

Alaska Medicaid  
Prior Authorization Criteria

**Extended-Release / Long-Acting Opioid Analgesics  
(All Strengths)**

**Safety Concerns with Chronic Opioid Use:**

- Individuals using opioid analgesics for extended periods of time are at increased risk of dependency, overdose and death. Patients using opioids in excess of 100mg of a total daily Morphine Equivalent Dose (MED) are at significant risk of overdose; however, even utilization at lower doses presents risk to the patient.<sup>1,2</sup> <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>
- When prescribing opioids, prescribers should always use caution, particularly when considering increasing doses above 50 MED, as doses of 50 MED or more have been shown to increase overdose risk and do not necessarily provide a corresponding benefit in pain control or patient function.<sup>2</sup>
- Prescribers are encouraged to utilize an opioid dose calculator to evaluate the total amount of MED a patient is receiving per day from all sources. An opioid dose calculator can be found at<sup>3</sup>: <http://www.agencymeddirectors.wa.gov/Calculator/DoseCalculator.htm>
- All extended-release/long-acting opioids are subject to an FDA REMS program.<sup>4,5</sup> Please refer to the following link for more information: <http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemsDetails.page&REMS=17>
- When faced with complex pain management regimens, prescribers are encouraged to consult with pain management specialists.
- Information on the State of Alaska's Prescription Drug Monitoring Program (PDMP) may be found at: <http://www.alaskapdmp.com/>

**Prior Authorization Requirements (more than one category may apply):**

- **Product Selection:** Alaska Medicaid PDL (preferred drug list) preferred agents which do not require prior authorization for product selection include:
  - Morphine ER tablets (generic MS Contin)
  - Fentanyl transdermal patches [12, 25, 50, 75, and 100mcg/hr] (generic Duragesic)
  - Buprenorphine transdermal patches (Butrans)All claims for PDL non-preferred and interim list extended-release/long-acting opioid analgesic products† shall require prior authorization.
- **Quantity limits:** Quantity limit edits will apply to extended-release/long-acting opioid analgesic products. Patients may not exceed the maximum units without a second-level review prior authorization. Refer to the maximum units list available at: <http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/maxunitsall.pdf>
- **Therapeutic duplication:** Therapeutic duplication edits will apply to all extended-release/ long-acting opioid analgesic products. Patients may not receive more than one extended-release/ long-acting opioid product† without a second-level review prior authorization. Refer to: [http://manuals.medicaidalaska.com/docs/dnld/AKRx\\_letter\\_Opioid\\_Theraputic\\_Duplication\\_Edits\\_02102012.pdf](http://manuals.medicaidalaska.com/docs/dnld/AKRx_letter_Opioid_Theraputic_Duplication_Edits_02102012.pdf)
- **Second-level Peer Review:** Prescribers wishing to appeal any prior authorization denials for exceeding quantity limits, therapeutic duplications, or specific products may submit a request for a second-level review. Forms are available by contacting the Magellan Clinical Call Center at 800-331-4475.

Extended Release Opioids

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**Preferred Extended Release Opioids:**

Morphine ER tablets (generic MS Contin), fentanyl transdermal patches [12.5, 25, 50, 75, 100 mcg/hr] (generic Duragesic), and buprenorphine transdermal patches will not require prior authorization unless a therapeutic duplication or quantity limit exception is requested.

**All Medication Criteria for Approval:**

1. All prior authorization requests (product selection, quantity limit exception, or therapeutic duplication exception) must include the patient's **full** medication list; **AND**
2. All prior authorization requests must include the patient's calculated MED [Morphine Equivalent Dose] or MME [Morphine Milligram Equivalents] for all opioids being used; an online calculator may be found at <http://agencymeddirectors.wa.gov/mobile.html>; **AND**
3. All prior authorization requests must clearly document that the patient is opioid tolerant.
  - "Opioid Tolerant" is defined by the FDA as having taken at least one of the following medications and doses for the previous week or longer: at least 60mg oral morphine per day, 25mcg transdermal fentanyl/hour, 30mg oral oxycodone per day, 8mg oral hydromorphone per day, 25mg oral oxymorphone, or an equianalgesic dose of another opioid;<sup>6</sup> **AND**
4. All requests for PDL non-preferred or interim list extended release opioids must be accompanied by a letter of medical necessity documenting the need for an around-the-clock opioid analgesic; **AND**
5. All requests for PDL non-preferred or interim list extended release opioids must be accompanied by an opioid agreement (aka "pain contract"); **AND**
6. All requests for PDL non-preferred or interim list extended release opioids<sup>†</sup> require a trial of morphine ER tablets, fentanyl transdermal patches [12.5, 25, 50, 75, 100 mcg/hr], or buprenorphine transdermal patches at an equivalent therapeutic dose that resulted in a documented adverse drug reaction, treatment failure, or other medical complication within the past year; **OR**
  - The prescriber must submit documentation of the medical rationale for the non-trial with morphine ER tablets, fentanyl transdermal, or buprenorphine patch.

**Length of Authorization:**

- Prior authorization approval may be granted for up to 6 months; shorter durations may be approved.

*Note: Starting May 1, 2015, prior authorization approvals entered into the pharmacy adjudication system will be set to expire on the last day of the month through which the approval was authorized.*

**Dispensing Limit:**

- Maximum dispensing limits apply. See the Maximum Units List available online at <http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/maxunitsall.pdf> for additional information.
- Authorization for lost, stolen or destroyed opioid medications will not be permitted.
- Authorization of an early refill due to travel or a vacation will not be permitted.

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### **Definitions:**

†Extended-release opioid analgesics for the purposes of these criteria shall be defined as FDA approved products containing at least one opioid ingredient where the mechanism of release of the medication is such that it provides for a longer period of drug release. With this longer duration of release the interval between doses is extended (i.e. decreases frequency of dosing). Products will be considered extended-release/long-acting opioids and will be subject to these criteria if they appear on the current REMS list maintained by the FDA.<sup>5</sup>

### **Additional Resources:**

- Example pain contracts from the NIH NIDA may be found at:  
<http://www.drugabuse.gov/sites/default/files/files/SamplePatientAgreementForms.pdf>
- Equianalgesic opioid dose calculator may be found at:<sup>7</sup> <http://clincalc.com/opioids/>
- Opioid and Pain Management CMEs/CEs from the NIH NIDA may be found at:  
<http://www.drugabuse.gov/opioid-pain-management-cmesces>

### **References:**

<sup>1</sup> Dunn KM, Saunders KW, Rutter CM, et al. Opioid prescriptions for chronic pain and overdose: a cohort study. *Ann Internal Med.* 2010;152(2):85-92. doi: 10.7326/0003-4819-152-2-201001190-00006

<sup>2</sup> Dowell D, Haegerich TM, Chou R. CDC. “CDC Guidelines for Prescribing Opioids for Chronic Pain – United States, 2016.” *Morbidity and Mortality Weekly Report (MMWR).* March 18, 2016 / 65(1);1–49.  
<https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

<sup>3</sup> Opioid Dose Calculator. Agency Medical Directors’ Group. Washington State. 2007-2015.  
<http://www.agencymeddirectors.wa.gov/Calculator/DoseCalculator.htm>

<sup>4</sup> FDA. Extended-release (ER) and long-acting (LA) opioid analgesics risk evaluation and mitigation strategy (REMS), revised June 2015. Available at:  
<http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf>

<sup>5</sup> FDA. Extended-release and long-acting opioid analgesics shared system: risk evaluation and mitigation strategy, updated 4/26/2016 (or current version).  
<http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM348818.pdf>  
<http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemsDetails.page&REMS=17>

<sup>6</sup> FDA. Information for Healthcare Professionals: Fentanyl Transdermal System (marketed as Duragesic and generics)- 12/21/2007 Update. Updated 12/21/2007.  
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm084307.htm>

<sup>7</sup> Equivalent Opioid Calculator. ClinCalc LLC. 2016. <http://clincalc.com/opioids/>

<sup>8</sup> Franklin G, Sabel J, Jones CM, et al. “A comprehensive approach to address the prescription opioid epidemic in Washington state: milestones and lessons learned.” *American Journal of Public Health:* March 2015, Vol. 105, No. 3, pp. 463-469. doi: 10.2105/AJPH.2014.302367

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<sup>9</sup> HHS Press Office. [2015-03-26] HHS takes strong steps to address opioid-drug related overdose, death and dependence. Available at: <http://www.hhs.gov/news/press/2015pres/03/20150326a.html>

<sup>10</sup> Boyer EW, "Management of Opioid Analgesic Overdose," N Engl J Med, 2012, 367(2):146-55. <http://www.nejm.org/doi/full/10.1056/NEJMra1202561>. Accessed 12/2/2015.

<sup>11</sup> "Injury Prevention and Control: Opioid Overdose." Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention. Atlanta, GA. March 14, 2016. <http://www.cdc.gov/drugoverdose/epidemic/index.html>. Accessed 6/2/2016.

<sup>12</sup> Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, Crosby AE, Paulozzi LJ. "Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities." JAMA. 2008;300(22):2613-2620.

<sup>13</sup> Laroche MR, Liebschutz JM, Zhang F, Ross-Degnan D, Wharam JF. "Opioid Prescribing After Nonfatal Overdose and Association With Repeated Overdose: A Cohort Study." Ann Intern Med. 2016;164(1):1-9.

<sup>14</sup> Darke S, Zador D. "Fatal heroin 'overdose': A review." Addiction, 1996; 91: 1765-1772.