

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	NA	X	X	X	NA	NA	NA

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Long-Acting Opioid Analgesics

Override(s)	Approval Duration
Prior Authorization Step Therapy Quantity Limit	<ul style="list-style-type: none"> 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

****Louisiana Medicaid – See State Specific Mandates below**

****Virginia Medicaid – See State Specific Mandates below**

****Washington Medicaid – See State Specific Mandates below**

Medications	Comments	Quantity Limits
Morphine Sulfate Tablets (generic MS Contin) [§]	Preferred	<ul style="list-style-type: none"> 15 mg, 30 mg, 60 mg: 3 per day 100mg, 200 mg: 2 per day
Methadone (Non-Preferred in WA) [§]		<ul style="list-style-type: none"> 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) [§]		<ul style="list-style-type: none"> 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, , 75 mcg/hr, 100 mcg/hr: 15 patches per 30 days
OxyContin Oxycodone ER (generic OxyContin) [§]		<ul style="list-style-type: none"> 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 ER) [§]	Non-Preferred	<ul style="list-style-type: none"> 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, 100 mg, 120 mg: 1 tablet per day
Zohydro ER (hydrocodone ER) [§]		<ul style="list-style-type: none"> 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg: 2 capsules per day
Opana ER [§] Oxymorphone ER (generic Opana ER) [§]		<ul style="list-style-type: none"> 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30mg, 40mg: 2 tablets per day
Exalgo [§] Hydromorphone ER (generic Exalgo) [§]		<ul style="list-style-type: none"> 8 mg, 12 mg, 16 mg, 32 mg: 1 tablet per day
Nucynta ER [§]		<ul style="list-style-type: none"> 50 mg, 100 mg, 150 mg, 200 mg, 250 mg*: 2 tablets per day
MS Contin (brand) [§]		<ul style="list-style-type: none"> 15 mg, 30 mg, 60 mg, 100 mg: 3 per day 200 mg: 2 per day
Targiniq ER (oxycodone ER/naloxone)		<ul style="list-style-type: none"> 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg*: 2 tablets per day
Conzip (brand) [§] Ultram ER (brand) [§] Tramadol ER (generic) [§]		<ul style="list-style-type: none"> 100 mg, 200 mg, 300 mg*: 1 tablet/capsule per day
Butrans (buprenorphine transdermal system)		<ul style="list-style-type: none"> 5 mcg/hr, 7.5 mcg/hr, 10 mcg/hr, 15 mcg/hr, 20 mcg/hr: 4 patches per 28 days
Avinza (brand) [§] Morphine Sulfate ER capsules (generic Avinza) [§]		<ul style="list-style-type: none"> 30 mg, 45 mg, 60 mg, 75 mg, 90 mg, 120 mg: 1 capsule per day
Kadian (brand) [§] Morphine sulfate ER capsules (generic Kadian) [§]	<ul style="list-style-type: none"> 10 mg, 20 mg, 30 mg, 40mg, 50 mg, 60 mg, 80 mg, 100 mg, 200 mg: 2 capsules per day 	

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Duragesic Patch (brand) [§] Fentanyl Patch (generic – specific strengths as listed) [§]	<ul style="list-style-type: none"> 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
Levorphanol [§]	<ul style="list-style-type: none"> 2 mg: 6 tablets per day
Belbuca (buprenorphine buccal film)	<ul style="list-style-type: none"> 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, 900 mcg*: 2 buccal films per day
Morphabond (morphine sulfate ER) [§]	<ul style="list-style-type: none"> 15 mg, 30 mg, 60 mg, 100 mg: 2 tablets per day
Xtampza ER [§]	<ul style="list-style-type: none"> 9 mg, 13.5 mg, 18 mg, 27 mg, 36 mg*: 2 capsules per day
Embeda [§]	<ul style="list-style-type: none"> 20mg/0.8mg, 30mg/1.2mg, 50mg/2mg, 60mg/2.4mg, 80mg, 3.2mg, 100mg/4mg: 2 tablets per day
Troxyca ER (oxycodone hydrochloride and naltrexone hydrochloride extended-release) [§]	<ul style="list-style-type: none"> 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg and 80 mg/9.6 mg: 2 capsules per day
Arymo ER (morphine sulfate ER) [§]	<ul style="list-style-type: none"> 15mg, 30mg, 60mg tablets; 3 tablets per day
Vantrela ER (hydrocodone extended-release) [§]	<ul style="list-style-type: none"> 15 mg, 30 mg, 45 mg, 60 mg, 90 mg*: 2 tablets per day

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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.
 - B. A diagnosis of cancer related pain; **OR**
 - C. 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

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

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- 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;

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.

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

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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, Targiniq ER, Embeda, MorphaBond, Xtampza ER, Troxyca ER, Vantrela 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 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.

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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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)

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Applicable	X	X	NA	NA	X	NA	X	NA	X	X	X	NA	NA	NA

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Washington	3/1/16	<p>Washington Health Care Authority (HCA) requires that methadone be tried only after all other preferred long-acting agents for chronic non-cancer pain; also, dose limited to 40mg per day.</p> <p>Methadone may be authorized at doses up to 40 mg per day per Washington Health Care Authority (HCA) if the following are met (in addition to PA criteria above):</p> <ul style="list-style-type: none"> I. Individual has been on methadone in the past 90 days and is clinically stable on methadone; OR II. Individual has tried and failed ALL of the following preferred long-acting generic opioids: <ul style="list-style-type: none"> a. Morphine sulfate (capsules or tablets) b. Fentanyl patch; OR III. Individual is using to treat cancer pain; OR IV. Individual is in hospice. <p>Doses of methadone/Methadose beyond 40mg per day will require authorization unless individual is currently stable on doses above 40mg per day.</p>
Louisiana	3/22/17	Louisiana Medicaid has state specific criteria for opioid analgesics. Please see Louisiana Medicaid criteria.
Virginia	11/2016; 4/2017	Virginia Medicaid has state specific criteria for long-acting opioid analgesics. Please see Virginia Medicaid criteria

Key References:

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

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