Clinical Pharmacy Program Guidelines for Long-Acting Opioids –ARIZONA

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Medical Necessity - Long-Acting Opioids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>Includes both brand and generic versions of the listed products unless otherwise noted:</td>
</tr>
<tr>
<td></td>
<td>Morphine sulfate controlled-release tablets, fentanyl transdermal*, Embeda (morphine sulfate and naltrexone), Hysingla ER (hydrocodone extended-release), Butrans (buprenorphine), OxyContin (oxycodone controlled-release)</td>
</tr>
<tr>
<td></td>
<td>Avinza (morphine sulfate extended-release capsules), Exalgo (hydromorphone extended-release), Kadian (morphine sulfate sustained-release capsules), MS Contin [brand name], Nucynta ER (tapentadol extended-release), Opana ER-crush resistant (oxymorphone extended-release), Xtramplaza ER (oxycodone extended-release), Belbuca (buprenorphine), fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, Zohydro ER (hydrocodone extended-release), oxymorphone ER (generic non-crush resistant), methadone, Arymo (morphine sulfate extended-release tablet) ER</td>
</tr>
</tbody>
</table>

*Note: Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr are non-preferred

(i) **Background:**

Long-acting opioid analgesics 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.

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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.

The CDC and the American Academy of Neurology recommends the following best practices in the prescription of long-acting opioids:

- Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain.
- Before starting opioid therapy, treatment goals should be established with patients that include realistic goals for pain and function and should consider how therapy will be discontinued if benefits do not outweigh risks. Track pain and function at every visit (at least every 3 months) using a brief, validated instrument. Continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended release/long-acting opioids.
- Document the daily morphine equivalent dose (MED) in mg/day from all sources of opioids. Access the state prescription drug monitoring program (PDMP) data at treatment initiation and periodically during treatment. Currently all states except for Missouri have a PDMP.
- To avoid increased risk of respiratory depression, long-acting opioids should not be prescribed concurrently with benzodiazepines. Screen for past and current substance abuse and for severe depression, anxiety, and PTSD prior to initiation.
- Use random urine drug screening prior to initiation and periodically during treatment with a frequency according to risk.
- Use a patient treatment agreement, signed by both the patient and prescriber that addresses risks of use and responsibilities of the patient.
- Methadone should not be the first choice for a long-acting opioid. Only clinicians who are familiar with methadone’s unique risk profile and who are prepared to educate and closely monitor their patients should consider prescribing methadone for pain.
- CDC recommends avoiding escalating doses above 50-90 mg/day MED unless sustained meaningful improvement in pain and function is attained, and not without consultation with a pain management specialist. A list of MED for the long-acting opioids is available in Table 1.
- The American Academy of Neurology recommends avoiding escalating doses above 80-120 mg/day MED unless sustained meaningful improvement in pain and function is attained, and not without consultation with a pain management specialist. A list of MED for the long-acting opioids is available in Table 1.
- Clinicians should evaluate benefits and harms of continued therapy at least every 3 months. If benefits do not outweigh harms, opioids should be tapered and discontinued. Evaluation should include assessment of substance use disorder/opioid

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Table 1. CDC Recommended Long-Acting Opioid Maximum Morphine Equivalents per Day*

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>FDA Label Max Daily Doses</th>
<th>Max MED (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(non treatment naïve)</td>
</tr>
<tr>
<td>Morphine</td>
<td>None</td>
<td>90mg</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>1800mcg</td>
<td>3000mcg</td>
</tr>
<tr>
<td>Buprenorphine transdermal patch</td>
<td>20mcg/hr</td>
<td>50mcg/hr</td>
</tr>
<tr>
<td>Morphine and naltrexone</td>
<td>None</td>
<td>90mg</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>None</td>
<td>22.5mg</td>
</tr>
<tr>
<td>Fentanyl transdermal, mcg/hr</td>
<td>None</td>
<td>37.5 mcg/hr</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>None</td>
<td>90mg</td>
</tr>
<tr>
<td>Methadone</td>
<td>None</td>
<td>30mg</td>
</tr>
<tr>
<td>Tapentadol</td>
<td>None</td>
<td>225mg</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>None</td>
<td>30mg</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>Xtampza Only =288mg</td>
<td>60mg</td>
</tr>
</tbody>
</table>

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.

REF:
Max MED is the maximum dose per day based on morphine equivalent dose allowed without consultation or prescription by a pain specialist. Max MED is based upon the CDC guidelines and adjusted for currently available product strengths. Fentanyl is dosed in mcg/hr rather than mg/day.


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 when a continuous, around-the-clock opioid analgesic is required for an extended period of time, and the patient cannot be managed by other means such as non-steroidal analgesics, opioid combination products, or immediate-release opioids. OxyContin is approved 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 in opioid-tolerant patients.
pediatric patients 11 years of age and older who are already receiving and tolerate a minimum daily opioid dose of at least 20 mg oxycodone orally or its equivalent. The American Pain Society suggests that opioids are rarely indicated in the long-term treatment of chronic nonmalignant pain in children, although they may be beneficial in certain painful conditions with clearly defined etiologies (e.g., sickle cell disease, incurable degenerative joint and neurodegenerative diseases, etc.). Consultation or referral to a pediatric chronic pain specialist should be strongly considered in these cases. Studies evaluating the use of long-acting opioids in children are lacking.

**FDA Approved Age Ranges for Long-Acting Opioids:**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Approved Age Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avinza (morphine sulfate ER capsules)</td>
<td>≥18 years</td>
</tr>
<tr>
<td>Belbuc (buprenorphine films)</td>
<td>≥18 years</td>
</tr>
<tr>
<td>Butrans (buprenorphine patches)</td>
<td>≥18 years</td>
</tr>
<tr>
<td>Embeda (morphine sulfate and naltrexone)</td>
<td>≥18 years</td>
</tr>
<tr>
<td>Exalgo (hydromorphone ER)</td>
<td>≥18 years</td>
</tr>
<tr>
<td>Fentanyl transdermal</td>
<td>≥2 years</td>
</tr>
<tr>
<td>Hysingla ER (hydrocodone ER)</td>
<td>≥18 years</td>
</tr>
<tr>
<td>Kadian (morphine sulfate ER capsules)</td>
<td>≥18 years</td>
</tr>
<tr>
<td>MS Contin (morphine sulfate ER tablets)</td>
<td>≥18 years</td>
</tr>
<tr>
<td>Nucynta ER (tapentadol ER)</td>
<td>≥18 years</td>
</tr>
<tr>
<td>Opana ER (oxymorphone ER)</td>
<td>≥18 years</td>
</tr>
<tr>
<td>OxyContin (oxycodone ER)</td>
<td>≥11 years</td>
</tr>
<tr>
<td>Xtampza ER (oxycodone ER)</td>
<td>≥18 years</td>
</tr>
<tr>
<td>Zohydro ER (hydrocodone ER)</td>
<td>≥18 years</td>
</tr>
</tbody>
</table>

(ii) **Coverage Criteria:**

A. **Long-Acting Opioids: Cancer related pain/Hospice care/end-of-life care (other than hospice)**

1. **Morphine sulfate controlled-release tablets, fentanyl transdermal*, Embeda (morphine sulfate and naltrexone), Hysingla ER (hydrocodone extended-release), Butrans (buprenorphine), or OxyContin (oxycodone controlled-release)** will be approved for cancer, hospice care, or end-of-life care (other than hospice) pain based on both of the following criteria:

   a. **One** of the following:

      (i) Patient is being treated for cancer (document diagnosis and date of diagnosis)
(ii) Patient is established on pain therapy with the requested medication for cancer, hospice care, or end-of-life care (other than hospice)-related pain, and the medication is not a new regimen for treatment of cancer, hospice care, or end-of-life care (other than hospice)-related pain. (Document date regimen was started)

(OR)

(iii) Patient is receiving hospice or end-of-life care (other than hospice)

(AND)

b. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.

*Note: Fentanyl transdermal 37.5 mcg/hr, 62.5 mcg/hr, and 87.5 mcg/hr are non-preferred

2. Avinza (morphine sulfate extended-release capsules), Exalgo (hydromorphone extended-release), Kadian (morphine sulfate sustained-release capsules), MS Contin [brand name], Nucynta ER (tapentadol extended-release), Opana ER-crush resistant (oxymorphone extended-release), Xtampza ER (oxycodone extended-release), Belbuca (buprenorphine), fentanyl transdermal 37.5 mcg/hr, 62.5 mcg/hr, and 87.5 mcg/hr, Zohydro ER (hydrocodone extended-release), oxymorphone ER (generic non-crush resistant), methadone, or Arymo (morphine sulfate extended-release tablet) ER will be approved based on all of the following criteria:

a. One of the following:
   i. Patient is being treated for cancer related pain (document cancer diagnosis and date of diagnosis)
ii. Patient is receiving hospice care or end-of-life care (other than hospice)

-AND-

(2) One of the following:

(a) The patient is any age AND has a history of failure, contraindication or intolerance to a trial of at least three of the following (Document drugs, dose, duration and date of trials):
   (i) morphine sulfate controlled release tablets (specifically generic MS Contin)
   (ii) preferred fentanyl transdermal
   (iii) Embeda (morphine sulfate and naltrexone)
   (iv) Hysingla ER (hydrocodone extended-release)
   (v) Butrans (buprenorphine)
   (vi) OxyContin (oxycodone controlled-release)

-OR-

(b) Patient is established on pain therapy with the requested medication for cancer, hospice care, or end-of-life care (other than hospice)-related pain, and the medication is not a new regimen for treatment of cancer, hospice care, or end-of-life care (other than hospice)-related pain. (Document date regimen was started)

-AND-

(3) Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
Authorization will be issued for 12 months.

B. Long-Acting Opioids: Non-cancer pain/Non-hospice care or end-of-life care (other than hospice)- related pain

1. Initial Authorization

   a. Morphine sulfate controlled-release tablets, fentanyl transdermal*, Embeda (morphine sulfate and naltrexone), Hysingla ER (hydrocodone extended-release), Butrans (buprenorphine), or OxyContin (oxycodone controlled-release) will be approved based on one of the following criteria:

      (1) All of the following:

        (a) The patient is being treated for moderate to severe chronic pain that is non-neuropathic (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia)

       -AND-

        (b) None of the following:

           i. For use as an as-needed PRN analgesic
           ii. For pain that is mild or not expected to persist for an extended period of time
           iii. For acute pain
           iv. For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time.
           v. Dose does not exceed maximum MED (see Section 3: Criteria for Quantity Limit and/or Morphine Equivalent Dose(MED) Reviews)

       -AND-
(c) Treatment goals are defined, including estimated duration of treatment. (Document treatment goals and estimated duration of treatment).

-AND-

(d) Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention. (Document other treatment interventions).

-AND-

(e) Patient has been screened for substance abuse/opioid dependence.

-AND-

(f) If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression.

-AND-

(g) Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days. (Document drug(s), dose, duration and date of trial). Unless the patient is already receiving chronic opioid therapy prior to surgery for postoperative pain, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time.

-AND-

(h) Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they
understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.

-OR-

(2) **All** of the following:

(a) The patient is being treated for moderate to severe **neuropathic pain or fibromyalgia**

-AND-

(b) Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose. (Document duration and date of trial)

-AND-

(c) Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to a therapeutic dose. (Document drug, date, and duration of trial).

-AND-

(d) Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days. (Document drug(s), dose, duration and date of trial).

-AND-

(e) **None** of the following:
   i. For use as an as-needed PRN analgesic
   ii. For pain that is mild or not expected to persist for an
extended period of time

iii. For acute pain

iv. For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time.

v. Dose does not exceed maximum MED (see Section 3: Criteria for Quantity Limit and/or Morphine Equivalent Dose(MED) Reviews)

-AND-

(f) Treatment goals are defined, including estimated duration of treatment. (Document treatment goals and estimated duration of treatment).

-AND-

(g) Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention. (Document other treatment interventions).

-AND-

(h) Patient has been screened for substance abuse/opioid dependence.

-AND-

(i) If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression.

-AND-
(j) Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.

*Note: Fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr are non-preferred.

b. Avinza (morphine sulfate extended-release capsules), Exalgo (hydromorphone extended-release), Kadian (morphine sulfate sustained-release capsules), MS Contin [brand name], Nucynta ER (tapentadol extended-release), Opana ER-crush resistant (oxymorphone extended-release), Xtampza ER (oxycodone extended-release), Belbuca (buprenorphine), fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, Zohydro ER (hydrocodone extended-release), oxymorphone ER (generic non-crush resistant), methadone, or Arymo (morphine sulfate extended-release tablet) ER will be approved based on one of the following criteria:

1. All of the following:

   a. The patient is being treated for moderate to severe chronic pain that is non-neuropathic (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia)

   -AND-

2. None of the following:

   i. For use as an as-needed PRN analgesic

   ii. For pain that is mild or not expected to persist for an extended period of time

   iii. For acute pain

   iv. For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time

   v. Dose does not exceed maximum MED (see Section 3:...
Criteria for Quantity Limit and/or Morphine Equivalent Dose (MED) Reviews

-AND-

(c) Treatment goals are defined, including estimated duration of treatment. (Document treatment goals and estimated duration of treatment).

-AND-

(d) Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention. (Document other treatment interventions).

-AND-

(e) Patient has been screened for substance abuse/opioid dependence.

-AND-

(f) If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression.

-AND-

(g) Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days. (Document drug(s), dose, duration and date of trial). Unless the patient is already receiving chronic opioid therapy prior to surgery for postoperative pain or if the postoperative pain is expected to be moderate to severe and persist for an extended period of
time.

-AND-

(h) The patient is any age **AND** has a history of failure, contraindication or intolerance to a trial of at least **three** of the following (Document drugs, dose, duration and date of trials):
   (1) morphine sulfate controlled release tablets (specifically generic MS Contin)
   (2) preferred fentanyl transdermal
   (3) Embeda (morphine sulfate and naltrexone)
   (4) Hysingla ER (hydrocodone extended-release)
   (5) Butrans (buprenorphine)
   (6) OxyContin (oxycodone controlled-release)

-AND-

(i) Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.

-OR-

(2) **All** of the following:

(a) The patient is being treated for moderate to severe **neuropathic pain or fibromyalgia**

-AND-

(b) Unless it is contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose. (Document duration and date of trial)
(c) Unless it is contraindicated, the patient has not exhibited an adequate response to at least 6 weeks of treatment with a tricyclic antidepressant titrated to the maximum tolerated dose. (Document drug, date, duration of trial).

AND

(d) Prior to the start of therapy with the long-acting opioid, the patient has failed an adequate (minimum of 2 week) trial of a short-acting opioid within the last 30 days. (Document drug(s), dose, duration and date of trial)

AND

(e) The patient is any age AND has a history of failure, contraindication or intolerance to a trial of at least three of the following (Document drugs, dose, duration and date of trials):

1. morphine sulfate controlled release tablets (specifically generic MS Contin)
2. preferred fentanyl transdermal
3. Embeda (morphine sulfate and naltrexone)
4. Hysingla ER (hydrocodone extended-release)
5. Butrans (buprenorphine)
6. OxyContin (oxycodone controlled-release)

AND

(f) None of the following:
   i. For use as an as-needed PRN analgesic
   ii. For pain that is mild or not expected to persist for an extended period of time
   iii. For acute pain
   iv. For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if the postoperative pain is expected to be moderate to severe
and persist for an extended period of time.
  v. Dose does not exceed maximum MED (see Section 3: Criteria for Quantity Limit and/or Morphine Equivalent Dose(MED) Reviews)

-AND-

(g) Treatment goals are defined, including estimated duration of treatment. (Document treatment goals and estimated duration of treatment).

-AND-

(h) Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention. (Document other treatment interventions).

-AND-

(i) Patient has been screened for substance abuse/opioid dependence.

-AND-

(j) If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression.

-AND-

(k) Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided.
Authorization will be issued for 6 months for non-cancer and non-hospice care or end-of-life care (other than hospice)-related pain. If the member has been established on the requested long-acting opioid for at least 30 days and does not meet the medical necessity initial authorization criteria requirements for long-acting opioids, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity.

2. Reauthorization

a. Fentanyl transdermal, methadone, morphine sulfate controlled release tablets (specifically generic MS Contin), Oxymorphone ER-non crush resistant (generic), Zohydro ER, Avinza (morphine sulfate 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 name], Nucynta ER (tapentadol extended-release), Opana ER-crush resistant (oxymorphone extended-release), OxyContin (oxycodone controlled-release), Xtampza ER (oxycodone extended-release), Belbuca (buprenorphine), Butrans (buprenorphine) or Arymo (morphine sulfate extended-release tablet) ER will be reauthorized based on all of the following:

   (1) Treatment goals are defined, including estimated duration of treatment. (Document treatment goals and estimated duration of treatment).
   (2) Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention. (Document other treatment interventions).
   (3) Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory) (Document score and instrument used).
   (4) Patient has been screened for substance abuse/opioid dependence.
   (5) Identify rationale for not tapering and discontinuing opioid. (Document rationale).
   (6) If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could
potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression.

(7) Dose does not exceed maximum MED (see Section 3: Criteria for Quantity Limit and/or Morphine Equivalent Dose (MED) Reviews)

Authorization will be issued for 6 months for non-cancer and non-hospice care or end-of-life care (other than hospice)- related pain

If the member has been established on the requested long-acting opioid for at least 30 days and does not meet the medical necessity reauthorization criteria requirements for long-acting opioids, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity.

(iii) Long-Acting Opioids: Criteria for Quantity Limit Reviews

Cancer Related Pain/Hospice Care/End-of-Life Care (other than hospice)

1. Doses exceeding the quantity limit will be approved up to the requested amount for ALL long-acting opioid products if the member has cancer pain or is receiving hospice care or end-of-life care (other than hospice)

-AND-

2. The requested dose cannot be achieved by moving to a higher strength of the product.

-AND-

3. The requested dose is within FDA maximum dose per day, where an FDA maximum dose per day exists (see table)

Authorization will be issued for 12 months for cancer pain/hospice care or end-of-life care-related pain

Non-cancer pain/Non-hospice care or end-of-life care (other than hospice)- related pain

BOTH of the following:

1. Doses exceeding the quantity limit will be approved for ALL long-acting opioid
products if they meet ONE of the following criteria:

i. If the requested dose does not exceed the maximum MED (see table), the requested dose cannot be achieved by moving to a higher strength of the product.

-OR-

ii. If the dose exceeds the maximum MED (see table), must meet BOTH of the following:
   1. If the dose exceeds the maximum MED (see table), the medication is being prescribed by or in consultation with a pain specialist (defined as a prescriber with board certification in pain management; or one of the following specialists: hematology, oncology, anesthesiology, neurology, or physiatry). (Document prescriber specialty and total daily dose).

-AND-

2. The requested dose cannot be achieved by moving to a higher strength of the product.

-AND-

2. The requested dose is within FDA maximum dose per day, where an FDA maximum dose per day exists (see table)

Authorization will be issued for 6 months for non-cancer pain/non-hospice care or end-of-life care (other than hospice)-related pain

If the member has been established on the requested long-acting opioid DOSE for at least 30 days and does not meet the supply limit criteria requirements for non-cancer pain/non-hospice care or end-of-life care (other than hospice)-related pain, a denial should be issued for the supply limit and a maximum 60-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity for transition to the maximum MED.

(iv) References:

2. Embeda Prescribing Information. Pfizer Inc. October 2014
9. OxyContin Prescribing Information. Purdue Pharma, August 2015.

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization - Long-Acting Opioid Pain Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Control</td>
<td>Date</td>
</tr>
<tr>
<td>---------</td>
<td>----------------</td>
</tr>
<tr>
<td>4/2017</td>
<td>Updated language throughout to clarify which diagnoses are applicable to each section. Updated quantity limit review criteria.</td>
</tr>
<tr>
<td>5/2017</td>
<td>Added Arymo to the policy. Removed the statement regarding use for an FDA approved age range for members under the age of 18 years. Defined a look-back period for the short-acting opioid trial in the long-acting opioid section. Updated authorization duration language. Updated excluded diagnoses to cancer, hospice care and end-of-life care (non hospice).</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated prescriber requirement language in the Non-cancer pain/Non-hospice care or end-of-life care (other than hospice)-related pain quantity limit section.</td>
</tr>
</tbody>
</table>