UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Long-Acting Opioid Products –ARIZONA

Program	Prior Authorization/Medical Necessity – Long-Acting Opioid Products
Medication	**<u>Long-Acting Opioids:</u>** **Includes both brand and generic versions of the listed products unless otherwise noted:** Morphine sulfate controlled-release tablets, fentanyl transdermal*, Embeda (morphine sulfate and naltrexone), Butrans (buprenorphine), Xtampza ER (oxycodone extended-release), tramadol extended release tablets (non-biphasic release tablets) Avinza (morphine sulfate extended-release capsules), Exalgo (hydromorphone extended-release), Kadian (morphine sulfate sustained-release capsules), MS Contin [brand name], Opana ER-crush resistant (oxymorphone 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, Morphabond ER (morphine sulfate extended-release), Troxyca ER (oxycodone and naltrexone extended-release), Vantrela ER (hydrocodone bitartrate extended-release), Hysingla ER (hydrocodone extended release), OxyContin (oxycodone controlled release), Nucynta ER (tapentadol extended release), tramadol extended release capsules, tramadol extended release biphasic release tablets
Markets in Scope	Arizona

*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 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 Long-Acting Opioid Maximum Morphine Equivalents per Day*

Active Ingredient	FDA Label Max Daily Doses	90 MED equivalent (mg/day) (non treatment naïve)-
Morphine	None	90mg
Buprenorphine	1800mcg	3000mcg
Buprenorphine transdermal patch	20mcg/hr	50mcg/hr
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	225mg
Oxymorphone	None	30mg
Oxycodone	Xtampza Only =288mg	60mg

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

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 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.

Members under 18 years of age

A prescriber shall limit the **initial and refill** prescriptions for any short-acting opioid medication for a member under 18 years of age to no more than a 5-day supply.

An **initial** prescription for a short-acting opioid medication is one in which the member has not previously filled any prescription for a short-acting opioid medication within 60 days of the date of the pharmacy filling the current prescription as evidenced by the member's Pharmacy Benefit Management (PBM) prescription profile.

Members 18 years of age and older

A prescriber shall limit the **initial** prescription for any short-acting opioid medication for a member 18 years of age and older to no more than a 5-day supply.

An **initial** prescription for a short-acting opioid medication is one in which the member has not previously filled any prescription for a short-acting opioid medication within 60 days of the date of the pharmacy filling the current prescription as evidenced by the member's Pharmacy Benefit Management (PBM) prescription profile.

Coverage Criteria:
(ii) Long-Acting Opioids:_Prior Authorization Requests

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

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

   a. **One** of the following:

      (i) Patient is being treated for cancer (document diagnosis and date of diagnosis)

-OR-

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

-AND-

b. If the request is for **Avinza (morphine sulfate extended-release capsules), Exalgo (hydromorphone extended-release), Kadian (morphine sulfate sustained-release capsules), MS Contin [brand name], Opana ER-crush resistant (oxymorphone 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, Morphabond ER (morphine sulfate extended-release), Troxyca ER (oxycodone and naltrexone extended-release), Vantrela ER (hydrocodone bitartrate extended-release), Hysingla ER (hydrocodone extended release), OxyContin (oxycodone controlled release), tramadol extended release capsules, tramadol extended release biphasic release tablets or Nucynta ER (tapentadol extended release) <u>both</u>** of the following:

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

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

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal
- Embeda (morphine sulfate and naltrexone)
- Butrans (buprenorphine)
- Xtampza ER (oxycodone extended-release)
- tramadol extended release tablets (non-biphasic release tablets)

-OR-

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

B. Long- Acting Opioids: Non-cancer pain/Non-hospice care/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)
- If the request is for a long-acting opioid, 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), 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-

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

   ii. 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-

4. If the request is for **Avinza (morphine sulfate extended-release capsules), Exalgo (hydromorphone extended-release), Kadian (morphine sulfate sustained-release capsules), MS Contin [brand name], Opana ER-crush resistant (oxymorphone 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, Morphabond ER (morphine sulfate extended-release), Troxyca ER (oxycodone and naltrexone extended-release), Vantrela ER (hydrocodone bitartrate extended-release), Hysingla ER (hydrocodone extended release), OxyContin (oxycodone controlled release) tramadol extended release capsules, tramadol extended release biphasic release tablets, Nucynta ER (tapentadol extended release)** the patient has a history of failure, contraindication or intolerance to at least **three** of the following (Document drugs, dose, duration and date of trials):

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal
- Embeda (morphine sulfate and naltrexone)
- Butrans (buprenorphine)
- Xtampza ER (oxycodone extended-release)
- tramadol extended release tablets (non-biphasic release tablets)

Authorization will be issued for 6 months for non-cancer, non-hospice care or non-end-of-life 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 criteria for ALL long-acting opioids for non-cancer/non-hospice/non-end-of life care pain

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

a. Long-acting opioids for non-cancer/non-hospice/non-end-of life care pain will be reauthorized based on **all** 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.

- Patient 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)
- If the request is for a long-acting opioid, pain management is required around the clock with a long-acting opioid

-AND-

b. If the request is for **Avinza (morphine sulfate extended-release capsules), Exalgo (hydromorphone extended-release), Kadian (morphine sulfate sustained-release capsules), MS Contin [brand name], Opana ER-crush resistant (oxymorphone 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, Morphabond ER (morphine sulfate extended-release), Troxyca ER (oxycodone and naltrexone extended-release), Vantrela ER (hydrocodone bitartrate extended-release), Hysingla ER (hydrocodone extended release), OxyContin (oxycodone controlled release), tramadol extended release capsules, tramadol extended release biphasic release tablets or Nucynta ER (tapentadol extended release)** the patient has a history of failure, contraindication or intolerance to at least **three** of the following (Document drugs, dose, duration and date of trials):

- morphine sulfate controlled release tablets (specifically generic MS Contin)
- preferred fentanyl transdermal
- Embeda (morphine sulfate and naltrexone)
- Butrans (buprenorphine)

- Xtampza ER (oxycodone extended-release)
- tramadol extended release tablets (non-biphasic release tablets)

Authorization will be issued for 6 months for non-cancer, non-hospice care or non-end-of-life 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

A. Cancer Related Pain/Hospice Care/End-of-life care

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 or end-of-life care.

-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/end-of-life care pain.

B. Non-cancer pain/Non-hospice/non-end-of-life care pain

1. **BOTH** of the following:

c. 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 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 a pain management specialty designated by the American Board of Anesthesiology; 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-

d. 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/non-end-of-life care pain.

If the member has been established on the requested long-acting opioid DOSE does not meet the supply limit criteria requirements for non-cancer 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..

APPENDIX

Copy of Exhibit 310-V-3 ICD-10-CM D

(iv)References:

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pain?source=search_result&search=long+acting+opioids&selectedTitle=1%7E150#H1
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Program	Prior Authorization - Long-Acting Opioid Pain Medications-ARIZONA

Change Control	
Date	Change
3/2017	New policy for Long-Acting Opioids for Arizona.
4/2017	Updated language throughout to clarify which diagnoses are applicable to each section. Updated quantity limit review 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. Updated excluded diagnoses to cancer, hospice care and end-of-life care (non hospice).
6/2017	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.
9/2017	Added Morphabond ER (morphine sulfate extended-release), Troxyca ER (oxycodone and naltrexone extended-release), and Vantrela ER (hydrocodone bitartrate extended-release), opium and butorphanol nasal spray to the policy. Combined SAO and LAO into one policy. Updated methadone daily max MED.
10/2017	Updated the SAO edit to a 5-days supply instead of a 7-days supply.
10/2017	Updated methadone daily max MED in background. Removed tramadol ER from long acting quantity limit review section. Removed note regarding tramadol ER listed under the medications section. Updated preferred products.
1/2018	Separated short-and long-acting opioids into individual policies. Removed attestation from cancer section. Added maximum dosage for tapentadol. Updated background. Updated quantity limit language to reflect that individual products have quantity limits to reflect the MED.
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 and reauthorization section: treatment goals, treatment plan, screening for substance abuse/opioid dependence, and medical comorbidities questions combined into an attestation and documentation requirements removed. Moved Nucynta to non-preferred and tramadol ER non-biphasic release tablets to preferred. Go-live 4/2018
3/2018 v2	Administrative changes to clarify intent.