Analgesics: Opioid Agonists

WA.PHAR.23 Effective November 1, 2019

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the current publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit: https://pharmacy.envolvehealth.com/content/dam/centene/envolve-pharmacy-solutions/pdfs/PDL/FORMULARY-CoordinatedCare_Washington.pdf

Background:

The opioid agonists is a class of medications that is reserved for the treatment of severe pain that cannot be managed by non-pharmacologic therapies or other pharmacologic treatments. Opioid agonists provide analgesia by acting on opioid receptors in the central and peripheral nervous systems that block the sensation of pain from signaling to the brain. Opioid agonists are available in many dosage forms, including short-acting and long-acting formulations.

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Products approved by the FDA for the treatment of acute or chronic pain which contain one or more of these ingredients: • benzhydrocodone • buprenorphine (pain indications only) • butorphanol • codeine • dihydrocodeine • fentanyl • hydrocodone • hydromorphone • levorphanol • meperidine • methadone • morphine • oxycodone • oxymorphone	**Note:** This criteria applies to all opioid prescriptions. Additional criteria applies to methadone, trans-mucosal fentanyl, and buprenorphine monotherapy. Please see their respective policies for the additional criteria: 1. Methadone: Policy 65.10.00.50 2. Transmucosal fentanyl: Policy 65.10.00.25 3. Buprenorphine for treating substance use disorder: Policy 65.20.00.10 **Note:** Requests for codeine and tramadol for patients age 20 and younger requires medical justification for the use of codeine and tramadol rather than non-pharmacologic or non-opioid medications in addition to the limits established below. Opioid prescriptions are covered to treat non-cancer, non-palliative care, non-hospice, and non-end of life related pain when the limits listed below are followed or when one of the exceptions applies. Opioid prescriptions exceeding the limits, which do not have an exception listed, but have unique circumstances supported by clinical judgement and documentation will be reviewed for authorization on a case-by-case basis.

• pentazocine • tapentadol • tramadol	**1. Maximum Daily Morphine Milligram Equivalent (MME):** ○ Use of opioids is limited to 120 MME per day. ○ All single or combined opioid claims that cumulatively **exceed 120 MME** per day **but no more than 200 MME** per day require consultation with a pain management specialist. See exceptions below. ○ All single or combined opioid claims that cumulatively **exceed 200 MME per day** will be reviewed on a case-by-case basis for medical necessity. Chart notes, including a consultation with a pain specialist for the requested dose are required. See exceptions below. **2. Use of short-acting opioids for the treatment of acute pain (non-cancer, non-palliative care, non-hospice, and non-end of life) is subject to the following limits:** ○ **Dose limits:** • A quantity limit of 18 dosages per prescription for children (≤20 years of age) up to and including 120 MME per day; **OR** • A quantity limit of 42 dosages per prescription for adults (≥21 years of age) up to and including 120 MME per day; **AND** ○ **Days supply limits** • Up to and including 42 calendar days of opioid use within a rolling 90-day period. • Use of any opioid(s) for more than 42 days within a 90-day period is considered chronic use of opioids and requires prior authorization. See the **chronic use of opioids section (#3)** below; **Note:** Only short-acting opioids will be authorized for the treatment of acute pain. Long-acting opioids for acute use will only be authorized under the exception criteria below. **3. Use of opioids for the treatment of chronic pain (non-cancer, non-palliative care, non-hospice, and non-end of life) is subject to the following limits:** ○ Maximum daily MME limited to 120 MME; and ○ Provider has submitted a signed Opioid Attestation Form attesting that the following criteria are met and are documented in the medical record: • There is an ongoing clinical need for chronic opioid use at the prescribed dose, not to exceed 120 MME per day

- Appropriate non-opioid medications, and/or non-pharmacologic therapies are being used or have been ineffective

- For long acting opioids: patient has used short-acting opioids for at least 42 days or there is clinical justification why short-acting opioids are inappropriate or were ineffective.
- Baseline and on-going assessments of measureable, objective pain scores and function scores order to demonstrate clinically meaningful improvements in pain and function
- Results of periodic urine drug screens
- Provider has checked the prescription drug monitoring program for any other opioid use and concurrent use of benzodiazepines or other sedatives
- Provider has discussed with patient the realistic goals of pain management therapy and has discussed discontinuation as an option during treatment.
- The provider confirms that the patient understands and accepts these conditions and the patient has signed a pain contract or informed consent document.

  - Authorization will be for up to 12 months or the time period requested on the Opioid Attestation, whichever is less;
  - Opioid Attestation requests for chronic opioid use will not be accepted until the patient has been on opioid therapy for at least 25 days in a 90-day period.

Note: Attestation must be signed by a prescriber who has written an opioid prescription for this patient within the previous 90 days.

Exceptions:

4. **For patients with a diagnosis or pharmacy claim for active cancer treatment, hospice, palliative care, or end-of-life care**
   - Prescriptions for greater than 18 dosages for children or greater than 42 dosages for adults for acute use of opioids are authorized for acute pain if the prescriber types or writes "CANCER PAIN", "HOSPICE", "PALLIATIVE CARE", OR "END OF LIFE CARE" on the prescription.
   - The pharmacy may submit the claim with the EA code 85000000540 to override the quantity limit and days supply, [this EA does not override the 120 MME limit (#1)];
   - By indicating "CANCER PAIN", "HOSPICE", "PALLIATIVE CARE", OR "END OF LIFE CARE" the provider acknowledges that the patient has a medically necessary need that requires the prescribed short-acting opioid and it is documented in the medical record;
   - If the medical condition is provided to the pharmacy telephonically documentation must include the criteria met,

who provided verification of the criteria, and the date the verification was provided. Example: a prescription should state, "cancer pain", "hospice care", or "palliative care" diagnosis provided by Jane Doe at provider's office on MM/DD/YYYY;

5. **For patients with a medically necessary need <u>other than</u> cancer related pain, hospice care, palliative care, or end-of-life care**
   - Prescriptions for greater than 18 dosages for children or greater than 42 dosages for adults for acute use of opioids are authorized for acute pain if the prescriber types or writes "EXEMPT" on the prescription.
   - The pharmacy may submit the claim with EA code 85000000541 [this EA does not override the 42 days chronic use limit (#3) or the 120 MME limit (#1)];
   - By indicating "EXEMPT" the provider acknowledges that the patient has a medically necessary need that requires the prescribed short-acting opioid [other than pain related to active cancer, hospice, palliative care, or end-of-life care] and it is documented in the medical record;
   - If the medical condition is provided to the pharmacy telephonically documentation must include the criteria met, who provided verification of the criteria, and the date the verification was provided. Example: a prescription should state, "cancer pain", "hospice care", or "palliative care" diagnosis provided by Jane Doe at provider's office on MM/DD/YYYY;

6. **For patients with a medically necessary need for a long-acting opioid for treatment of acute pain**
   - Prescriptions for long-acting opioids in the acute phase are authorized when the prescriber indicates "CANCER PAIN", "HOSPICE", "PALLIATIVE CARE", OR "END OF LIFE CARE" on the prescription.
     - The pharmacy may submit the claim with the EA code 85000000540 to override the quantity limit and days supply, [this EA does not override the 120 MME limit (#1)];
   - Prescriptions for long-acting opioids in the acute phase are authorized when the prescriber types or writes "EXEMPT" on the prescription
   - The pharmacy may submit the claim with the appropriate EA [this EA does not override the 42 days chronic use limit (#3) or the 120 MME limit (#1)];
   - By indicating "EXEMPT" the provider acknowledges that the patient has a medically necessary need that requires the prescribed long acting opioid and has documented in the medical record:

	• The reason for inadequate response to short-acting opioid therapy is documented in the medical record; OR • Justification of beginning an opiate naïve patient on a long-acting opioid is documented in the medical record; ○ If the medical condition is provided to the pharmacy telephonically, documentation must include the criteria met, who provided verification of the criteria, and the date the verification was provided. Example: a prescription should state, "EXEMPT" diagnosis provided by Jane Doe at provider's office on MM/DD/YYYY 7. **Patients with a medically necessary need to exceed 120 MME per day will be authorized when the following criteria have been met.** ○ Patient has received an opioid prescription written by a provider in an emergency room setting or by a prescriber in an urgent care facility associated with a hospital for no more than a 10-day supply; • May only be authorized for 2 times within a 12-month period; OR ○ The prescriber has submitted a signed Opioid Attestation form attesting that the following criteria are met and are documented in the medical record: • Patient is currently on chronic opioid therapy and requires an escalation in opioid dosage that exceeds 120 MME per day but less than or equal to 200 MME per day, for no more than 42 days ; OR • Patient is following a tapering schedule with a starting dose greater than 120 MME per day but less than or equal to 200 MME per day; OR • Patient has a medically necessary need to exceed 120 MME per day documented in the medical record; AND • The prescriber is a pain specialist as defined in: ▪ WAC 246-817-965; ▪ WAC 246-840-493; ▪ WAC 246-853-750 ▪ WAC 246-919-945; ▪ WAC 246-922-750; OR • The prescriber that has successfully completed a minimum of twelve continuing education hours on chronic pain management within the previous four years. At least two of these hours must be dedicated to substance use disorders; OR • The prescriber is a pain management practitioner working in a multidisciplinary chronic pain treatment center or a multidisciplinary academic research facility; OR

	• The prescriber has a minimum of three years of clinical experience in a chronic pain management setting, and at least thirty percent of their current practice is the direct provision of pain management care; OR • The prescriber has obtained a consultation with a pain management specialist via one of the following: ▪ An office visit with patient and pain management specialist; OR ▪ Telephone, electronic, or in-person consultation between the pain management specialist and the prescriber; OR ▪ An audio-visual evaluation conducted by the pain management specialist remotely where the patient is present with either the physician or a licensed health care practitioner designated by the physician or the pain management specialist, • Use of opioids exceeding 120 MME but no more than 200 MME may be authorized for a duration up to provider's judgement but not to exceed 12 months when the prescriber signs the Opioid Attestation form. **Note:** Requests for doses above 200 MME per day will be considered on a case-by-case basis. Patients previously established on treatment regimens over 200 MME before October 1, 2019, including those new to Medicaid, are allowed to remain at their current dose for 1 year after which all applicable attestations will be required. **Note:** Attestation must be signed by a prescriber who has written an opioid prescription for this patient within the previous 90 days.
	Criteria (Reauthorization)
	An opioid agonist or combination of opioid agonists may be reauthorized for a duration up to provider's judgement but not to exceed 12 months once an updated and signed attestation is received.

Definitions

Term	Description
Acute opioid use	0 - 42 days of opioid use in a 90 day period
Chronic opioid use	Greater than 42 days of opioid use in a 90 day period
Dosage	One dosage equals one tablet, one capsule, one suppository, or 5 ml.
MME	Morphine milligram equivalent dose (also called morphine equivalent doses [MED]) as determined using the SUPPORT Act HCA MME Conversion Factors document which is a combination of the Washington State Agency Medical Directors' (AMDG) calculations and the Centers for Disease Control and Prevention (CDC) methodology for opioids.
Long-acting opioid	An extended release opioid that is FDA-approved to manage pain severe enough to require daily, around-the-clock, long-term opioid treatment for opioid-tolerant patients and for which alternative treatment options are inadequate (includes fentanyl patches, tramadol ER, buprenorphine patches, and methadone except when methadone is prescribed for the treatment of opioid use disorder).
Short-acting opioid	An opioid that is FDA-approved to manage pain severe enough to require opioid treatment and for which alternative treatment options are inadequate (includes tramadol, tapentadol, trans-mucosal fentanyl, and buprenorphine products not indicated for the treatment of opioid use disorder).

History

Date	Action and Summary of Changes
09/11/2023	Removed preferred therapies box
08/11/2023	Reformatted history table.
08/08/2023	Added note and Apple Health PDL link to the top of the page.
3/31/2020	• Updated days patient must be on opioid therapy before an attestation will be accepted for chronic use. • Added clarification for opioids prescribed in an emergency setting.
9/18/2019	• Added clarification for opioid prescriptions exceeding the limits, which do not have an exception listed.

	• Added exception for opioids prescribed in an emergency room setting.
8/01/2019	Updated to include MME limit criteria and Exceptions on MME.
11/01/2017	New Policy.