UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Long-Acting Opioid Products

Program	Prior Authorization/Medical Necessity – Long-Acting Opioid Products
Medication	**Long-Acting Opioids:** **Includes both brand and generic versions of the listed products unless otherwise noted:** Morphine sulfate controlled-release tablets, fentanyl transdermal* hydrocodone extended-release, oxymorphone ER (generic non-crush resistant) morphine sulfate extended-release capsules, Exalgo (hydromorphone extended-release), Hysingla ER (hydrocodone extended-release), Kadian (morphine sulfate sustained-release capsules), MS Contin [brand name], Nucynta ER (tapentadol extended-release), oxymorphone extended-release, OxyContin (oxycodone controlled-release), Xtampza ER (oxycodone extended-release), 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 tablet), tramadol extended release tablets and capsules, Duragesic [brand name], Zohydro ER [brand name]
Markets in Scope	Hawaii, New York, New York EPP, New Jersey, California, Nevada, Pennsylvania- CHIP, South Carolina
Issue Date	7/2016
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

*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 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 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 milligram equivalents (MME) 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 MME unless sustained meaningful improvement in pain and function is attained, and not without consultation with a pain management specialist. A list of MME for the long-acting opioids is available in Table 1.

- The American Academy of Neurology recommends avoiding escalating doses above 80-120 mg/day MME unless sustained meaningful improvement in pain and function is attained, and not without consultation with a pain management specialist. A list of MME 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 Milligram Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses	90 MME Equivalent (mg/day) (non treatment naïve)
Morphine	None	90mg
Morphine and naltrexone	None	90mg
Hydromorphone	None	22.5mg
Fentanyl transdermal, mcg/hr	None	37.5 mcg/hr
Hydrocodone	None	90mg
Methadone	None	Conversion factor is variable based upon dose
Tapentadol	500mg ER products	225mg
Oxymorphone	None	30mg
Oxycodone	Xtampza Only =288mg	60mg
Tramadol	300mg ER products	900mg

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

Max MME is the maximum dose per day based on morphine milligram equivalents allowed without consultation or prescription by a pain specialist. Max MME 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 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.

Black boxed warnings may include but are not limited to: addiction/abuse/misuse, life threatening respiratory depression, accidental ingestion, neonatal opioid withdrawal syndrome, cytochrome P450 3A4 interaction, and risk from concomitant use with benzodiazepines or other CNS depressants. Please see full prescribing information for additional details.

Coverage Criteria:

(ii) Long-Acting Opioids: Prior Authorization Requests

A. Long- Acting Opioids: Cancer/Hospice/End of life related pain

1. Requests for long-acting opioids will be approved for cancer, hospice, or end of life related pain based on the following criteria:

   a. **<u>One</u>** of the following:

      (i) Patient is being treated for cancer related pain

      -OR-

      (ii) Patient is in hospice or is receiving end of life care.

      -AND-

   b. If the request is for **Oxymorphone ER-non crush resistant (generic) or Hydrocodone extended-release (generic)**, **both** of the following:

      (i) **<u>ONE</u>** of the following:

      (a) The patient has a history of failure, contraindication or intolerance to a trial of at least **<u>one</u>** of the following (Document drugs and date of trials):

      - morphine sulfate controlled release tablets (specifically generic MS Contin)
      - preferred fentanyl transdermal

      -OR-

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

-AND-

(ii) 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.

-AND-

c. If the request is for **morphine sulfate extended-release capsules, Exalgo (hydromorphone extended-release), Hysingla ER (hydrocodone extended-release), Kadian (morphine sulfate sustained-release capsules), MS Contin [brand name], Nucynta ER (tapentadol extended-release), oxymorphone extended-release, OxyContin (oxycodone controlled-release), Xtampza ER (oxycodone extended-release), 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), Duragesic [brand name], Zohydro ER [brand name], both** of the following:

(i) **ONE** of the following:

(a) The patient has a history of failure, contraindication or intolerance to a trial of at least **three** of the following (Document drugs and date of trials):

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal
- oxymorphone ER non-crush resistant (generic)
- hydrocodone extended-release (generic)

-OR-

(b) Patient is established on pain therapy with the requested medication

for cancer-related pain, hospice related pain, or end of life care related pain, and the medication is not a new regimen for treatment of cancer-related pain, hospice, or end of life care pain. (Document date regimen was started)

-AND-

(ii) 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.

If the member is <u>currently</u> taking the requested long-acting opioid for at least 30 days and <u>does not meet the medical necessity authorization criteria</u> requirements for treatment with an opioid, a denial should be issued 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 an alternative treatment.

If the request is for Oxymorphone ER-non crush resistant (generic) or Hydrocodone extended-release (generic) and the member is <u>currently</u> taking the requested long-acting opioid for at least 30 days and <u>has met the medical necessity authorization criteria</u> requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued 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 an alternative treatment. Additionally, a 12 month authorization should be entered for morphine sulfate controlled release tablets (specifically generic MS Contin) and preferred fentanyl transdermal.

If the request is for a non-preferred product and the member is <u>currently</u> taking the requested long-acting opioid for at least 30 days and <u>has met the medical necessity authorization criteria</u> requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued 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 an alternative treatment. Additionally, a 12 month authorization should be entered for preferred products, depending on what the patient has already tried:

- **If the patient has tried morphine sulfate controlled release tablets (specifically generic MS Contin) or preferred fentanyl transdermal, an**

authorization should be entered for Oxymorphone ER-non crush resistant (generic) and Hydrocodone extended-release (generic).

- **If the patient has not tried any of the preferred products [morphine sulfate controlled release tablets (specifically generic MS Contin), preferred fentanyl transdermal, Oxymorphone ER-non crush resistant (generic) or Hydrocodone extended-release (generic), an authorization should be entered for morphine sulfate controlled release tablets (specifically generic MS Contin) and preferred fentanyl transdermal.**

B. Long- Acting Opioids: Non-cancer pain/Non-hospice/Non-end of life care pain

1. Initial Authorization

a. Requests for long-acting opioids for non-cancer/non-hospice/non-end of life care pain will be approved based on **ALL** of the following criteria:

1. Prescriber attests to **ALL** of 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.
   - Treatment goals are defined, including estimated duration of treatment.
   - Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
   - Patient has been screened for substance abuse/opioid dependence
   - 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.
   - Pain is moderate to severe and expected to persist for an extended period of time
   - Pain is chronic
   - Pain is not postoperative (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)
   - Pain management is required around the clock with a long-acting opioid

-AND-

2. 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) 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-

3. If the request for neuropathic pain (examples of neuropathic pain include neuralgias, neuropathies, fibromyalgia), **both** of the following:
   a. 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 date of trial)

-AND-

   b. 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 and date of trial).

-AND-

4. If the request is for **Oxymorphone ER-non crush resistant (generic) or Hydrocodone extended-release (generic),** the patient has a history of failure, contraindication or intolerance to a trial of at least **one** of the following (Document drugs and date of trials):
   - morphine sulfate controlled release tablets (specifically generic MS Contin)
   - preferred fentanyl transdermal

-AND-

5. If the request is for **morphine sulfate extended-release capsules, Exalgo (hydromorphone extended-release), Hysingla ER (hydrocodone extended-release), Kadian (morphine sulfate sustained-release capsules),**

MS Contin [brand name], Nucynta ER (tapentadol extended-release), oxymorphone extended-release, OxyContin (oxycodone controlled-release), Xtampza ER (oxycodone extended-release), 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), Duragesic [brand name], Zohydro ER [brand name], the patient has a history of failure, contraindication or intolerance to a trial of at least **three** of the following (Document drugs and date of trials):

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal
- oxymorphone ER non-crush resistant (generic)
- hydrocodone extended-release (generic)

Authorization will be issued for 6 months for non-cancer pain/non-hospice/non-end of life care pain.

If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued 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 an alternative treatment.

If the request is for Oxymorphone ER-non crush resistant (generic) or Hydrocodone extended-release (generic)and the member is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued 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 an alternative treatment. Additionally, a 6 month authorization should be entered for morphine sulfate controlled release tablets (specifically generic MS Contin) and preferred fentanyl transdermal.

If the request is for a non-preferred product and the member is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued 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 an alternative treatment. Additionally, a 6 month authorization should be entered for preferred products, depending on what the patient has already tried:

- **If the patient has tried morphine sulfate controlled release tablets (specifically generic MS Contin) or preferred fentanyl transdermal, an authorization should be entered for Oxymorphone ER-non crush resistant (generic) and Hydrocodone extended-release (generic).**
- **If the patient has not tried any of the preferred products [morphine sulfate controlled release tablets (specifically generic MS Contin), preferred fentanyl transdermal, Oxymorphone ER-non crush resistant (generic) or Hydrocodone extended-release (generic), an authorization should be entered for morphine sulfate controlled release tablets (specifically generic MS Contin) and preferred fentanyl transdermal.**

2. Reauthorization criteria for <u>ALL</u> long-acting opioids for non-cancer/non-hospice/non-end of life care pain

a. Long-acting opioids for non-cancer/non-hospice/non-end of life care pain will be reauthorized based on **<u>all</u>** of the following:

(1) Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement).

-AND-

(2) Identify rationale for not tapering and discontinuing opioid. (Document rationale).

-AND-

(3) Prescriber attests to **ALL** of 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.
- Treatment goals are defined, including estimated duration of treatment.
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention

- Patient has been screened for substance abuse/opioid dependence
- 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.
- Pain is moderate to severe and expected to persist for an extended period of time
- Pain is chronic
- Pain is not postoperative (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)
- Pain management is required around the clock with a long-acting opioid

-AND-

(4) If the request is for **Oxymorphone ER-non crush resistant (generic) or Hydrocodone extended-release (generic),** the patient has a history of failure, contraindication or intolerance to a trial of at least **one** of the following (Document drugs and date of trials):

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal

-AND-

(5) If the request is for **morphine sulfate extended-release capsules, Exalgo (hydromorphone extended-release), Hysingla ER (hydrocodone extended-release), Kadian (morphine sulfate sustained-release capsules), MS Contin [brand name], Nucynta ER (tapentadol extended-release), oxymorphone extended-release, OxyContin (oxycodone controlled-release), Xtampza ER (oxycodone extended-release), 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),**

Duragesic [brand name], Zohydro ER [brand name], the patient has a history of failure, contraindication or intolerance to a trial of at least **three** of the following (Document drugs and date of trials):

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal
- oxymorphone ER non-crush resistant (generic)
- Hydrocodone extended-release (generic)

Authorization will be issued for 6 months for non-cancer pain/non-hospice/non-end of life care pain.

If the member is currently taking the requested long-acting opioid for at least 30 days and does not meet the medical necessity authorization criteria requirements for treatment with an opioid, a denial should be issued 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 an alternative treatment.

If the request is for Oxymorphone ER-non crush resistant (generic) or Hydrocodone extended-release (generic) and the member is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued 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 an alternative treatment. Additionally, a 6 month authorization should be entered for morphine sulfate controlled release tablets (specifically generic MS Contin) and preferred fentanyl transdermal.

If the request is for a non-preferred product and the member is currently taking the requested long-acting opioid for at least 30 days and has met the medical necessity authorization criteria requirements for treatment with an opioid, but has not tried the preferred alternatives a denial should be issued 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 an alternative treatment. Additionally, a 6 month authorization should be entered for preferred products, depending on what the patient has already tried:

- **If the patient has tried morphine sulfate controlled release tablets (specifically generic MS Contin) or preferred fentanyl transdermal, an authorization should be entered for Oxymorphone ER-non crush resistant**

(generic) and Hydrocodone extended-release (generic).

- **If the patient has not tried any of the preferred products [morphine sulfate controlled release tablets (specifically generic MS Contin), preferred fentanyl transdermal, Oxymorphone ER-non crush resistant (generic) or Hydrocodone extended-release (generic), an authorization should be entered for morphine sulfate controlled release tablets (specifically generic MS Contin) and preferred fentanyl transdermal.**

(iii) Prior Authorization Requests: Tramadol ER

One of the following:

A. The patient has a history of failure, contraindication or intolerance to a trial of tramadol IR.

-OR-

B. **Both** of the following:
   i. **One** of the following:
      (a) Patient is being treated for cancer related pain

-OR-

      (b) Patient is in hospice or is receiving end of life care.

-AND-

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

-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.

Authorization will be issued for 12 months.

(iv) Criteria for Quantity Limit Reviews
NOTE: This section applies to all medications, including tramadol ER

A. **BOTH** 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)

Authorization will be issued for 12 months for cancer pain/hospice/end of life related pain and for all Tramadol ER requests.

Authorization will be issued for 6 months for non-cancer pain/non-hospice/non-end of life related pain

(v). Morphine Milligram Equivalents (MME) Reviews: For Requests Exceeding the 90MME Cumulative Threshold
NOTE: This section applies to all medications, including tramadol ER

A. Criteria for Morphine Milligram Equivalents (MME) Reviews:

1. Cancer/Hospice/End of Life Related Pain

a. Doses exceeding the cumulative MME of 90 mg will be approved up to the requested amount for ALL opioid products if the member has cancer pain, hospice pain, or an end of life diagnosis.

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

2. Non-cancer/non-hospice/non-end of life related pain (Initial Authorization)

a. If the dose exceeds the maximum cumulative MME of 90mg, must meet **ALL** of the following:

(1) Prescriber attests to ALL of 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.
- Treatment goals are defined, including estimated duration of treatment.
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- 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-

(2) BOTH of the following:
(a) Patient has tried and failed non-opioid pain medication (document drug name and date of trial)
(b) Opioid medication doses of less than 90 MME have been tried and did not adequately control pain (document drug regimen or MME and dates of therapy)

Authorization will be issued for 6 months for non-cancer/non-hospice/non-end of life related pain up to the current requested MME plus 90 MME.

If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested MME dose.

3. Non-cancer/non-hospice/non-end of life related pain (Reauthorization)

a. If the dose exceeds the maximum cumulative MME of 90mg, must meet **ALL** of the following:

(1) Prescriber attests to ALL of 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.

- Treatment goals are defined, including estimated duration of treatment.
- Treatment plan includes the use of a non-opioid analgesic and/or non-pharmacologic intervention
- Patient has been screened for substance abuse/opioid dependence
- 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-

(2) Identify rationale for not tapering and discontinuing opioid (Document rationale)

-AND-

(3) Patient demonstrates meaningful improvement in pain and function (Document improvement in function or pain score improvement).

Authorization will be issued for 6 months for non-cancer/non-hospice/non-end of life related pain up to the current requested MME plus 90 MME.

If the member has been established on the requested MME dose for at least 30 days and does not meet the medical necessity authorization criteria requirements, a denial should be issued and a maximum 60-day authorization may be authorized one time for the requested MME dose.

(vi) Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

(vii) References:

1. Morphine Sulfate Extended Release [package insert]. North Wales, PA: Teva Pharmaceuticals; October 2019.
2. Exalgo [package insert]. Websters Grove, MO: SpecGx LLC; October 2019.
3. Hysingla ER [package insert]. Stamford, CT: Purdue Pharma; October 2019.
4. Kadian [package insert]. Parsippany, NJ: Actavis LLC; December 2016.
5. MS Contin [package insert]. Stamford, CT. Purdue Pharma; December 2016.
6. Nucynta ER [package insert]. Stoughton, MA: Collegium Pharmaceuticals, Inc. October 2019.
7. Oxymorphone Extended Release [package insert]. Brookhaven, NY. Amneal Pharmaceuticals of NY; January 2020.
8. OxyContin [package insert]. Stamford, CT: Purdue Pharma; October 2019.
9. Zohydro ER [package insert]. Princeton, NJ: Perison Therapeutics; October 2019.
10. Duragesic [package insert]. Titusville, NJ: Janssen Pharmaceuticals Inc.; October 2019.
11. Xtampza ER [package insert]. Cincinnati, OH: Patheon Pharmaceuticals. October 2019.
12. Arymo ER [package insert]. Wayne, PA: Zyla Life Sciences US Inc.; October 2019.
13. Morphabond ER [package insert]. Basking Ridge, NJ: Daiichi Sankyo Inc.; October 2019.
14. Methadone [package insert]. Eatontown, NJ: West-Ward Pharmaceuticals Corp. February 2018.Tramadol hydrochloride tablet, extended release [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; July 2020.
15. Martell, Bridget A., Patrick G. O'Connor, Robert D. Kerns, William C. Becker, Knashawn H. Morales, Thomas R. Kosten, and David A. Fiellin. Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction. Annals of Internal Medicine 2007;146: 116-127.
16. Palermo T, et al. Assessment and management of children with chronic pain. A position statement from the American Pain Society. 2012. Available at: http://americanpainsociety.org/uploads/get-involved/pediatric-chronic-pain-statement.pdf
17. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. Published online March 15, 2016.

Program	Prior Authorization - Long-Acting Opioid Pain Medications
Change Control	
Date	Change
7/2016	New program
9/2016	Updated MED for Belbuca, Butrans, and Duragesic.
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
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 applicable sections.
4/2017	Renamed policy to "Opioid Products". Added all short-acting opioid criteria to the policy. Added opioid over-utilization criteria.
5/2017	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.
6/2017	Updated short-and long-acting opioids section. Added MED section.
7/2017	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.
10/2017	Updated methadone daily max MED in background. Added short

	acting opioid cough and cold products and added criteria for MED review of cough and cold products. Removed approvable MED table for approved requests exceeding the MED limit and replaced with language to approve at the requested MED plus 90 MED.
1/2018	Separated short-and long-acting opioids into individual policies. Updated background. Removed attestation from cancer section to match what occurs at the point of sale pharmacy. Updated step therapy criteria for tramadol ER to step through only tramadol IR. Go-live 2/2018.
3/2018	Condensed preferred, preferred with step therapy and non-preferred drugs into one section to prevent duplication of criteria. Expanded attestation for the prior authorization section, reauthorization section, and MED section: treatment goals, treatment plan, screening for substance abuse/opioid dependence, and medical comorbidities questions combined into an attestation and documentation requirements removed. Go-live 5/2018
4/2018	Administrative changes to clarify intent, removed prescriber check, moved tramadol ER to its own section of the policy.
5/2018	Updated MED language to include confirmation that less than 90 MED is not adequate. Moved Belbuca and Butrans into their own policy.
8/2018	Separated MED into initial and reauthorization. Removed statements from the MED attestation that would have been evaluated in the authorization for the drug itself. Updated authorization duration language for requests that are denied.
4/2019	Changed MED to MME throughout. Updated references. Removed medical record submission requirement for cancer related pain.
10/2019	Updated operational notes for denied requests.
10/2020	Removed Embeda, Opana brand, Avinza brand. Removed Vantrela ER and Troxyca ER- products never brought to market. Changed Zohydro ER from brand to generic. Changed approval duration for denied requests to 60 days to match the language for denied requests in the MME section. Updated references.