



Original Effective Date: 09/01/2016  
 Current Effective Date: 04/04/2025  
 Last P&T Approval/Version: 01/29/2025  
 Next Review Due By: 01/2026  
 Policy Number: C16263-A

## Opioid Global Criteria

### PRODUCTS AFFECTED

acetaminophen/codeine, Actiq ( fentanyl lozenge) Apadaz (benzhydrocodone/APAP), Arymo ER (morphine sulfate ER AD), Belbuca (buprenorphine buccal film), benzhydrocodone/acetaminophen, buprenorphine TD patch, butorphanol nasal soln, Butrans (buprenorphine transdermal system), codeine sulfate, Conzip (tramadol ER biphasic), Demerol, dilaudid, Dolophine (methadone tab), Duragesic (fentanyl) patch, Endocet (oxycodone/APAP), fentanyl patch, fentanyl, Fentora (fentanyl) buccal tabs, hydrocodone bitartrate ER, hydrocodone/APAP, hydrocodone/ibuprofen, hydromorphone, Hysingla ER (hydrocodone bitartrate ER), Kadian (morphine sulfate ER), Lazanda (fentanyl citrate nasal spray), levorphanol tartrate tabs, meperidine, Methadone TBSO, Methadone, Methadose TBSO (methadone tab for oral susp), morphine sulfate, MS Contin (morphine sulfate tab ER), Nalocet (oxycodone/APAP), Norco (hydrocodone/acetaminophen), Nucynta (tapentadol), Nucynta ER (tapentadol ER), Oxaydo (oxycodone AD), oxycodone, oxycodone ER, oxycodone/APAP, oxycodone/ASA, OxyContin (oxycodone ER), oxymorphone ER, oxymorphone, Percocet (oxycodone/APAP), Prolate (oxycodone/ APAP), Qdolo (tramadol) Roxicodone (oxycodone) tabs, RoxyBond (oxycodone AD), Stadol (butorphanol tartrate), Subsys (fentanyl SL spray), Synapryn FusePaq (tramadol oral susp), tramadol ER, tramadol, tramadol/acetaminophen, Ultram (tramadol), Xodol (hydrocodone/acetaminophen), Xtampza ER (oxycodone ER AD), Zohydro (hydrocodone bitartrate ER AD)

\*AD= abuse deterrent

### COVERAGE POLICY

*Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.*

#### **Documentation Requirements:**

*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

#### **DIAGNOSIS:**

Chronic or acute pain

## Drug and Biologic Coverage Criteria

### REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

#### A. CHRONIC, SEVERE NON-CANCER PAIN:

1. Member has a diagnosis of severe pain AND the same source of pain is chronic (> 3 months) in nature  
AND
2. Documentation member is opioid-tolerant and requires around-the clock-long-term opioid treatment.  
MOLINA REVIEWER NOTE: The FDA defines opioid tolerant as 30mg or greater oxycodone equivalents per day for 7 days. Review for opioid tolerant to formulary preferred products or review history for new to Molina member (if applicable).  
AND
3. Prescriber attestation that non-pharmacologic therapy (e.g., physical therapy, exercise, Cognitive Behavioral Therapy, weight loss) and non-opioid therapy [e.g., topical diclofenac, nonsteroidal anti-inflammatory drugs (NSAIDs), tricyclic antidepressants (TCAs), and serotonin and norepinephrine reuptake inhibitors (SNRIs), or anticonvulsants] were maximized prior to prescribing opioids or as concurrent therapy  
AND
4. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs):  
Prescriber attestation that they utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request  
OR  
(b) FOR STATES WITHOUT PDMPs: Prescriber attestation that they will review member's records on a periodic basis or as necessary to ensure no abuse or diversion  
AND
5. Prescriber attestation that the member can safely take the requested dose of the requested drug based on their current opioid use history, concurrent medications, and comorbid conditions  
AND
6. Prescriber attestation that member has a signed Patient-Provider agreement (or equivalent) for controlled substance therapy  
AND
7. Prescriber attests that member has a treatment plan or other measures to provide a baseline status for stabilization/improvement in the patient. A treatment plan may include: Pain intensity (scales or ratings), Functional status (physical and psychosocial), Patient's goal of therapy (level of pain acceptable and/or functional status), and current non- pharmacological treatment  
AND
8. If the requested product contains acetaminophen, documentation that the treatment plan does not include doses higher than 4,000mg of acetaminophen per day from all sources  
AND
9. (a) FOR NON-PREFERRED/NON-FORMULARY IMMEDIATE ACTING PRODUCTS:  
Documentation that the member had an adequate trial and therapeutic failure or documented serious side effects to up to 3 preferred/formulary ORAL immediate acting products at maximally tolerated doses  
OR  
(b) FOR LONG-ACTING PRODUCTS:

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- i. Documentation that the member had an adequate trial (MINIMUM OF 2 WEEKS) and therapeutic failure or documented serious side effects to ONE formulary/preferred ORAL immediate acting products  
AND
    - ii. IF NON-FORMULARY/NON-PREFERRED LONG-ACTING PRODUCT REQUEST:  
Documentation that the member had an adequate trial (MINIMUM OF 2 WEEKS) and therapeutic failure or documented serious side effects to ONE formulary/preferred LONG-ACTING PRODUCT  
AND
  10. FOR DOSING REQUESTS GREATER THAN MORPHINE EQUIVALENT DOSING (MED) LIMIT (PER STATE/LOB) [DOCUMENTATION REQUIRED]:
    - (a) (i) INITIAL MED LIMIT FOR MEMBERS NEW REQUEST- FOR DOSING REQUESTS GREATER THAN MED LIMIT (PER STATE/LOB): Documentation that prescriber has (1) discussed the high dose with the patient, (2) provides a therapeutic clinical rationale for a dose higher than the maximum allowed MED, (3) an appropriate titration schedule to the current dose and (4) plan for maintenance dosing once goals are reached.  
OR
    - (ii) FOR MEMBERS ESTABLISHED ON GREATER THAN MED LIMIT (PER STATE/LOB):  
Dose requested is titrated down from utilization history. If not titrated down or no history available, the prescriber has explained medical necessity for continued dosing above maximum state/line of business MED: (1) A treatment plan that includes a proposed regimen for reducing the dose of opioid or a reason is given why a dose decrease is not recommended for the member. (2) Documentation of member's response to the requested medication (ex. Decreased pain, improved level of functioning or quality of life.)  
AND
    - (b) Provider has submitted an attestation that the following risk assessment was performed WITHIN THE LAST 2 WEEKS: Checked the state's Prescription Monitoring Program/Prescription Drug Monitoring Program (PMP/PDMP) for opioid over dosages or dangerous combinations, Considered a urine drug screen (UDS) or serum medication level, Offered a prescription for naloxone to patients or patient's household if member has risk factors of prior overdose, substance use disorder, doses in excess of 90 Morphine Equivalent Dosing (MED)/ day or concomitant benzodiazepines use, For evidence of Substance use Disorder, prescriber will offer or arrange for evidence based treatment where needed  
AND
    - (c) Documentation of sustained improvement in Pain or Function (e.g., PEG scale with a 30% response from baseline); if no response, a tapering plan has been initiated to discontinue treatment  
AND
  11. FOR BELBUCA REQUESTS: Documentation that member has tried, failed, or has a contraindication to buprenorphine transdermal patch (Butrans) OR member's current daily MED exceeds 80mg
- B. ACTIVE TREATMENT OF CANCER RELATED PAIN, PALLIATIVE CARE OR END-OF LIFE CARE:
1. Documentation of cancer diagnosis or palliative care or end of life care and need for pain therapy  
AND
  2. Prescriber attestation that the member can safely take the requested dose of the requested drug based on their current opioid use history, concurrent medications, and comorbid conditions  
AND
  3. FOR BELBUCA REQUESTS: Documentation that member has tried, failed, or has a contraindication to buprenorphine transdermal patch (Butrans) OR member's current daily MED exceeds 80mg  
AND
  4. (a) FOR NON-PREFERRED/NON-FORMULARY IMMEDIATE ACTING PRODUCTS: Documentation that the member had an adequate trial and therapeutic failure or documented serious side effects to

## Drug and Biologic Coverage Criteria

up to 3 (three) preferred/formulary ORAL immediate acting products at maximally tolerated doses  
OR

### (b) FOR LONG-ACTING PRODUCTS:

- i. Documentation that the member had an adequate trial (MINIMUM OF 2 WEEKS) and therapeutic failure or documented serious side effects to ONE formulary/preferred ORAL immediate acting products  
AND
- ii. IF NON-FORMULARY/NON-PREFERRED LONG-ACTING PRODUCT REQUEST:  
Documentation that the member had an adequate trial (MINIMUM OF 2 WEEKS) and therapeutic failure or documented serious side effects to ONE formulary/preferred LONG-ACTING PRODUCT

## C. ACUTE PAIN [LESS THAN 3 MONTHS OF CONTINUOUS USE OF ANY OPIOID]:

MOLINA REVIEWER NOTE: Includes Butorphanol review

1. (a) Documentation of medical necessity for use of opioids beyond 7 days [DOCUMENTATION REQUIRED]

OR

(b) Prescriber attests or reviewer has found evidence the member has received 7 cumulative days of an opioid in the last 90 days

MOLINA REVIEWER NOTE: For pediatric members 12-18 years of age, see Background American Academy of Pediatrics.

AND

2. If the requested agent contains acetaminophen, then the requested dose of acetaminophen does NOT exceed 4 g/day  
AND
3. If the requested agent contains tramadol, dihydrocodeine, OR codeine, then ONE of the following:  
(a) The member is 18 years of age or over OR (b) The member is between 12 and 18 years of age AND the requested agent will NOT be used for post-operative pain management following a tonsillectomy and/or adenoidectomy  
AND
4. FOR DOSING REQUESTS GREATER THAN MORPHINE EQUIVALENT DOSING (MED) LIMIT (PER STATE/LOB) [DOCUMENTATION REQUIRED]:  
(a) (i) INITIAL MED LIMIT FOR MEMBERS NEW REQUEST- FOR DOSING REQUESTS GREATER THAN MED LIMIT (PER STATE/LOB): Documentation that prescriber has (1) discussed the high dose with the patient, (2) provides a therapeutic clinical rationale for a dose higher than the maximum allowed MED, (3) an appropriate titration schedule to the current dose and (4) plan for maintenance dosing once goals are reached.  
OR  
(ii) FOR MEMBERS ESTABLISHED ON GREATER THAN MED LIMIT (PER STATE/LOB): Dose requested is titrated down from utilization history. If not titrated down or no history available, the prescriber has explained medical necessity for continued dosing above maximum state/line of business MED: (1) A treatment plan that includes a proposed regimen for reducing the dose of opioid or a reason is given why a dose decrease is not recommended for the member. (2) Documentation of member's response to the requested medication (ex. Decreased pain, improved level of functioning or quality of life.)  
AND  
(b) Provider has submitted an attestation that the following risk assessment was performed WITHIN THE LAST 2 WEEKS: Checked the state's Prescription Monitoring Program/Prescription Drug Monitoring Program (PMP/PDMP) for opioid over dosages or dangerous combinations, Considered a urine drug screen (UDS) or serum medication level, Offered a prescription for naloxone to patients or patient's household if member has risk factors of prior overdose, substance use disorder, doses in excess of 90 Morphine Equivalent Dosing (MED)/ day or concomitant benzodiazepines use, For evidence of Substance use Disorder, prescriber will offer or arrange for evidence based treatment where needed

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AND

(c) Documentation of sustained improvement in Pain or Function (e.g., PEG scale with a 30% response from baseline); if no response, a tapering plan has been initiated to discontinue treatment

AND

### 5. (a) FOR NON-FORMULARY/NON-PREFERRED IMMEDIATE ACTING PRODUCTS:

Documentation that the member had a historic trial and therapeutic failure or documented serious side effects to three PREFERRED/FORMULARY ORAL immediate acting products at maximally tolerated doses

OR

### (b) FOR LONG-ACTING PRODUCTS:

i. Documentation that the member had an adequate trial (MINIMUM OF 2 WEEKS) and therapeutic failure or documented serious side effects to ONE formulary/preferred ORAL immediate acting products

AND

### ii. IF NON-FORMULARY/NON-PREFERRED LONG-ACTING PRODUCT REQUEST:

Documentation that the member had an adequate trial (MINIMUM OF 2 WEEKS) and therapeutic failure or documented serious side effects to ONE formulary/preferred LONG-ACTING PRODUCT

D. METHADONE USE FOR OPIOID USE DISORDER: By law [Certification of Opioid Treatment Programs, 42 Code of Federal Regulations (CFR) 8], only a SAMHSA-certified treatment program (OTP) can dispense methadone for the treatment of OUD. Members taking methadone to treat OUD must receive the medication under the supervision of a practitioner. If needed please send a referral to case management for substance use disorder support.

### E. GREATER THAN 7 DAY SUPPLY OF INITIAL OPIOID FILL:

1. Prescriber attests or reviewer has found evidence the member has received 7 cumulative days of an opioid in the last 90 days (member is not opioid naïve)

OR

2. See ACUTE PAIN [LESS THAN 3 MONTHS OF CONTINUOUS USE OF ANY OPIOID]

### F. EXTENDED RELEASE/LONG-ACTING USE IMMEDIATE RELEASE FIRST:

1. Documentation that the member had an adequate trial (MINIMUM OF 2 WEEKS) and therapeutic failure or documented serious side effects to ONE formulary/preferred ORAL immediate acting products

### G. GREATER THAN MORPHINE EQUIVALENT DOSING (MED) LIMIT (PER STATE/LOB):

1. (a) INITIAL MED LIMIT FOR MEMBERS NEW REQUEST- FOR DOSING REQUESTS GREATER THAN MED LIMIT (PER STATE/LOB): Documentation that prescriber has (1) discussed the high dose with the patient, (2) provides a therapeutic clinical rationale for a dose higher than the maximum allowed MED, (3) an appropriate titration schedule to the current dose and (4) plan for maintenance dosing once goals are reached [DOCUMENTATION REQUIRED].

OR

(b) FOR MEMBERS ESTABLISHED ON GREATER THAN MED LIMIT (PER STATE/LOB): Dose requested is titrated down from utilization history. If not titrated down or no history available, the prescriber has explained medical necessity for continued dosing above maximum state/line of business MED: (1) A treatment plan that includes a proposed regimen for reducing the dose of opioid or a reason is given why a dose decrease is not recommended for the member. (2) Documentation of member's response to the requested medication (ex. Decreased pain, improved level of functioning or quality of life.) [DOCUMENTATION REQUIRED]

AND

2. Provider has submitted an attestation that the following risk assessment was performed WITHIN THE LAST 2 WEEKS: Checked the state's Prescription Monitoring Program/Prescription Drug Monitoring Program (PMP/PDMP) for opioid over dosages or dangerous combinations, Considered

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a urine drug screen (UDS) or serum medication level, Offered a prescription for naloxone to patients or patient's household if member has risk factors of prior overdose, substance use disorder, doses in excess of 90 Morphine Equivalent Dosing (MED)/ day or concomitant benzodiazepines use, For evidence of Substance use Disorder, prescriber will offer or arrange for evidence based treatment where needed

AND

3. Documentation of sustained improvement in Pain or Function (e.g., PEG scale with a 30% response from baseline); if no response, a tapering plan has been initiated to discontinue treatment

## H. QUANTITY LIMIT:

An exception may be granted for increased quantity of a drug on the formulary or the number of doses available under a dose restriction for the prescription formulary drug if:

1. The requested agent is being used to treat a medical condition/disease state that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)  
AND
2. (a) Requested drug is being used for an FDA-approved indication  
OR  
(b) Requested drug is being used for a medically accepted indication that is supported by information from the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.)  
NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy  
AND
3. The maximum allowed dose or frequency has been ineffective in the treatment of the member's disease or medical condition  
AND
4. (a) The requested dose and/or dosing frequency cannot be made with a higher strength and fewer dosages per day.  
OR  
(b) Prescriber attests that the member requires a higher quantity with a lower dose for titration, therapy adjustments, dose alternating schedules, or to accommodate member swallowing issues [treatment plan must be provided for titration/dosage adjustment needs]  
OR  
(c) The prescriber attest that the toxicity risk is not greater than the probable benefit, and there is a specific lab measurement showing inadequate dosing, or there is reasonable clinical rationale to suggest inadequate absorption, or there is reasonable clinical rationale to suggest more rapid metabolism of the drug.

## I. AGE LIMIT:

1. The requested agent is being used to treat a medical condition/disease state that is not otherwise excluded from coverage (i.e., recognized as a covered benefit by the applicable health plan's program)  
AND
2. (a) Requested drug is being used for an FDA-approved indication  
OR  
(b) Requested drug is being used for a medically accepted indication that is supported by information from the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.)  
NOTE: Requests for off-label use will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy  
AND
3. Use for the member's age for the requested indication is FDA labeled or supported by the appropriate compendia of current literature (e.g., AHFS, Micromedex, current accepted guidelines, etc.)

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NOTE: Requests for off-label age will be reviewed using the Off-Label Use of Drugs and Biologic Agents policy  
AND

4. FOR LIQUID DOSAGE FORM REQUESTS: Documentation member is unable to ingest preferred solid dosage form (i.e., tablet or capsule) due to ONE of the following: age, oral/motor difficulties, dysphagia, or member utilizes a feeding tube for medical administration

### CONTINUATION OF THERAPY:

#### A. CHRONIC, SEVERE NON-CANCER PAIN:

1. Documentation of updated treatment plan within the last 6 months OR Prescriber attests opioid therapy continues to be medically necessary  
AND
2. (a) FOR STATES WITH PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): Prescriber attestation that they utilized (and will continue to utilize) the applicable State PDMP prior to issuance of a prescription or continuation of therapy request  
OR  
(b) FOR STATES WITHOUT PDMPs: Prescriber attestation that they will review member's records on a periodic basis or as necessary to ensure no abuse or diversion  
AND
3. Documentation of positive clinical response as demonstrated by improvement or stabilization in pain symptoms and/or pain control.  
AND
4. FOR DOSING REQUESTS GREATER THAN MORPHINE EQUIVALENT DOSING (MED) LIMIT (PER STATE/LOB) [DOCUMENTATION REQUIRED]:
  - (a) Dose requested is titrated down from initial authorization. If not, the prescriber has explained medical necessity for continued dosing above maximum state/line of business MME: (i) A treatment plan that includes a proposed regimen for reducing the dose of opioid or a reason is given why a dose decrease is not recommended for the member. (ii) Documentation of member's response to the requested medication (ex. Decreased pain, improved level of functioning or quality of life.)  
AND
  - (b) Provider has submitted an attestation that the following risk assessment was performed WITHIN THE LAST 2 WEEKS: Checked the state's Prescription Monitoring Program/ Prescription Drug Monitoring Program (PMP/PDMP) for opioid over dosages or dangerous combinations, Considered a urine drug screen (UDS), offered a prescription for naloxone to patients or patient's household if member has risk factors of prior overdose, substance use disorder, doses in excess of 90 Morphine Equivalent Dosing (MED)/day or concomitant benzodiazepines use, For evidence of Substance use Disorder, prescriber will offer or arrange for evidence based treatment where needed  
AND
  - (c) Documentation of sustained improvement in Pain or Function (e.g., PEG scale with a 30% response from baseline); if no response, a tapering plan has been initiated to discontinue treatment

#### B. ACTIVE TREATMENT OF CANCER RELATED PAIN, PALLIATIVE CARE OR END OF LIFE CARE:

1. Documentation of positive clinical response as demonstrated by improvement or stabilization in pain symptoms and/or pain control

#### C. ACUTE PAIN [LESS THAN 3 MONTHS OF CONTINUOUS USE OF ANY OPIOID]:

1. Documentation of positive clinical response as demonstrated by improvement or stabilization in pain symptoms and/or pain control  
AND
2. FOR DOSING REQUESTS GREATER THAN MORPHINE EQUIVALENT DOSING (MED) LIMIT (PER STATE/LOB) [DOCUMENTATION REQUIRED]:
  - (a) Dose requested is titrated down from initial authorization. If not, the prescriber has

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explained medical necessity for continued dosing above maximum state/line of business MME: (i) A treatment plan that includes a proposed regimen for reducing the dose of opioid or a reason is given why a dose decrease is not recommended for the member. (ii) Documentation of member's response to the requested medication (ex. Decreased pain, improved level of functioning or quality of life.)  
AND

- (b) Provider has submitted an attestation that the following risk assessment was performed WITHIN THE LAST 2 WEEKS: Checked the state's Prescription Monitoring Program/ Prescription Drug Monitoring Program (PMP/PDMP) for opioid over dosages or dangerous combinations, Considered a urine drug screen (UDS), offered a prescription for naloxone to patients or patient's household if member has risk factors of prior overdose, substance use disorder, doses in excess of 90 Morphine Equivalent Dosing (MED)/day or concomitant benzodiazepines use, For evidence of Substance use Disorder, prescriber will offer or arrange for evidence based treatment where needed  
AND
- (c) Documentation of sustained improvement in Pain or Function (e.g., PEG scale with a 30% response from baseline); if no response, a tapering plan has been initiated to discontinue treatment

D. GREATER THAN MORPHINE EQUIVALENT DOSING (MED) LIMIT (PER STATE/LOB): N/A refer to initial authorization criteria

E. QUANTITY LIMIT: N/A refer to initial authorization criteria

F. AGE LIMIT: N/A refer to initial authorization criteria

### **DURATION OF APPROVAL:**

Initial authorization: Chronic Pain: 6 months, Cancer, End-of-Life, Palliative Care: 12 months, Acute Pain: 30 days or less

Continuation of Therapy: Chronic Pain: 12 months, Cancer, End-of-Life, Palliative Care: 12 months, Acute Pain: 3 months, All others: N/A refer to initial authorization criteria

### **PRESCRIBER REQUIREMENTS:**

Prescribed by or in consultation with a surgeon, pain management specialist, hematologist/oncologist, hospice provider or palliative care specialist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

Prescriptions for ACUTE PAIN (and within state/LOB MME): will be exempt from prescriber requirements

### **AGE RESTRICTIONS:**

Tramadol, dihydrocodeine, or codeine containing agents: 12 years of age and older

Meperidine: 64 years of age or younger

Belbuca (buprenorphine buccal film), Butrans (buprenorphine transdermal): 18 years of age and older

Methadone: 18 years of age and older

Stadol: 18 years of age and older

### **QUANTITY:**

Belbuca (buprenorphine buccal film): maximum 900mcg every 12 hours

Butrans (buprenorphine transdermal): maximum 20 mcg/hr transdermal every 7 days

Fentanyl patches: 10 patches per 30 days

NOTE: For request for quantities above 10 patches/30 days (1 patch every 72 hours): Prescriber to provide documentation that member has failed 72-hour dosing and is experiencing end of dosage pain AND prescriber has evaluated if the member has had patch exposure to heat that could be increasing the rate of absorption of fentanyl from the transdermal patch. Maximum quantity is 1 patch every 48 hours if met.

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## Drug and Biologic Coverage Criteria

Methadone: 5mg and 10mg tablets formulary quantity limit 360 tabs/30 days (can approve up to requested quantity if MED exception met)

Stadol (butorphanol): 15ml per 30 days formulary quantity limit

\*Medications with a Morphine Equivalent Dosing (MED) > 200 for those patients without a diagnosis of cancer, end-of-life or palliative care, will require a medical director review

### PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that transdermal medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that intranasal medications in this policy will be for pharmacy benefit coverage and patient self-administered.

## DRUG INFORMATION

### ROUTE OF ADMINISTRATION:

Transdermal, Intranasal, Oral

### DRUG CLASS:

Antiperistaltic Agents, Opioid Agonists, Opioid Combinations, Codeine Combinations, Hydrocodone Combinations, Tramadol Combinations, Opioid Partial Agonists

### FDA-APPROVED USES:

Refer to individual product

### COMPENDIAL APPROVED OFF-LABELED USES:

None

## APPENDIX

### APPENDIX:

#### ***State Specific Information***

#### **State Marketplace**

**Illinois** (Source: [Illinois General Assembly](#))

“(720 ILCS 570/315.7 new) Sec. 315.7. Chronic pain treatment. (a) In this Section: "Chronic pain" means a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or which may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years. "Chronic pain" is considered to be pain that persists for more than 12 weeks and is adversely affecting the function or well-being of the individual. "Opioid" means a narcotic drug or substance that is a Schedule II controlled substance under paragraph (1), (2), (3), or (5) of subsection (b) or under subsection (c) of Section 206. (b) Decisions regarding the treatment of patients experiencing chronic pain shall be made by the prescriber with dispensing by the pharmacist in accordance with the corresponding responsibility as described in 21 CFR 1306.04(a) and 77 Ill. Adm. Code 3100.380(a). (c) *Ordering, prescribing, dispensing, administering, or paying for controlled substances, including opioids, shall not in any way be predetermined by specific morphine milligram equivalent guidelines* except as provided under federal law. (d) Nothing in this Section shall interfere with the review of prescriptions by the Prescription Monitoring Program's Peer Review Committee. In reviewing prescriptions for chronic pain, the peer review committee members shall review the most updated clinical guidelines on treating chronic pain for the period the prescriptions were written.”

**APPENDIX 1:**

OPIOID (doses in mg/day except where noted)	CONVERSION FACTOR
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1
Hydromorphone	4
Methadone	
1-20 mg/day	4
21-40 mg/day	8
41-60 mg/day	10
≥ 61-80 mg/day	12
Morphine	1
Oxycodone	1.5
Oxymorphone	3

**BACKGROUND AND OTHER CONSIDERATIONS**

**BACKGROUND:**

90 MME/day:

- 90 mg of hydrocodone (9 tablets of hydrocodone/ acetaminophen 10/325)
- 60 mg of oxycodone (~2 tablets of oxycodone sustained release 30 mg)
- ~20 mg of methadone (4 tablets of methadone 5 mg)

CDC Guidelines:

The CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 includes recommendations for managing acute (duration of <1 month), subacute (duration of 1–3 months), and chronic (duration of >3 months) pain. The recommendations do not apply to pain related to sickle cell disease or cancer or to patients receiving palliative or end-of-life care. The CDC recommends that persons with pain receive appropriate pain treatment, with careful consideration of the benefits and risks of all treatment options in the context of the patient’s circumstances. Recommendations should not be applied as inflexible standards of care across patient populations. The clinical practice guideline is intended to improve communication between clinicians and patients about the benefits and risks of pain treatments, including opioid therapy; improve the effectiveness and safety of pain treatment; mitigate pain; improve function and quality of life for patients with pain; and reduce risks associated with opioid pain therapy, including opioid use disorder, overdose, and death.

Chronic Pain Management in Sickle Cell Disease

The American Society of Hematology 2020 guidelines for sickle cell disease pain management recommends AGAINST the initiation of chronic opioid therapy for emerging or chronic pain unless pain is refractory to multiple other treatment modalities (conditional recommendation). For those receiving opioids who are functioning well and have perceived benefit, the guidelines suggest shared decision making for continuation of opioids (conditional recommendation). Nonopioid therapies recommended for chronic pain in sickle cell disease with no identifiable cause for pain beyond sickle disease include: SNRIs (e.g., duloxetine and milnacipran), TCAs (e.g., amitriptyline), and gabapentinoids (e.g., pregabalin) (conditional recommendations).

Methadone:

Do not abruptly discontinue methadone in a physically dependent member.

American Academy of Pediatrics:

The 2024 AAP Opioid Prescribing for Acute Pain Management in Children and Adolescents in Outpatient Settings: Clinical Practice Guideline is the first guideline regarding opioid use in children with acute pain.

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## Drug and Biologic Coverage Criteria

The goal of the guidelines was to provide clinicians with a clear, objective framework for the safe treatment of acute pain in the outpatient setting while reducing the risk of addiction, overdose, or other harmful effects. The AAP advises clinicians to start with the lowest possible dose based on age and weight, to use an immediate-release formula, and provide no more than a 5-day supply, unless trauma or surgery calls for longer-term pain management. Opioids should not be used as the only strategy when treating pain in this population. Naloxone is recommended to be prescribed along with each opioid prescription and overdose recognition training should be provided to caregivers. The AAP also suggests restricting the use of codeine or tramadol among children under age 12; teens aged 12-18 with obesity, obstructive sleep apnea, or severe lung disease; and patients under age 18 with postsurgical pain after tonsillectomy or adenoidectomy. Caution should be used when prescribing opioids for children or teens who are already taking sedating medications, such as benzodiazepines. When treating acute, worsening pain in patients with preexisting chronic pain, clinicians should prescribe opioids when indicated and partner with any other opioid-prescribing clinicians involved in the patient's care and with specialists in chronic pain and other opioid stewardship programs. By following these guidelines, clinicians can provide adequate pain management in this population while reducing risks of adverse outcomes.

### **Conditions for Distribution and Use of Methadone Products for The Treatment Of Opioid Addiction Code of Federal Regulations, Title 42, Sec 8**

Methadone products when used for the treatment of opioid addiction in detoxification or maintenance programs, shall be dispensed only by opioid treatment programs (and agencies, practitioners, or institutions by formal agreement with the program sponsor) certified by the Substance Abuse and Mental Health Services Administration and approved by the designated state authority. Certified treatment programs shall dispense and use methadone in oral form only and according to the treatment requirements stipulated in the Federal Opioid Treatment Standards (42 CFR 8.12). See below for important regulatory exceptions to the general requirement for certification to provide opioid agonist treatment. Failure to abide by the requirements in these regulations may result in criminal prosecution, seizure of the drug supply, revocation of the program approval, and injunction precluding operation of the program.

Regulatory Exceptions to The General Requirement for Certification To Provide Opioid Agonist Treatment: During inpatient care, when the member was admitted for any condition other than concurrent opioid addiction (pursuant to 21CFR 1306.07(c)), to facilitate the treatment of the primary admitting diagnosis). During an emergency period of no longer than 3 days while definitive care for the addiction is being sought in an appropriately licensed facility (pursuant to 21CFR 1306.07(b)). Note: Outpatient maintenance and outpatient detoxification treatment may be provided only by Opioid Treatment Programs (OTPs) certified by the Federal Substance Abuse and Mental Health Services Administration (SAMHSA) and registered by the Drug Enforcement Administration (DEA). This does not preclude the maintenance treatment of a member with concurrent opioid addiction who is hospitalized for conditions other than opioid addiction and who requires temporary maintenance during the critical period of his/her stay, or of a member whose enrollment has been verified in a program which has been certified for maintenance treatment with methadone.

### **CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of opioids are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy. Contraindications to opioids include: Significant respiratory depression, Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment, Known or suspected gastrointestinal obstruction, including paralytic ileus, Hypersensitivity to the requested agent. Contraindications to fentanyl include: patients who are not opioid-tolerant, the management of acute or intermittent pain, or in patients who require opioid analgesia for a short period of time, the management of post-operative pain, including use after out-patient or day surgeries, (e.g., tonsillectomies), the management of mild pain, patients with significant respiratory depression, patients with acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, in patients with known or suspected gastrointestinal obstruction, including paralytic ileus, patients with hypersensitivity to fentanyl.

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Contraindications to methadone include: Hypersensitivity (e.g., anaphylaxis) to methadone or any component of the formulation; significant respiratory depression (in the absence of resuscitative equipment or in unmonitored settings); acute or severe bronchial asthma (in the absence of resuscitative equipment or in an unmonitored setting); hypercarbia; GI obstruction, including paralytic ileus (known or suspected).

Contraindications to codeine include: Significant respiratory depression, Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days, Known or suspected gastrointestinal obstruction, including paralytic ileus, Hypersensitivity to codeine (e.g., anaphylaxis).

### **OTHER SPECIAL CONSIDERATIONS:**

Food and Drug Administration (FDA) Black Box warning on concomitant use with benzodiazepines: Food and Drug Administration (FDA) black box warning: Health care professionals should limit prescribing opioid pain medicines with benzodiazepines or other central nervous system (CNS) depressants only to patients for whom alternative treatment options are inadequate. If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect.

Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation and the associated signs and symptoms. Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other central nervous system (CNS) depressants, including alcohol.

[www.fda.gov/Drugs/DrugSafety/ucm518473.htm](http://www.fda.gov/Drugs/DrugSafety/ucm518473.htm)

Methadone FDA Black Box Warning for risk of medication errors; addiction, abuse and misuse; risk evaluation and mitigation strategy (REMS); life-threatening respiratory depression; accidental ingestion; life-threatening QT prolongation; neonatal opioid withdrawal syndrome; interactions with drugs affecting cytochrome p450 isoenzymes; risks from concomitant use with benzodiazepines or other CNS depressants; and treatment for opioid addiction.

Butorphanol nasal spray has a Black Box Warning for serious and life-threatening risks from use of butorphanol tartrate nasal spray due to addiction, abuse, and misuse, life-threatening respiratory depression, accidental exposure, risks from concomitant use with benzodiazepines or other CNS depressants, neonatal opioid withdrawal syndrome, and cytochrome P450 3A4 interactions. There is a REMS program.

Opioids are controlled substances controlled substance under the Controlled Substances Act.

## **CODING/BILLING INFORMATION**

***CODING DISCLAIMER.*** Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

<b>HCPCS CODE</b>	<b>DESCRIPTION</b>
NA	

### **AVAILABLE DOSAGE FORMS:**

acetaminophen/codeine, Apadaz (benzhydrocodone/APAP), Belbuca (buprenorphine buccal film), Benzhydrocodone-Acetaminophen, buprenorphine TD patch, butorphanol nasal soln, Butrans (buprenorphine transdermal system), codeine sulfate, ConZip (tramadol ER), dilaudid, Endocet (oxycodone/APAP), fentanyl, fentanyl patch, hydrocodone bitartrate ER, hydrocodone/APAP, hydrocodone/ibuprofen, hydromorphone ER AD, hydromorphone, Hysingla ER (hydrocodone bitartrate

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ER), levorphanol tartrate tabs, meperidine solution, meperidine tabs, methadone concentrate, methadone intensol, methadone solution, methadone tabs, methadone TBSA, Methadose TBSO (methadone tab for oral susp), morphine sulfate concentrate oral solution, morphine sulfate ER beads, morphine sulfate ER capsules, morphine sulfate ER tabs, morphine sulfate soln, morphine sulfate suppository, morphine sulfate tabs, MS Contin (morphine sulfate tab ER), Nalocet (oxycodone/APAP), Nucynta ER (tapentadol ER), Nucynta (tapentadol), oxycodone caps, oxycodone concentrate solution, oxycodone tabs, oxycodone/APAP, OxyContin (oxycodone ER), oxymorphone ER, oxymorphone, Percocet (oxycodone/APAP), Prolate (oxycodone/APAP), Qdolo (tramadol soln), Roxicodone (oxycodone) tabs, RoxyBond (oxycodone AD), Synapryn FusePaq (tramadol oral susp), tramadol ER, tramadol, tramadol/acetaminophen, Xtampza ER (oxycodone ER AD)

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Products Affected Required Medical Information Age Restrictions Background	Q1 2025
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REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Duration of Approval Age Restrictions Quantity Route of Administration Drug Class FDA-Approved Uses Background Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2023
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Age Restrictions Available Dosage Forms	Q3 2022
Q2 2022 Established tracking in new format	Historical changes on file