Original Effective Date: 09/01/2016
Current Effective Date: 03/24/2023
Last P&T Approval/Version: 01/25/2023
Next Review Due By: 01/2024
Policy Number: C16263-A

Opioid Global Criteria

PRODUCTS AFFECTED

Abstral (fentanyl SL tab), acetaminophen/codeine, Actiq (fentanyl lozenge) Apadaz (benzhydrocodone/APAP), Arymo ER (morphine sulfate ER AD), Belbuca (buprenorphine buccal film), buprenorphine TD patch, Butrans (buprenorphine transdermal system), codeine sulfate, ConZip (tradmadol ER), Conzip (tramadol ER biphasic), Demerol, dilaudid, Dolophine (methadone tab), Duragesic (fentanyl) patch, Embeda (morphine/naltrexone), Endocet (oxycodone/APAP), fentanyl patch, fentanyl 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), Morphabond (morphine sulfate ER AD), morphine sulfate, MS Contin (morphine sulfate tab ER), Nalocet (oxycodone/APAP), Nucynta (tapentadol), Nucynta ER (tapentadol ER), Opana (oxymorphone), Opium Tincture, Oxaydo (oxycodone AD), oxycodone, oxycodone/APAP, oxycodone/ASA, oxycodone/Ibuprofen, OxyContin (oxycodone ER), oxymorphone ER, oxymorphone, Paregoric TINC., Percocet (oxycodone/APAP), Primlev (oxycodone/ APAP), Roxicodone (oxycodone) tabs, Roxybond (oxycodone AD), Subsys (fentanyl SL spray), Synapryn FusePaq (tramadol oral susp), tramadol ER, tramadol, Ultram (tramadol),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

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.

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.
      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 (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

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 rational 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
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 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]:

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
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 rational 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

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 rational 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 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.)
   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 CONTINOUS 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 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

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

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

Prescriptions for ACUTE PAIN [LESS THAN 6 MONTHS OF CONTINUOUS USE OF ANY OPIOID]: 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

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

*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.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Transdermal and 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:

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.

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. 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
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

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Abstral (fentanyl SL tab), acetaminophen/codeine, Actiq (fentanyl lozenge), Apadaz (benzhydrocodone/APAP), Arymo ER (morphine sulfate ER AD), codeine sulfate, ConZip (tradmadol ER), Demerol, dilaudid, Embeda (morphine/naltrexone), Endocet (oxycodone/APAP), fentanyl hydrocodone/APAP, hydrocodone/ibuprofen, hydromorphone ER AD, hydromorphone tabs, Hysingla ER (hydrocodone bitartrate ER), Kadian, (morphine sulfate ER), Lazanda (fentanyl citrate nasal spray), levorphanol tartrate tabs, meperidine solution, meperidine tabs, methadone concentrate, methadone intensol, methadone solution, methadone tabs, Morphabond (morphine sulfate ER AD), morphine sulfate concentrate oral solution, morphine sulfate ER beads, morphine sulfate ER capsules, morphine sulfate ER tabs, morphine sulfate suppository, morphine sulfate tabs, MS Contin (morphine sulfate tab ER), Nalocet (oxycodone/APAP), Nucynta ER (tapentadol ER), Nucynta (tapentadol), Opana (oxymorphone), Oxaydo (oxycodone AD), oxycodone caps, oxycodone concentrate solution, oxycodone ER tabs, oxycodone tabs, oxycodone/APAP, oxycodone/ASA, Oxycodone/Ibuprofen, OxyContin (oxycodone ER), oxymorphone ER, oxymorphone, Percocet (oxycodone/APAP), Primlev (oxycodone/APAP), Roxicodone (oxycodone) tabs, Roxybond (oxycodone AD), Subsys (fentanyl SL spray), Synapryn FusePaq (tramadol oral susp), tramadol ER, tramadol, Ultram (tramadol), Conzip (tramadol ER biphasic), Xtampza ER (oxycodone ER AD), Zohydro (hydrocodone bitartrate ER AD), Opium tincture, Paregoric tincture, Belbuca (buprenorphine buccal film), Butrans (buprenorphine transdermal system), buprenorphine TD patch, Duragesic (fentanyl) patch, fentanyl patch, Dolophine (methadone tab), Methadone, Methadose TBSO (methadone tab for oral susp), Methadone TBSO, Stadol (butorphanol tartrate), butorphanol nasal soln

REFERENCES

1. Butrans Prescribing Information. Stamford, CT. Purdue Pharma L.P. June 2022.
2. Belbuca Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. June 2022.
3. Duragesic (fentanyl) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; March 2021.
4. Fentanyl transdermal patch [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc; November 2019.
5. Fentanyl transdermal system [prescribing information]. Caldwell, NJ: LTS Lohmann Therapy Systems Corp; August 2021.
6. Dolophine (methadone) [prescribing information]. Eatontown, NJ: West-Ward Pharmaceuticals; June 2021.
7. Methadone Hydrochloride Intensol [prescribing information]. Eatontown, NJ: Hikma Pharmaceuticals USA Inc; April 2021.
8. Methadone Hydrochloride oral solution [prescribing information]. Eatontown, NJ: West-Ward Pharmaceuticals Corp; July 2020
9. Methadone Hydrochloride tablets [prescribing information]. Largo, FL: VistaPharm Inc; September 2021.
10. Methadose oral concentrate and Methadose sugar-free oral concentrate (methadone hydrochloride) [prescribing information]. Webster Groves, MO: Mallinckrodt Inc; June 2021.
11. Methadose (methadone) tablet for oral suspension [prescribing information]. WebsterGroves, MO: SpecGx LLC; September 2021.
12. Kurt Kroenke, Daniel P Alford, Charles Argoff, Bernard Canlas, Edward Covington, Joseph W Frank, Karl J Haake, Steven Hanling, W Michael Hooten, Stefan G Kertesz, Richard L Kravitz, Erin E Krebs, Steven P Stanos, Mark Sullivan; Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report, Pain Medicine, , pny307, https://doi.org/10.1093/pm/pny307
13. Cdc.gov. (2019). CDC Guideline for Prescribing Opioids for Chronic Pain | Drug Overdose CDC Injury Center. [online] Available at: https://www.cdc.gov/drugoverdose/prescribing/guideline.html [Accessed 20 Feb. 2019].
14. Aacc.org.(2019).[online]Availableat:https://www.aacc.org/-/media/Files/Science-and-Practice/Practice-Guidelines/Pain- Management/LMPGPain- Management20171220.pdf
15. Centers for Disease Control and Prevention. 2018 Annual Surveillance Report of Drug-Related Risks and Outcomes — United States. Surveillance Special Report 2. Centers for Disease Control

and Prevention, U.S. Department of Health and Human Services. Published August 31,2018.
16. FDA News Release. SAMHSA and FDA Join to Educate the Public on the Safe Use of Methadone. Food and Drug Administration Website. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149572.htm
17. Medication-Assisted Treatment for Substance Use Disorders. Follow Directions: How-to Use Methadone Safely. Division of Pharmacologic Therapies Website. http://www.dpt.samhsa.gov/methadonesafety/
18. DEA Methadone Fact Sheet.http://www.justice.gov/dea/druginfo/drug_data_sheets/Methadone.pdf. 2015
19. Kampman, K. and Jarvis, M. (2015). American Society of Addiction Medicine (ASAM)National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. Journal of Addiction Medicine, 9(5), pp.358-36
20. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1
21. Brandow, A. M., Carroll, C. P., Creary, S., Edwards-Elliott, R., Glassberg, J., Hurley, R. W., Lang, E. (2020). American Society of Hematology 2020 Guidelines for Sickle Cell Disease: Management of acute and chronic pain. Blood Advances, 4(12), 2656-2701. doi:10.1182/bloodadvances.2020001851

SUMMARY OF REVIEW/REVISIONS	DATE
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