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.[1]
- 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: *http://agencymeddirectors.wa.gov/mobile.html*
- All extended-release/long-acting opioids are subject to an FDA REMS program.[2,3] Please refer to the following link for more information: *http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm*
- 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:*** All claims for PDL non-preferred and interim list extended-release/long-acting opioid analgesic products† shall require prior authorization; PDL 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)
- ☐ ***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 additional information at: *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.

Criteria for Approval:

1. Morphine ER tablets (generic MS Contin) and fentanyl transdermal patches [12.5, 25, 50, 75, 100 mcg/hr] (generic Duragesic) will not require prior authorization unless a therapeutic duplication or quantity limit exception is requested.
2. All prior authorization requests for extended-release/long-acting opioids (product selection, quantity limit exception, or therapeutic duplication exception) must include the patient's ***full*** medication list and calculated MED [Morphine Equivalent Dose] for all opioids; an online calculator may be found at http://agencymeddirectors.wa.gov/mobile.html.
3. All prior authorization requests for extended-release opioids must clearly document that the patient is opioid tolerant and has taken 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 for a week or longer; **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 an opioid agreement (aka "pain contract"); **AND**
5. All requests for PDL non-preferred or interim list extended release opioids† require a trial of morphine ER tablets or fentanyl transdermal patches [12.5, 25, 50, 75, 100 mcg/hr] at an equivalent therapeutic dose that resulted in a documented adverse drug reaction, treatment failure, or other medical complication within the past year; **OR**
6. The prescriber must submit documentation of the medical rationale for the non-trial with morphine ER tablets or fentanyl transdermal.

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 the approval was authorized through.

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.

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.[3]

Additional Resources:

- Example pain contracts from the NIH NIDA may be found at: *http://www.drugabuse.gov/sites/default/files/files/SamplePatientAgreementForms.pdf*
- Opioid and Pain Management CMEs/CEs from the NIH NIDA may be found at: *http://www.drugabuse.gov/opioid-pain-management-cmesces*

References:

1. 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*

2. FDA. Extended-release (ER) and long-acting (LA) opioid analgesics risk evaluation and mitigation strategy (REMS), revised 2014-12. Available at: *http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf* *http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm*

3. FDA. Extended-release and long-acting opioid analgesics shared system: risk evaluation and mitigation strategy, updated 2015-04-08 (or current version). *http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM348818.pdf* *http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm*

4. 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*

5. 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*