-  

   b. **One** of the following:

      (1) The patient has a history of failure, contraindication or intolerance to a trial of at least **three** of the following:
(a) Nucynta ER
(b) Opana ER
(c) morphine sulfate controlled release tablets (specifically generic MS Contin)
(d) Fentanyl transdermal (generic only)
(e) Embeda

-OR-

(2) Patient is established on pain therapy with the requested medication for cancer-related pain, and the medication is not a new regimen for treatment of cancer-related pain.

Authorization will be issued for 12 months.

3. Additional Clinical Programs:
Prior Authorization/Medical Necessity criteria and supply limits may also be in place.

^ Avinza (brand only), Embeda, Exalgo (brand and generic), Hysingla ER, Kadian (brand and generic), oxycodone extended-release (authorized generic for OxyContin), oxymorphone extended-release (generic Opana ER) are typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

4. References:
2. Embeda Prescribing Information. Pfizer Inc. April 2014

<table>
<thead>
<tr>
<th>Program</th>
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<tbody>
<tr>
<td><strong>Change Control</strong></td>
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<tr>
<td>2/2015</td>
<td>New program.</td>
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<tr>
<td>10/2015</td>
<td>Provided clarification regarding which brand and generic versions of listed products are included in the criteria (e.g. which generic morphine sulfate product is preferred and which are non-preferred). Added age limit to criteria. Added Maryland specific criteria and Continuation of Care. Added Maine specific criteria.</td>
</tr>
<tr>
<td>7/2016</td>
<td>Added Indiana and West Virginia coverage information.</td>
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