UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Short-Acting Opioid Products

Program	Prior Authorization/Medical Necessity – Short-Acting Opioid Products
Medication	**Short-Acting Opioids:** **Includes both brand and generic versions of the listed products unless otherwise noted:** All salt forms, single and combination ingredient products, and all brand and generic formulations of the following: butorphanol tartrate nasal spray, codeine, morphine, hydrocodone, hydromorphone, oxycodone, oxymorphone, pentazocine, tramadol, tapentadol, meperidine, levorphanol tartrate, dihydrocodeine, opium, benzhydrocodone **Short-Acting Opioids – Cough and cold products:** **Includes both brand and generic versions of the listed products unless otherwise noted:** Products containing codeine or hydrocodone in combinations with one or more of the following: homatropine, chlorpheniramine, guaifenesin, pyrilamine, brompheniramine, phenylephrine, triprolidine, dexchlorpheniramine, promethazine, pseudoephedrine.
Markets in Scope	New York, New York EPP, California, New Jersey, Nevada, Pennsylvania- CHIP
Issue Date	7/2016
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	2/2021

1. Background:

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
Hydromorphone	None	22.5mg
Hydrocodone	None	90mg
Tapentadol	600mg IR products	225mg
Oxymorphone	None	30mg

Oxycodone	None	60mg
Codeine	360mg	600mg
Pentazocine	None	243mg
Tramadol	400mg IR products	900mg
Meperidine	600mg	900mg
Butorphanol	None	12.86mg
Opium	4 suppositories/day Deodorized tincture: 24mg/day Camphorated tincture: 16mg/day	90mg
Benzhydrocodone**	None	73.77mg
Levorphanol	None	8.18mg

*Doses are not considered equianalgesic and table does not represent a dose conversion chart.
**Morphine Milligram Equivalents is derived from the package insert.

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.

Opioid (codeine or hydrocodone) containing cough and cold products are FDA labeled for use in adults 18 years of age and older. Use of prescription opioid cough and cold medicines containing codeine or hydrocodone should be limited in children younger than 18 years old due to serious risks associated with use.

Coverage Criteria:

2. Short-Acting Opioids: Criteria for Opioid Naïve Members, including Non-Preferred Reviews and Quantity Limits
NOTE: An opioid-naïve member is defined as not having filled an opioid in the past 60 days.
Patients 20 years and older will be limited to a 7 day supply and less than 50 MME/day for their initial short-acting opioid fill

Patients under the age of 20 years will be limited to a 3 day supply and less than 50 MME/day for their initial short-acting opioid fill.

NOTE: This section does NOT apply to cough and cold products.

A. Short-Acting Opioids

1. Opioid naïve members (defined as not having filled an opioid in the past 60 days) may receive greater than the supply limit and/or greater than 50 MME based on **ALL** of the following:

a. If the request is for greater than the supply limit **ONE** of the following:

(1) Cancer diagnosis
(2) End of life care, including hospice care
(3) Palliative care
(4) Sickle cell anemia
(5) **Both** of the following:
(a) **ONE** of the following:
i. Traumatic injury
ii. Post-surgical procedures, excluding dental procedures
iii. Prescriber attests that the patient has received an opioid within the past 60 days

-AND-

(b) Prescriber attests to **both** of the following:
i. 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.
ii. If requested for traumatic injury or post-surgical procedure, prescriber attests that based on injury or surgical procedure performed the member requires greater than a 7 day supply for patients 20 years and older or greater than a 3 day supply for patients under the age of 20 years of short-acting opioid to adequately control pain.

-AND-

b. If the request is for 50 MME or greater **ONE** of the following:
NOTE: If the request exceeds 90 MME, please skip Section b-Requests for 50 MME or greater and proceed to Section IV-Morphine Milligram Equivalents (MME) Reviews

(1) Diagnosis of cancer, end of life pain (including hospice care), palliative care or sickle cell anemia
(2) Patient is currently exceeding 50 MME and prescriber attests patient has been on a short-acting opioid in the past 60 days.
(3) All of the following:
(a) Document **all** of the following:
i. The diagnosis associated with the need for pain management with opioids.

ii. 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.
iii. The prescriber has acknowledged that they have completed an addiction risk and risk of overdose assessment.
iv. Prescriber attests the member requires more than 50 MME per day to adequately control pain.

-AND-

c. **One** of the following:
(1) If the request is for tramadol 100mg tablets, the physician has provided rationale for needing to use the 100mg tramadol tablet instead of two 50mg tramadol tablets.

-OR-

(2) If the request is for Qdolo, one of the following:
(a) The patient has a history of failure, contraindication or intolerance to a trial of tramadol 50mg tablets

-OR-

(b) Patient is unable to swallow a solid dosage form

-OR-

(c) Patient utilizes a feeding tube for medication administration

-OR-

(3) If the request is for another 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 for cancer, end of life, palliative care, or sickle cell pain will be issued for 12 months. All other approvals will be issued for the requested duration, not to exceed one month.

3. Short-Acting Opioids: Criteria for Opioid Experienced Members: Non-Preferred Reviews

NOTE: This section does NOT apply to cough and cold products.

A. **One** of the following:

(1) If the request is for tramadol 100mg tablets, the physician has provided rationale for needing to use the 100mg tramadol tablet instead of two 50mg tramadol tablets.

-OR-

(2) If the request is for Qdolo, one of the following:
(a) The patient has a history of failure, contraindication or intolerance to a trial of tramadol 50mg tablets

-OR-

(b) Patient is unable to swallow a solid dosage form

-OR-

(c) Patient utilizes a feeding tube for medication administration

-OR-

(3) If the request is for another 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.

4. Morphine Milligram Equivalents (MME) Reviews: For Requests Exceeding the 90 MME Cumulative Threshold.

NOTE: This section does NOT apply to cough and cold products.

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 or an end of life diagnosis (hospice care).

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.

5. Cough and Cold Products
Quantity Limit Rules:

- **120mL/fill**
- **360mL/30 days**

A. Criteria for Morphine Milligram Equivalents (MME) Reviews

1. Doses exceeding the cumulative MME of 90 mg will be approved up to the requested amount if the prescriber attests they are aware of patient's current opioid therapy and MME dose and feels the treatment with the requested product is medically necessary.

   Authorization will be issued for up to 30 days for cough and cold related treatment. The authorization should be entered for the MME requested.

B. Criteria for Reviews for Members Under the Age of 18 Years

1. **Opioid containing cough and cold products** will be approved based on **all** of the following criteria:

   a. Prescriber attests they are aware of FDA labeled contraindications regarding use of opioid containing cough and cold products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary. (Document rationale for use)

   -AND-

   b. Patient does not have a comorbid condition that may impact respiratory depression (e.g., asthma or other chronic lung disease, sleep apnea, body mass index > 30)

   -AND-

   c. Patient has tried and failed at least one non-opioid containing cough and cold remedy

   Authorization will be issued for 30 days.

C. Criteria for Requests Exceeding the Quantity Limit

1. Requests exceeding the quantity limit will be approved based on **both** of the following:
   a. Doses exceeding the quantity limit will be approved up to the requested amount if the prescriber attests that a larger quantity is medically necessary.

-AND-

   b. The requested dose is within FDA maximum dose per day, where an FDA maximum dose per day exists.

Authorization will be issued for up to 30 days. The authorization should be entered for the quantity requested.

D. Criteria for Non-Preferred Reviews

1. 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 cough and cold products.

Authorization will be issued for 30 days.

6. 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.

7. References:

1. 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.
2. 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
3. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. Published online March 15, 2016.
4. Approach to Cough in Children. UpToDate. February 2018. FDA Round Table. Use of Cough Suppressants in Children; Expert Roundtable Meeting; April 27, 2017.

5. FDA Drug Safety Communication (2018a). FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older. US Food and Drug Administration website. https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm. Published January 22, 2018. Accessed July 6, 2020.

Program	Prior Authorization - Short-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. Added criteria for members new to therapy (days supply and MED limit). Removed efficient medication dosing question and FDA max dosing questions from quantity limit section to accommodate operational edits for new to therapy limits. Go-live 3/2018.
3/2018	Expanded attestation for the 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	Added criteria for opioid containing cough and cold products for members who are under the age of 18.
4/2018v2	Administrative changes to clarify intent, removed prescriber check, added opium to the policy/background.
5/2018	Added criteria for cough and cold products for patients exceeding the quantity limit.
5/2018 v2	Updated MED language to include confirmation that less than 90 MED is not adequate.
7/2018	Revised NTT edit for patients under the age of 20 years (3 days supply). Updated MED language.

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	Added Apadaz. Updated references. Changed MED to MME throughout.
3/2020	Added tramadol 100mg tablets. Updated references.
4/2020	Revised criteria for members established on >50 MME.
12/2020	Added Qdolo criteria.