Washington State Health Care Authority (HCA):
Opioid Clinical Policy
(Effective November 1, 2017)

NOTE: If prescriber writes EXEMPT on the face of the prescription, allow override for quantity per prescription or use of long-acting opioids for acute pain in opioid naïve individuals (no history of >42 days of short-acting opioid therapy). Duration limits may be exceeded with prescriber attestation (*SEE WA Chronic Opioid Attestation Form*).

ADDITIONAL AUTHORIZATION INFORMATION (see criteria below for further instructions):

- Individuals with diagnoses of active cancer treatment, hospice, palliative care, or end-of-life care will not be required to adhere to quantity or duration limits.
- Also, individuals with a history of chronic opioid use (≥ 90 days of opioid therapy in the previous 120 days) will not be subject to quantity or duration limits. Use of preferred products still required (See below for direction regarding use of NON-PREFERRED AGENTS)
- Long-Acting opioids – new starts: Initial prescription allowed if short-acting opioid use of >42 days duration prior to use of long-acting opioid. Use of preferred products still required (See below for direction regarding use of NON-PREFERRED AGENTS)

NON-PREFERRED AGENTS:

- Preferred short-acting opioids should be used prior to non-preferred agents. Trial of and insufficient response or intolerance to two preferred agents should be confirmed.
- Preferred long-acting opioids should be used prior to non-preferred agents. Trial of and insufficient response or intolerance to two preferred agents should be confirmed (current preferred agents for WA are fentanyl patch and morphine sulfate ER [generic MS Contin]).

Requests for a non-preferred long-acting opioid analgesic must also meet the following criteria:

I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to two preferred long- acting agents (preferred long-acting agents: morphine sulfate ER tablets (generic MS Contin), fentanyl patch (generic Duragesic)); **OR**
II. Individual has completed titration and is already maintained on a stable dose of the requested drug; **OR**
III. The preferred long-acting opioids are not acceptable due to concomitant clinical situations, such as but not limited to:
    A. Known hypersensitivity to any ingredient which is not also in the requested non-preferred agent;

    OR
IV. Embeda ER, Hysingla ER, MorphaBond, Xtampza ER, Troxyca ER, Arymo ER, or Vantrela ER may be approved if the individual has need for an abuse deterrent formulation based upon a history of substance abuse disorder OR individual's family member or household resident has active substance abuse disorder or a history of substance abuse disorder; **OR**
V. Butrans (buprenorphine transdermal patch) or Belbuca (buprenorphine buccal film) may be approved if there is concern for abuse or dependence with pure opioid agents.

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Acute use of opioids for the treatment of *non-cancer, non-palliative care, non-hospice, non-end of life pain* (applies to both short acting and long acting formulations):

1) Grandfathering
   a) Patients who have a history of opioid use (other than methadone) for ≥ 90 calendar days in the previous 120 days. No consultation or attestation needed.
      i) The dose, quantity and 42 day supply limits do not apply.
      ii) These patients must be identified and an authorization must be established with no expiration date, prior to October 1, 2017.
   b) Methadone has its own coverage criteria patients taking methadone are exempt from this policy [*SEE Washington Methadone Criteria*]
   c) Buprenorphine has its own coverage criteria, patients taking trans-mucosal buprenorphine are exempt from this policy. [*SEE Washington Buprenorphine Criteria*]
2) In general, only short acting opioids will be approved for acute use. Long-acting opioids for acute use will be approved only under the exception criteria listed in (4) below.
3) **All short and long acting opioid** prescriptions are covered without prior authorization to treat non-cancer, non-palliative care, non-hospice, and non-end of life related pain when the limits listed in (3a) and (3b) below are followed or when one of the exceptions listed in (4) applies. Limits apply as follows:
   a) For short acting opioids only:
      i) A quantity limit of 18 dosages per prescription for children (≤20 years of age); [Note: Prescriber indicating EXEMPT overrides quantity limit] **OR**
      ii) A quantity limit of 42 dosages per prescription for adults (≥21 years of age); [Note: Prescriber indicating EXEMPT overrides the quantity]; **AND**
   b) For both long and short acting opioids:
      i) No more than 42 calendar days of opioid use within a rolling 90 day period. Use of any opioid 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** below; **AND**
4) **Exceptions** (Quantity and Dose Limits in Table 1 below apply) (4a and 4b require separate codes):
   a) Patient with a diagnosis or pharmacy claim for active cancer treatment, hospice, palliative care, or end-of-life care and pharmacy submitted the claim with an **expedited authorization code;** [Note: Day supply limits do not apply]; **OR**
   b) Provider wrote/typed "EXEMPT" on the prescription or the pharmacist has contacted the provider and the provider confirmed the patient had an "EXEMPT" medical condition.
      i) By indicating "EXEMPT" the provider is attesting that the patient has a medically necessary need that requires the prescribed long or 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
      ii) The pharmacy may submit the claim with an **expedited authorization code**
      iii) Prescriber indicating EXEMPT overrides the dosage limit
   c) New members are exempted for the first 120 days of enrollment.
      i) If your system cannot identify new members automatically when the claim is submitted you may implement as follows:
         (1) Reject the claim, with messaging to call pharmacy help desk if a chronic opioid user. Pharmacy Help Desk must be able to enter an override when the pharmacy calls and the pharmacist attests that the patient is a chronic opioid user at the prescribed dose.
         (2) Expedited Authorization code submitted by the pharmacy where the pharmacist attests that the patient is a chronic opioid user at the prescribed dose, even if over the dosage limits per prescription.
      ii) Documentation from the pharmacist or prescriber is not required

iii) Quantity limits and 42 day supply limit do not apply.

d) Current prior authorization on file.

5) Opioid prescriptions exceeding the limits in (3a) and (3b) that do not have an exception listed in (4) are not authorized unless provider submits attestation.

Chronic use of opioids for the treatment of non-cancer pain (applies to both short acting and long acting formulations) [Duration limits]

6) Use of opioids for more than 42 days may be authorized in 12 month intervals when the prescriber signs the attestation below. Dose limits **do not apply** for existing chronic users; these are considered "grandfathered" as above, and do not require prior authorization or dose restriction at this time.

Attestation:

"I [Doctor's Name] attest that all of the below criteria are met, or there is documentation in the chart for why one or more are not applicable:

a) The patient has an on-going clinical need for chronic opioid use at the prescribed dose (more than 42 days per 90 day calendar period) that is documented in the medical record.
b) The patient is using appropriate non-opioid medications, and/or non-pharmacologic therapies; OR
c) The patient has tried and failed non-opioid medications and non-pharmacologic therapies for the treatment of this pain condition; AND
d) For long-acting opioids**,** the patient must be using or had trials of short-acting opioid therapy for at least 42 days; OR
    i) The reason for inadequate response to short-acting opioid therapy is documented in the medical record; OR
    ii) Justification of beginning an opiate naïve patient on a long-acting opioid is documented in the medical record;
e) The provider has recorded baseline and ongoing assessments of measurable, objective pain scores and function scores. These should be tracked serially in order to demonstrate clinically meaningful improvements in pain and function; AND
f) The patient has been screened for mental health disorders, substance use disorder, naloxone use; AND
g) The provider will conduct periodic urine drug screens; AND
h) The provider has checked the PDMP for any other opioid use and concurrent use of benzodiazepines and other sedatives; AND
i) The provider has discussed with the patient the realistic goals of pain management therapy and has discussed discontinuation as an option during treatment; AND
j) The provider confirms that the patient understands and accepts these conditions and the patient has signed a pain contract or informed consent document.

By signing this attestation, I hereby certify that the above information is true, accurate and complete. That the requested treatment is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical record. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to recoupment upon an audit.

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Definitions:

- **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 and tapentadol; excludes trans-mucosal fentanyl and trans-mucosal buprenorphine products).
- **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 and buprenorphine patches, and tramadol ER; excludes methadone).
- **Dosage:** One dosage equals one tablet, one capsule, one suppository, or 5 ml.
- **Opioid:** Drugs containing the following ingredients
  - Codeine
  - Fentanyl
  - Hydrocodone
  - Hydromorphone
  - Meperidine
  - Morphine
  - Oxycodone
  - Oxymorphone
  - Tapentadol
  - Tramadol
- **MED:** Morphine equivalent doses per the calculator published on the Washington State Agency Medical Directors' Group website(http://agencymeddirectors.wa.gov/opioiddosing.asp)

Table 1: Quantity and Days' Supply Limits

ACUTE USE			
		Short acting opioids	**Long acting opioid**
Standard limits when exceptions are not met	Quantity Limits for children ≤ 20 years old	18 tablets or capsules, or 90 ml per prescription	Not allowed for acute use unless exempt
	Quantity Limits for adults ≥ 21years old	42 tablets or capsules, or 210 ml per prescription	
Limits when exceptions are met	Dosage	No MED limits at this time.	
	Day Supply	30 days maximum in a single fill. Use of opioids not to exceed 42 calendar days within a rolling 90 day period. Greater than 42 days require attestation or prior authorization.	
CHRONIC USE			
Limits	Dosage	No MED limit at this time.	
	Day Supply	30 day supply	

*http://agencymeddirectors.wa.gov/opioiddosing.asp