Clinical Pharmacy Program Guidelines for Opioid Products

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Medical Necessity – Opioid Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td><strong>Long-Acting Opioids:</strong></td>
</tr>
<tr>
<td></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*</td>
</tr>
<tr>
<td></td>
<td>Zohydro ER (hydrocodone extended-release), oxymorphone ER (generic non-crush resistant)</td>
</tr>
<tr>
<td></td>
<td>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), fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, methadone, Arymo (morphine sulfate extended-release tablet) ER, Morphabond ER (morphine sulfate extended-release), Troxyca ER (oxycodone and naltrexone extended-release), Vantrela ER (hydrocodone bitartrate extended-release), tramadol extended release tablets and capsules**</td>
</tr>
<tr>
<td></td>
<td><strong>Short-Acting Opioids:</strong></td>
</tr>
<tr>
<td></td>
<td>Includes both brand and generic versions of the listed products unless otherwise noted:</td>
</tr>
<tr>
<td></td>
<td>All salt forms, single and combination ingredient products, and all brand and generic formulations of the following: codeine, morphine, hydrocodone, hydromorphone, oxycodone, oxymorphone, pentazocine, tramadol, tapentadol, meperidine, levorphanol tartrate, dihydrocodeine</td>
</tr>
</tbody>
</table>

| Issue Date   | 7/2016 |
| Pharmacy and Therapeutics Approval Date | 7/2017 |
Effective Date | 9/2017
---|---

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

**Note: The long-acting opioids prior authorization criteria is not applicable to tramadol ER. Only the quantity limits and MED sections will apply to tramadol ER.

(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 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 dependence. Validated scales (such as the DAST-10) are available at www.drugabuse.gov.

### Table 1. CDC Recommended 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>Morphine</td>
<td>None</td>
<td>90mg REF</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>X tampza Only =288mg</td>
<td>60mg</td>
</tr>
<tr>
<td>Codeine</td>
<td>360mg</td>
<td>600mg</td>
</tr>
<tr>
<td>Pentazocine</td>
<td>None</td>
<td>243mg</td>
</tr>
</tbody>
</table>
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 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>Belbuca (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>&gt;2 years</td>
</tr>
</tbody>
</table>

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.*
Hysingla ER (hydrocodone ER) | ≥18 years
---|---
Kadian (morphine sulfate ER capsules) | ≥18 years
MS Contin (morphine sulfate ER tablets) | ≥18 years
Nucynta ER (tapentadol ER) | ≥18 years
Opana ER (oxymorphone ER) | ≥18 years
OxyContin (oxycodone ER) | ≥11 years
Xtampza ER (oxycodone ER) | ≥18 years
Zohydro ER (hydrocodone ER) | ≥18 years

(ii) Coverage Criteria:

A. Long-Acting Opioids: Cancer related pain/Palliative care

1. **Fentanyl transdermal*, morphine sulfate controlled release tablets**
   (specifically generic MS Contin) will be approved for cancer related pain or palliative care based on **both** 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)

      -OR-

      (ii) 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. (Document date regimen was started)

      -OR-

      (iii) Patient is receiving palliative care

   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 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr are non-preferred
2. **Oxymorphone ER-non crush resistant (generic) or Zohydro ER** will be approved for cancer related pain or palliative care pain based on **all** of the following criteria:

   a. **One** of the following:
      
      (1) Patient is being treated for cancer related pain (document cancer diagnosis and date of diagnosis)

      - **OR** -

      (2) Patient is receiving palliative care

      - **AND** -

   b. **One** of the following:
      
      (1) Patient is established on pain therapy with the requested medication for cancer-related pain or palliative care pain, and the medication is not a new regimen for treatment of cancer-related pain or palliative care pain. (Document date regimen was started)

      - **OR** -

      (2) The patient is any age **AND** has a history of failure, contraindication or intolerance to a trial of at least **one** of the following (Document drugs, dose, duration and date of trials):
         
         (a) morphine sulfate controlled release tablets (specifically generic MS Contin)
         
         (b) preferred fentanyl transdermal

      - **AND** -

   c. 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.
3. Avinza (morphine sulfate extended-release capsules), Embeda (morphine sulfate and naltrexone), Exalго (hydromorphone extended-release), Hysingla ER (hydrocodone extended-release), Kadian (morphine sulfate sustained-release capsules), MS Contin [brand name], Nucyntа ER (tapentadol extended-release), Opanа ER-crush resistant (oxymorphone extended-release), OxyContin (oxycodone controlled-release), Xtampza ER (oxycodone extended-release), Belbuca (buprenorphine), or Butrans (buprenorphine), fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, methadone, Arymo (morphine sulfate extended-release tablet) ER, Morphabond ER (morphine sulfate extended-release), Troxyca ER (oxycodone and naltrexone extended-release), Vantrelа ER (hydrocodone bitartrate extended-release) will be approved based on all of the following criteria:

a. All of the following:

(1) One of the following:
   (a) Patient is being treated for cancer related pain (document cancer diagnosis and date of diagnosis)

   -OR-

   (b) Patient is receiving palliative care

   -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) oxymorphone ER non-crush resistant (generic)
      (iv) Zohydro ER
-OR-

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

1. Initial Authorization

   a. **Fentanyl transdermal** or **morphine sulfate controlled release tablets (specifically generic MS Contin)** 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.
(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.

(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. **Oxymorphone ER-non crush resistant (generic) or Zohydro 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)

(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.
(h) The patient is any age AND has a history of failure, contraindication or intolerance to a trial of at least one 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

(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.

(2) All of the following:

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

(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).
(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).

(e) The patient is any age AND has a history of failure, contraindication or intolerance to a trial of at least one 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

(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)

(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.

c. 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), or Butrans (buprenorphine), fentanyl transdermal 37.5mcg/hr, 62.5mcg/hr, and 87.5mcg/hr, methadone, Arymo (morphine sulfate extended-release tablet) ER, Morphabond ER (morphine sulfate extended-release), Troxyca ER
(oxycodone and naltrexone extended-release), Vantrela ER
(hydrocodone bitartrate extended-release) will be approved for non-
cancer related pain 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) 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) oxymorphone ER non-crush resistant (generic)
   4) Zohydro ER

-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)

-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 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) oxymorphone ER non-crush resistant (generic)
4) Zohydro ER

-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 pain/non-palliative care 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, Morphabond ER (morphine sulfate extended-release), Troxyca ER (oxycodone and naltrexone extended-release), Vantrela ER (hydrocodone bitartrate extended-release) 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. (Document rationale).
(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 pain/non-palliative care 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 including Tramadol ER Reviews
A. **ALL** of the following:

1. 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)

-**AND**-

3. If the request is for tramadol ER capsules or tablets the patient must have a history of failure, contraindication or intolerance to a trial of at least **three** preferred alternatives.

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

(iv) **Short Acting Opioids: Criteria for Quantity Limit and Non-Preferred Reviews**

A. **ALL** of the following:

1. 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)

-**AND**-

3. If the requested drug contains acetaminophen, the requested dose does not exceed four grams of acetaminophen per day.

-**AND**-

4. If the requested drug contains ibuprofen, the requested dose does not exceed 3200mg of ibuprofen per day.

-**AND**-

5. If the requested drug contains aspirin, the requested dose does not exceed 2080mg of aspirin per day.
6. If the request is for a non-preferred medication the patient must have a history of failure, contraindication or intolerance to a trial of at least three preferred short-acting opioids.

Authorization will be issued for 12 months.

(v) Morphine Equivalent Dosing (MED) Reviews: For Requests Exceeding the 90MED Cumulative Threshold.

NOTE: This criteria applies to the following markets: Market roll-out currently TBD

A. Criteria for Morphine Equivalent Dosing (MED) Reviews:

1. Cancer/Hospice Related Pain

   i. Doses exceeding the cumulative MED of 90 mg will be approved up to the requested amount for ALL opioid products if the member has cancer pain or an end of life diagnosis (hospice care).

   Authorization will be issued for 12 months for cancer pain/hospice related pain. The authorization should be entered for an MED of 9999 so as to prevent future disruptions in therapy if the patient’s dose is increased.

2. Non-cancer/non-hospice related pain

   i. If the dose exceeds the maximum cumulative MED of 90mg, must meet ALL of the following:

      1. Provides diagnosis associated with the need for pain management with opioids.
      2. Treatment goals are defined, including estimated duration of treatment. (Document treatment goals and estimated duration of treatment).
      3. Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention. (Document other treatment interventions).
      4. Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory) (Document score and instrument used).
      5. Patient has been screened for substance abuse/opioid dependence.
      6. Identify rationale for not tapering and discontinuing opioid. (Document rationale).
7. 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.

8. The medication is being prescribed by or in consultation with a pain specialist (defined as a prescriber with a board certification in pain management; or one of the following specialists: hematology, oncology, anesthesiology, neurology, or physiatry). (Document prescriber specialty and total daily dose).

Authorization will be issued for 6 months for non-cancer pain. Approvable MED is based on the following table:

<table>
<thead>
<tr>
<th>Requested MED</th>
<th>New MED Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>90-180 MED</td>
<td>180 MED</td>
</tr>
<tr>
<td>181-270 MED</td>
<td>270 MED</td>
</tr>
<tr>
<td>271-360 MED</td>
<td>360 MED</td>
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<td>361-450 MED</td>
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<tr>
<td>451-540 MED</td>
<td>540 MED</td>
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<tr>
<td>541-630 MED</td>
<td>630 MED</td>
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<tr>
<td>631-720 MED</td>
<td>720 MED</td>
</tr>
<tr>
<td>721-810 MED</td>
<td>810 MED</td>
</tr>
<tr>
<td>811-900 MED</td>
<td>900 MED</td>
</tr>
<tr>
<td>901-990 MED</td>
<td>990 MED</td>
</tr>
</tbody>
</table>

If the member has been established on the requested MED dose for at least 30 days and does not meet the supply limit criteria requirements for non-cancer pain/non-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 MED dose.

(vi) References:

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><strong>Change Control</strong></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>7/2016</td>
<td>New program</td>
</tr>
<tr>
<td>9/2016</td>
<td>Updated MED for Belbuca, Butrans, and Duragesic.</td>
</tr>
</tbody>
</table>
| 11/2016 | • Added “none of the following” to the neuropathic pain segments (same criteria as non-neuropathic pain segments)  
• Added criteria from the re-auth criteria into the initial auth criteria for non-cancer pain  
• Created a quantity limit/MED section to review separately for dose to align with E&I.  
• Changed all the MED section in the policy to reference the new MED section.  
• 90 MED dose change  
• Clarified preferred fentanyl strengths |
<p>| 12/2016 | Clarified that preferred fentanyl products should be tried and added methadone to list of trial/failure products. Removed “tablets” following references to methadone since both the tablet and oral solution are included in this policy. |
| 2/2017 | Added authorization duration for requests exceeding quantity limit or Morphine Equivalent Dose (MED). Updated authorization duration language to allow for 60 day transition. Moved methadone from preferred to non-preferred in all |</p>
<table>
<thead>
<tr>
<th>Date</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/2017</td>
<td>Renamed policy to “Opioid Products”. Added all short-acting opioid criteria to the policy. Added opioid over-utilization 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. Removed short-acting opioids and short-acting opioid quantity limit section as this is under evaluation for 7/1 implementation.</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated short-and long-acting opioids section. Added MED section.</td>
</tr>
<tr>
<td>7/2017</td>
<td>Added Morphabond ER (morphine sulfate extended-release), Troxyca ER (oxycodone and naltrexone extended-release), and Vantrela ER (hydrocodone bitartrate extended-release) to policy. Changed MED limit from 180 to 90 MED.</td>
</tr>
</tbody>
</table>