Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	NA	NA	X	NA

Long-Acting Opioid Analgesics

Override(s)	Approval Duration
Prior Authorization Step Therapy Quantity Limit	• Initial request: 3 months • Maintenance Therapy: Additional prior authorization required for each additional 6 months • Individuals receiving for terminal diagnosis and receiving palliative care/end-of-life therapy: Lifetime • Individuals receiving for cancer pain related to active cancer therapy: 1 year

Medications	Comments	Quantity Limits
Morphine Sulfate (generic MS Contin)§	Preferred	• 15 mg, 30 mg, 60 mg: 3 tablets per day • 100mg, 200 mg: 2 tablets per day
Methadone §		• 5 mg: 6 tablets per day • 10 mg: 6 tablets per day • 40 mg: 1 tablet per day • 10 mg/5 mL: 30 mL per day • 5 mg/5 mL: 30 mL per day • 10 mg/mL injection: 1 mL per day • 10 mg/mL oral concentrate: 6 mL per day
Fentanyl Patch (generic Duragesic – specific strengths as listed)§		• 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, , 75 mcg/hr, 100 mcg/hr: 15 patches per 30 days
OxyContin (oxycodone extended-release tablets) §	Non-Preferred	• 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg: 2 tablets per day

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Hysingla ER (hydrocodone extended-release tablets)[§]		• 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, 120 mg: 1 tablet per day
Zohydro ER (hydrocodone extended release capsules)[§]		• 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg: 2 capsules per day
Oxymorphone extended-release tablets)[§]		• 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30mg, 40mg: 2 tablets per day
Exalgo (hydromorphone extended release tablets)[§]		• 8 mg, 12 mg, 16 mg, 32 mg: 1 tablet per day
Nucynta ER (tapentadol extended-release tablets) [§]		• 50 mg, 100 mg, 150 mg, 200 mg, 250 mg*: 2 tablets per day
MS Contin (brand)[§]		• 15 mg, 30 mg, 60 mg, 100 mg: 3 per day • 200 mg: 2 per day
Conzip capsules (brand)[§] Tramadol ER tablets (generic)[§] Branded Tramadol ER capsules[§]		• 100 mg, 150 mg 200 mg, 300 mg*: 1 tablet/capsule per day
Butrans (buprenorphine transdermal system)		• 5 mcg/hr, 7.5 mcg/hr, 10 mcg/hr, 15 mcg/hr, 20 mcg/hr: 4 patches per 28 days
Morphine sulfate extended-release capsules (24 hour) (generic Avinza)[§]		• 30 mg, 45 mg, 60 mg, 75 mg, 90 mg, 120 mg: 1 capsule per day
Kadian (morphine sulfate extended-release capsules)[§]		• 10 mg, 20 mg, 30 mg, 40mg, 50 mg, 60 mg, 80 mg, 100 mg, 200 mg: 2 capsules per day
Duragesic Patch (brand)[§] Fentanyl Patch (generic – specific strengths as listed)[§]		• Duragesic Patch:12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr: 15 patches per 30 days • Fentanyl Patch: 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr: 15 patches per 30 days

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Levorphanol§	• 2 mg, 3 mg: 6 tablets per day
Belbuca (buprenorphine buccal film)	• 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, 900 mcg*: 2 buccal films per day
Morphabond (morphine sulfate extended-release tablets)§	• 15 mg, 30 mg, 60 mg, 100 mg: 2 tablets per day
Xtampza ER (oxycodone extended-release capsules)§	• 9 mg, 13.5 mg, 18 mg, 27 mg, 36 mg*: 2 capsules per day
Embeda (morphine sulfate/naltrexone extended-release tablets)§	• 20mg/0.8mg, 30mg/1.2mg, 50mg/2mg, 60mg/2.4mg, 80mg, 3.2mg, 100mg/4mg: 2 tablets per day
Arymo ER (morphine sulfate extended-release tablets)§	• 15mg, 30mg, 60mg tablets: 3 tablets per day

Quantity Limit Override Criteria

For approval of increased quantities of select long-acting opioid agents (denoted with §), the following criteria must be met:

I. Individual has one of the following:
   A. A diagnosis of cancer related pain; **OR**
   B. A terminal condition and is receiving palliative/end-of-life care; **OR**

II. Individual has a severe pain condition requiring higher daily doses.

Note: It may be possible in some instances to use a higher strength of the requested medication and take fewer tablets/capsules to achieve the same total daily dosage requested.

FDA maximum recommended dose

Tramadol Extended Release Agents may be subject to the following age requirements via prior authorization, in addition to Long-Acting Opioid Approval Criteria:

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 postsurgical removal of tonsils and/or adenoids. (FDA Safety Announcement 2017)

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

APPROVAL CRITERIA

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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**

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**
   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 reviewed the prescription drug monitoring program (PDMP) to evaluate use of controlled substances (if available).

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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; **OR**
III. Methadone is prescribed for a diagnosis of opioid use disorder in the retail setting.

Requests for a non-preferred long-acting opioid analgesic **(except generic fentanyl patch (specific strengths:** 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr) **or brand name Duragesic)** must also meet the following criteria (in addition to the above criteria in **I.-III.**):

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. OxyContin, Hysingla ER, Embeda, MorphaBond, Xtampza ER or Arymo 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 brand Duragesic and **generic fentanyl (specific strengths:** 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr) patch may be approved and 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 **generic**

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fentanyl (specific strengths: 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr) 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 **generic fentanyl (specific strengths:** 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr) patch; **OR**
   B. Individual has difficulty swallowing tablets/capsules.

NOTES:

1. Specific drug therapy and contraindication to therapy should be reported
2. 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:

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