

Opioid Analgesics

- Long-Acting Opioid Prior Authorization
- Use of >90 milligram morphine equivalents (MME) AND 30 day quantity limit
- Short-Acting Opioid for Acute Pain Duration of Use
- Tramadol Agents Age Prior Authorization
- Codeine Agents Age Prior Authorization

Maryland Medicaid

Override(s)	Approval Duration
Prior Authorization – Long-acting opioids Quantity Limit – Long and short-acting opioids Tramadol containing products Codeine containing products	<ul style="list-style-type: none"> • Initial request: 3 months • Maintenance Therapy: Additional prior authorization required for each additional 6 months • Individuals with Cancer, Sickle Cell Anemia, in Hospice or Long-Term facility are excluded from prior authorization requirement and quantity limitations (approve for 1 year)

***NOTE: Maryland Medicaid also has a 30 day quantity limit for opioid analgesics in addition to the current daily quantity limit – see MD Analgesic Opioid QL spreadsheet. Criteria outlined below must be met in order to exceed quantity limits*

QUANTITY LIMIT APPROVAL CRITERIA

FOR >90 MME per day AND 30 day quantity limit – All opioid agents (short-acting and long-acting):

- I. Individual has one of the following conditions:
 - A. Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis); **OR**
 - B. Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis); **OR**
 - C. Diagnosis of sickle cell disease; **OR**
 - D. Individual currently resides at a long-term care facility;
- OR**
- II. Prescriber has attested to the following:
 - A. Prescriber has reviewed Controlled Dangerous Substance (CDS) Prescriptions in Prescription Drug Monitoring Program (PDMP) (CRISP); **AND**
 - B. Patient has had/will have random Urine Drug Screens before and during treatment; **AND**
 - C. Naloxone prescription was provided or offered to patient/patient’s household; **AND**
 - D. Patient-Prescriber Pain Management/Opioid Treatment Agreement/Contract signed and in Medical record; **AND**

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- E. Prescriber has certified that the benefits of Opioid treatment for the patient outweigh the risks of treatment.

FOR SHORT-ACTING OPIOIDS for acute pain duration of use:

Requests for greater than 7 days' supply of short-acting opioid analgesics for the treatment of acute pain in individuals not consistently receiving opioids may be approved for the following:

- I. Individual has a diagnosis of cancer related pain and/or is actively undergoing cancer treatment (provide diagnosis); **OR**
- II. Individual has a terminal condition and is receiving palliative/end-of-life care (provide diagnosis); **OR**
- III. Individual has a diagnosis of sickle cell anemia;

All other requests for greater than 7 days' supply of short-acting opioid analgesics and/or greater than 14 days' supply in 30 days for individuals who are not consistently receiving opioid analgesics will be reviewed.

NOTE: Individuals consistently receiving opioids is defined as prescribed daily use for 80 out of the past 90 days based on prescription dispensing history.

APPROVAL CRITERIA:

FOR LONG-ACTING OPIOIDS (Note: for approval for > 90 MME per day and/or 30 day quantity limit, please see above)

Requests for a **long-acting opioid analgesic** may be approved when the following criteria are met:

- I. Individual has one of the following:
 - A. Diagnosis of cancer related pain and/or is actively undergoing cancer therapy (provide cancer diagnosis); **OR**
 - B. Diagnosis of terminal illness and is receiving palliative/end-of-life care (provide terminal diagnosis); **OR**
 - C. Diagnosis of sickle cell disease; **OR**
 - D. Individual currently resides at a long-term care facility;
- OR**
- II. Individual has pain severe enough to require daily, around-the-clock, long term opioid treatment (provide diagnosis); **AND**
- III. Individual has one of the following:
 - A. An inadequate response to alternative treatment options, such as but not limited to non-opioid analgesics and immediate-release opioids; **OR**
 - B. Alternative treatment options would otherwise be inadequate to provide sufficient management of pain; **OR**

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C. Individual has contraindications to non-opioid analgesics (such as NSAID use in individuals with active ulcer condition/gastrointestinal bleeding, renal failure)¹;

AND

IV. Individual is 18 years of age or older unless the following agents are requested:

A. If requested agent is OxyContin, individual is 11 years of age or older **AND** already receiving and tolerating a minimum daily opioid dose of at least 20 mg oxycodone orally or its equivalent; **OR**

B. If requested agent is fentanyl transdermal patch (Duragesic) and individual is 2 years of age or older **AND** already receiving at least 60 mg/day of oral morphine, 30 mg/day of oral oxycodone, 8 mg/day of oral hydromorphone, or an equianalgesic dose of another opioid;

AND

V. One of the following:

A. For initial therapy, individual is not opioid naïve as noted by the following:

1. Individual is currently on a short-acting opioid analgesic, including use of opioid analgesia as an inpatient for post-surgical pain; **OR**
2. Individual is transitioning from one long-acting opioid analgesic to another long-acting opioid analgesic;

OR

B. For continued therapy, attestation that long-acting opioid therapy has provided meaningful improvement in pain and/or function compared to baseline;

AND

VI. Prescriber has consulted with individual regarding risks of opioid therapy; **AND**

VII. Clear treatment goals have been defined and outlined as part of overall plan; **AND**

VIII. Prescriber has attested to the following:

A. Prescriber has reviewed Controlled Substance Prescriptions in PDMP (CRISP);

AND

B. Patient has/will have random Urine Drug Screens; **AND**

C. Naloxone prescription was provided or offered to patient/patient's household;

AND

D. Patient-Prescriber Pain Management/Opioid Treatment Agreement/Contract signed and in Medical record; **AND**

E. Prescriber has certified that the benefits of Opioid treatment for the patient outweigh the risks of treatment.

Requests for all **long-acting opioid analgesics** may not be approved for the following:

I. Individual is requesting or using as an as-needed analgesic; **OR**

II. Individual has one of the following conditions:

A. Significant respiratory depression; **OR**

B. Acute or severe bronchial asthma or hypercarbia; **OR**

C. Known or suspected paralytic ileus.

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Requests for a **non-preferred long-acting opioid analgesic (except single source brand fentanyl patch or brand name Duragesic)** must also meet the following criteria (in addition to the above criteria in I.-VIII.):

- 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), methadone, 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, or Troxyca 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.

Requests for a **Brand fentanyl (brand Duragesic and brand fentanyl) patch** may be approved_must also meet the following criteria (in addition to the above criteria in I.-III.):

- I. Individual has had a trial and inadequate response or intolerance to one preferred oral long-acting opioid analgesic agent (preferred oral long-acting agents: Morphine sulfate tablets (generic MS Contin), methadone; **OR**
- II. Individual is already maintained on the requested brand Duragesic or brand fentanyl patch; **OR**
- III. The preferred oral long-acting opioid analgesic agents 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 brand Duragesic or brand fentanyl patch; **OR**
 - B. Individual has difficulty swallowing tablets/capsules.

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Tramadol Agents Age Prior Authorization

Protocol	Rationale
To require prior authorization for the use of tramadol containing agents in pediatric individuals.	To encourage appropriate use of tramadol containing analgesic agents in accordance with FDA recommendations.
Override Criteria	
<p>Requests for tramadol containing agents may be approved if the following criteria is met:</p> <ul style="list-style-type: none"> I. Individual is 18 years of age or older; OR II. Individual is 12 years of age or older and treating for pain conditions other than post-surgical removal of tonsils and/or adenoids. (FDA Safety Announcement 2017) <p>NOTE: An FDA Safety advisory released on 4-20-2017 noted that the label for tramadol containing agents would be updated to include the following contraindications: contraindication for use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids, and contraindication for use in treating pain in children younger than 12 years. This is due to serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years (https://www.fda.gov/drugs/drugsafety/ucm549679.htm).</p>	

Codeine Agents Age Prior Authorization

Protocol	Rationale
To require prior authorization for the use of codeine containing agents in pediatric individuals.	To encourage appropriate use of codeine containing analgesic agents in accordance with FDA recommendations.
Override Criteria	
<p>Requests for codeine containing agents may be approved if the following criteria is met:</p> <ul style="list-style-type: none"> I. Individual is 12 years of age or older. (FDA Safety Announcement 2017) <p>NOTE: An FDA Safety advisory released on 4-20-2017 noted that the label for codeine containing agents would be updated to include a contraindication for use in treating pain or cough in children younger than 12 years. This is due to serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years (https://www.fda.gov/drugs/drugsafety/ucm549679.htm).</p>	

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NOTES:

- I. Specific drug therapy and contraindication to therapy should be reported
- II. Long-acting opioid analgesics have a black box warning regarding risk of addiction, abuse and misuse, respiratory depression, risks of accidental exposure and risks for neonatal opioid withdrawal syndrome. Long-acting opioid analgesic use can lead to addiction, abuse and misuse which can lead to overdose and death. Individuals should be assessed before prescribing and monitored regularly during therapy for development of these behaviors or conditions. Serious, life-threatening or fatal respiratory depression may occur while using long-acting opioid analgesics. Individuals should be monitored, particularly upon initiation or upon dose increases. Accidental exposure, especially in children, can result in fatal overdose. Prolonged exposure to long-acting opioid analgesics during pregnancy can result in neonatal opioid withdrawal syndrome. If opioid use is required for prolonged periods of time in a pregnant woman, the individual should be advised of the risk of neonatal opioid withdrawal syndrome and ensure appropriate treatment will be available. Some long-acting analgesics (hydrocodone based) may interact with cytochrome P450 3A4 inhibitors, resulting in increased opioid concentration. In addition, discontinuation of a cytochrome P450 3A4 inducer may also result in an increase in opioid concentration. Monitor individuals receiving these opioid analgesics and any cytochrome P450 3A4 inhibitor or inducer. Co-ingestion with alcohol can increase plasma concentrations of some long-acting opioid analgesics (i.e., Embeda). This can potentially lead to a fatal overdose.

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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