# Pharmacy Medical Necessity Guidelines:

# Opioids and Analgesics

*Effective: May 12, 2025*

| | | | |
|---|---|---|---|
| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | RX | Department to Review | RXUM |
| These pharmacy medical necessity guidelines apply to the following:<br>☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans | | **Fax Numbers:**<br>RXUM: 617.673.0939 | |

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

## OVERVIEW

### FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Per the Centers for Disease Control and Prevention (CDC) opioid treatment guidelines, nonpharmacologic and nonopioid pharmacologic therapy is often preferred for the treatment of pain. Opioid therapy should be considered only if the expected benefits for pain and function are expected to outweigh the risks associated with opioid therapy.

Prior to initiating opioid therapy, it is recommended that prescribers establish realistic treatment goals with patients and discuss the risks of opioid therapy. Clinicians should also consider how opioid therapy will be discontinued if benefits do not outweigh the risks. Opioid therapy should only be considered if there is a clinically significant improvement in pain and function that outweighs the risk to patient safety. Before starting and periodically during opioid therapy, providers should consider risk factors for opioid-related harm, and incorporate into the treatment plan strategies to decrease risk. This includes offering naloxone when there are factors present that increase the risk of opioid overdose (e.g., history of overdose, history of substance abuse disorder, higher opioid dosages [≥ 50 MME/day], concurrent benzodiazepine use).

Long-acting opioids should be reserved for severe, continuous pain and are not indicated for as-needed use. Long-acting opioids should not be used to treat acute pain, nor should they be used to initiate treatment for subacute or chronic pain.

A number of MME dose calculators are available online. The CDC includes a MME conversion table in the 2022 opioid prescribing guidelines, which can be found at the following link: https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm#T1_down.

Journavx is the first new class of pain medicine to be approved for the treatment of moderate to severe acute pain in many years. It is an oral medication designed to selectively inhibit the NaV1.8 voltage-gated sodium channel, which plays a crucial role in transmitting pain signals in peripheral nociceptors.86 Journavx® is a non-opioid, reportedly non-addictive, alternative to current standards of care for pain severe enough to justify the use of opioid medications.

Tufts Health Together participates in the MassHealth Unified Formulary. MassHealth permits managed care organizations to have different daily MME and quantity limits. The criteria in this medical necessity guideline incorporate MassHealth's criteria with Tufts Health Plans quantity limits and daily MME restrictions. Please read further for descriptions of MassHealth's clinical opioid programs requiring prior authorization.

### MME Daily Dose Limits

Tufts Health Together requires prior authorization if a member's opioid regimen exceeds 120 morphine milligram equivalents (MME) per day, regardless of whether the regimen consists of one or multiple opioids. Requests for opioid regimens exceeding 120 MME/day will be reviewed against the criteria listed under "High Dose Regimens: Exceeds 120 MME/day for opioid (single- or multi-agent) regimen." Please note that buprenorphine is not included in the MME daily dose limit.

### Opioid Quantity Limits

Tufts Health Together's opioid quantity limits restrict each dosage form to either 90 MME/day or the recommended dose listed in the FDA-approved package labeling. Quantity limits are listed in the "Limitations" section of this Medical Necessity Guideline. Requests to exceed the Plan's quantity limits will be reviewed against criteria listed under "Quantity Limits." **Note: regimens that are within the quantity limits but exceed the daily MME dose limit will still require prior authorization.**

## High Dose Short-Acting

The following short-acting and combination agents will require prior authorization if the agent is being used as monotherapy (i.e., no claim for a long-acting opioid agent in the last 30-days) and the dosage limits listed below are exceeded. Requests will be reviewed against criteria listed under "High Dose Short-Acting Monotherapy."

| Drug | Dose Limit |
|---|---|
| **Single-Agent Opioids** | |
| Codeine | 360 mg/day |
| Hydrocodone | 120 mg/day |
| Hydromorphone | 24 mg/day |
| Morphine IR | 120 mg/day |
| Nucynta† | 300 mg/day |
| Oxaydo | 80 mg/day |
| Oxycodone IR | 80 mg/day |
| Oxymorphone IR | 40 mg/day |
| Tramadol IR | 400 mg/day |
| Tramadol solution | 400 mg/day |
| **Combination Products** | |
| Acetaminophen/codeine | Codeine: 360 mg/day |
| Benzhydrocodone/acetaminophen | 65.28 mg/day |
| Butalbital/acetaminophen/caffeine/codeine | Codeine: 360 mg/day |
| Butalbital/aspirin/caffeine/codeine | Codeine: 360 mg/day |
| Carisoprodol/aspirin/codeine | Codeine: 360 mg/day |
| Hydrocodone/acetaminophen | Hydrocodone: 80 mg/day |
| Hydrocodone/ibuprofen | Hydrocodone: 80 mg/day |
| Oxycodone/acetaminophen | 80 mg/day |
| Oxycodone/aspirin | Aspirin: 4 grams/day<br>Oxycodone: 80 mg/day |
| Seglentis (celecoxib/tramadol) | Tramadol: 400 mg/day |
| Tramadol/acetaminophen | Tramadol: 400 mg/day |

IR = immediate release

## Duplicate Long-Acting Opioids

For any combination of the long-acting opioids listed below, if there is greater than two months of duplicate claims in a member's claims history, the opioid will require prior authorization. Requests will be reviewed against criteria listed under "Duplicate Long-Acting Opioid Regimen."

| | | | |
|---|---|---|---|
| Belbuca | Buprenorphine transdermal | Conzip | Fentanyl transdermal |
| Hydrocodone ER capsule, tablet | Hydromorphone ER | Levorphanol tablet | Methadone injection |
| Methadone oral | Morphine ER capsule (Avinza, Kadian) | Morphine CR tablet | Nucynta ER† |
| Oxycodone ER tablet | Oxymorphone ER oral | Tramadol ER | Xtampza ER† |

## Duplicate Short-Acting Opioids

For any combination of the short-acting opioids, powders, and combination products listed below, if there is greater than two months of duplicate claims in a member's claims history, the opioid will require prior authorization. Requests will be reviewed against criteria listed under "Duplicate Short-Acting Opioid Regimen."

| | | | |
|---|---|---|---|
| APAP/codeine | Benzhydrocodone/APAP | Butalbital/APAP/ caffeine/codeine | Butalbital/ASA/ caffeine/codeine |
| Butorphanol nasal spray | Carisoprodol/ASA/ codeine | Codeine | Dihydrocodeine/APAP/ caffeine |
| Fentanyl buccal tablet | Fentanyl transmucosal | Hydrocodone/APAP | Hydrocodone/ibuprofen |
| Hydromorphone | Meperidine | Morphine IR | Nucynta† |
| Oxaydo | Oxycodone IR | Oxycodone/APAP | Oxycodone/ASA |
| Oxymorphone IR oral | Pentazocine/naloxone | Seglentis | Tramadol IR |
| Tramadol/APAP | Tramadol solution | | |

## Concurrent Therapy with Opioid Dependence Agents

Prior authorization is required if a member is stable on any buprenorphine product used for substance use disorder and is attempting to fill a long-acting opioid (for any length of time), a short-acting opioid

for more than a 7-day supply, or short-acting opioid(s) for more than 7 days of therapy within the last 30 days. "Stability" is defined as the following:

- Buprenorphine/naloxone film or tablet, Zubsolv, or Bunavail: 60 days of therapy within the last 90 days
- Probuphine (buprenorphine implant): history in the past 210 days
- Brixadi or Sublocade: ≥ 56 days of therapy in the last 84 days

Requests will be reviewed against criteria listed under "Concurrent Therapy with Opioid Dependence Agents."

**Concomitant Opioid and Benzodiazepine Initiative (COBI)**

All opioids that are new additions to a member's regimen will require prior authorization if there is history of concomitant use of any benzodiazepine (with the exception of clobazam, diazepam nasal spray, diazepam rectal gel, midazolam nasal spray, and injectables) for at least 15 day supply within the past 45-day period.

## COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred opioid analgesic for Members when **ALL** of the following criteria are met:

### INITIAL CRITERIA

#### DUPLICATE THERAPY

**Duplicate Long-Acting Opioid Regimen**

1. Individual prior authorization criteria met, if applicable

**AND**

2. Documentation of clinical rationale for not maximizing monotherapy

**Duplicate Short-Acting Opioid Regimen**

1. Individual prior authorization criteria met, if applicable

**AND**

2. Documentation of clinical rationale for not maximizing monotherapy

**Concurrent Therapy with Opioid Dependence Agents**

1. Individual prior authorization criteria met, if applicable

**AND**

2. Clinical rationale why concurrent therapy with buprenorphine is clinically appropriate

#### QUANTITY/HIGH DOSE LIMITS

**Quantity Limits**

1. Individual prior authorization criteria met, if applicable

**AND**

2. Requested dose cannot be obtained within the established quantity limits

**High Dose Short-Acting Monotherapy *(Claims for short-acting and combination agents exceeding dosage limits and being used as monotherapy [i.e., no claims for long-acting opioid agent within the last 30 days])***

1. Individual drug prior authorization criteria met, if applicable

**AND**

2. Medical records documenting treatment plan, including rationale for high dose and titration of medication up to current dose

**AND**

3. Pain consult from pain specialist supporting the high dose of opioid requested

**AND**

4. Clinical rationale for not utilizing a long-acting agent in a member requiring high dose short-acting opioid therapy for the treatment of chronic pain

**AND**

5. Signed and dated patient-prescriber agreement

**AND**

6. Member is co-prescribed naloxone or has naloxone filled within the previous year and is unused

**High Dose Regimens: Exceeds 120 MME/day for opioid (single- or multi-agent) regimen (excluding buprenorphine)**

1. Individual drug prior authorization criteria met, if applicable

**AND**

2. ONE of the following:
    a. Diagnosis of sickle cell disease

    **OR**

    b. Diagnosis of active cancer pain

    **OR**

    c. Member's pain control is currently managed by palliative care

    **OR**

    d. Member is currently in hospice or is transitioning to hospice

    **OR**

    e. ONE of the following:
        i. ALL of the following:
            1. Medical records documenting a treatment plan including the rationale for high dose and titration of medication up to the current dose

            **AND**

            2. Pain consult from pain specialist supporting the high dose or opioid requested or anticipated date of upcoming pain consult is provided

            **AND**

            3. Signed and dated patient-prescriber agreement

            **AND**

            4. Member is co-prescribed naloxone or has naloxone filled within the previous year and is unused in

        **OR**

        ii. ALL of the following:
            1. Medical records documenting treatment plan to initiate a taper of requested medication within the next 90 days

            **AND**

            2. Sign and dated patient-prescriber agreement

            **AND**

            3. Member is co-prescribed naloxone or has naloxone filled within the previous year and is unused

**High Dose Formulations (≥ 90 MME/day with one unit dose or as prescribed per the FDA-approved package labeling): Fentanyl 50 mcg/hour (Duragesic) patch, Morphine sulfate extended-release (MS Contin) 60, 100, 200 mg tablet**

1. ONE of the following:
    a. Diagnosis of sickle cell disease

    **OR**

    b. Diagnosis of active cancer pain

    **OR**

    c. Member's pain control is currently managed by palliative care

    **OR**

    d. Member is currently in hospice or is transitioning to hospice

    **OR**

    e. ONE of the following:
        i. ALL of the following:
            1. Medical records documenting a treatment plan including the rationale for high dose and titration of medication up to the current dose

            **AND**

            2. Pain consult from pain specialist supporting the high dose or opioid requested

**AND**

3. Signed and dated patient-prescriber agreement

**AND**

4. Member is co-prescribed naloxone or has naloxone filled within the previous year and is unused

**OR**

ii. ALL of the following:

1. Medical records documenting treatment plan to initiate a taper of requested medication within the next 90 days

**AND**

2. Sign and dated patient-prescriber agreement

**AND**

3. Member is co-prescribed naloxone or has naloxone filled within the previous year and is unused

**Acetaminophen > 4 grams/day, aspirin > 4 grams/day, ibuprofen > 3,200 mg/day**

1. Documentation individual prior authorization criteria is met first, when applicable

**AND**

2. Documentation of clinical rationale for utilizing greater than 4 grams of acetaminophen, greater than 4 grams of aspirin, or greater than 3,200 mg of ibuprofen per day

**CONCOMITANT OPIOIDS AND BENZODIAZEPINES (COBI)**

**Claims for ≥ 15 day supply for opioid(s) (new to therapy and benzodiazepine(s) for ≥ 15 day supply (does not include clobazam, nasal diazepam, rectal diazepam, nasal midazolam, or injectable benzodiazepine formulations) within the past 45-day period**

1. Documentation individual prior authorization criteria is met first, when applicable

**AND**

2. Documentation of appropriate diagnosis for the opioid (e.g., acute pain, chronic pain, cancer pain)

**AND**

3. Documentation of appropriate diagnosis for the benzodiazepines (e.g., anxiety disorder, panic disorder, musculoskeletal disorder, sleep disorder, seizure disorder)

**AND**

4. Documentation of ONE of the following:
    a. Member is currently stable on chronic opioid
    b. Member's treatment is currently managed by palliative care
    c. Member is currently in hospice or is transitioning to hospice
    d. Member is currently being treated for sickle cell disease or cancer pain
    e. Inadequate response or adverse reaction to THREE non-opioid therapies (e.g., prescription NSAIDs, topical analgesics, physical therapy)
    f. Clinical rationale for the use of opioids instead of non-opioid alternatives
    g. Treatment plan to taper off opioid therapy
    h. Treatment plan to taper off or taper down from benzodiazepine therapy
    i. Clinical rationale for the concomitant use of opioids and benzodiazepines

**AND**

5. Member will be co-prescribed naloxone

**DRUG-SPECIFIC CRITERIA**

**Actiq (fentanyl transmucosal system)**

1. Documented indication of breakthrough pain

**AND**

2. Documentation of adverse reaction or contraindication to ALL of the following:
    a. Hydromorphone immediate-release
    b. Morphine immediate-release
    c. Oxycodone immediate-release

**AND**

3. Documentation member is maintained on a long-acting opioid regimen

**AND**

4. Documentation the prescriber is an oncologist or pain specialist

**Belbuca (buprenorphine buccal film)**

1. Documented diagnosis of pain

**AND**

2. Documentation of ONE of the following:
    a. Adverse reaction or contraindication to morphine sulfate extended-release

    **OR**

    b. Medical necessity for buccal formulation (i.e., inability to take oral medications)

    **OR**

    c. Prescriber wants to avoid using a full opioid agonist

    **OR**

    d. Treatment plan to microdose buprenorphine with the intent to taper off full agonist opioid therapy (to include opioid taper plan, buprenorphine dosing, and tapering schedule)

    **AND**

3. Requested dose is ≤ 1,800 micrograms/day

**Benzhydrocodone/acetaminophen (Apadaz); hydrocodone 5 mg, 10 mg/ibuprofen; oxycodone/acetaminophen 300 mg; dihydrocodeine/acetaminophen/caffeine**

1. Documented diagnosis of pain

**AND**

2. Medical records documenting an inadequate response, adverse reaction, or contraindication to one agent from ALL of the following combination analgesics:
    a. Codeine/acetaminophen
    b. Hydrocodone/acetaminophen
    c. Hydrocodone/ibuprofen
    d. Oxycodone/acetaminophen

**Buprenex (buprenorphine injection)**

1. Documentation of diagnosis of pain

**AND**

2. Documentation of clinical rationale why oral pain medications cannot be used

**AND**

3. Adverse reaction or contraindication to BOTH of the following:
    a. Butrans (buprenorphine transdermal)
    b. Fentanyl transdermal

**Butorphanol nasal spray**

**Acute Pain**

1. Documented diagnosis of acute pain

**AND**

2. Medical records documenting ONE of the following:
    a. Adverse reaction or contraindication to ALL of the following generic short-acting opioids:
        i. Codeine
        ii. Hydromorphone
        iii. Morphine
        iv. Oxycodone

    **OR**

    b. ALL of the following:
        i. Medical necessity for nasal spray formulation (inability to swallow oral tablets or capsules)
        ii. Adverse reaction or contraindication to BOTH of the following:

1. Morphine immediate-release solution
2. Oxycodone immediate-release solution

**AND**

3. Requested quantity is ≤ 2 canisters per 30 days

**Acute Migraine**

1. Butorphanol being used for treatment of acute migraine

**AND**

2. Medical records documenting an inadequate response or adverse reaction to TWO or contraindication to ALL triptans

**AND**

3. Documentation of ONE of the following:
    a. Medical records documenting an inadequate response or adverse reaction to ONE additional triptan

    **OR**

    b. Medical records documenting an inadequate response, adverse reaction, or contraindication to ONE agent from a different anti-migraine medication class (ergotamine products [Migranal or Cargot], Fioricet, or Fiorinal)

**AND**

4. Requested quantity is ≤ 2 canisters per 30 days

**Acute Migraine – Tapering off Butorphanol**

1. Butorphanol being used for treatment of acute migraine

**AND**

2. Medical records documenting that member is on chronic butorphanol

**AND**

3. Treatment plan including taper period for discontinuation

**AND**

4. Requested quantity is ≤ 2 canisters per 30 days

**Fentanyl transdermal 37.5 mcg/hour, 62.5 mcg/hour, 87.5 mcg/hour**

1. Documented diagnosis of pain

**AND**

2. Documentation of clinical rationale why two patches cannot be combined to obtain the equivalent strength of the patch requested

**Fentora (fentanyl buccal tablet)**

1. Documented indication of breakthrough cancer pain

**AND**

2. Documented adverse reaction or contraindication to ALL of the following:
    a. Fentanyl transmucosal system (generic Actiq)
    b. Hydromorphone immediate-release
    c. Morphine immediate-release
    d. Oxycodone immediate-release

**AND**

3. Documentation the member is maintained on a long-acting opioid regimen

**AND**

4. Prescriber is an oncologist or pain specialist

**Hydromorphone extended-release, Hysingla ER (hydrocodone extended-release tablet), Nucynta ER (tapentadol extended-release)†, Oxymorphone extended-release (oral), Xtampza ER (oxycodone extended-release capsule)†, hydrocodone extended-release capsule (Zohydro ER†)**

1. Documented diagnosis of pain

**AND**

2. Documented adverse reaction or contraindication to ALL of the following:
    a. Fentanyl transdermal

b. Morphine extended-release
c. Oxycodone extended-release

**Hydromorphone suppository**

1. Documented diagnosis of pain

**AND**

2. Medical necessity for the requested formulation instead of solution or tablet formulation

**AND**

Documentation of Inadequate response, adverse reaction or contraindication to morphine suppositories

**Journavx**

1.Documented diagnosis of a NEW acute episode of moderate to severe pain

**AND**

2. Appropriate dosing

**AND**

3. Member is ≥ 18 years of age

**AND**

4. Documentation of medical necessity for another 14-day course of therapy (i.e., new episode of acute pain unrelated to the original indication)

**Levorphanol tablet**

1. Documented diagnosis of pain

**AND**

2. Documentation of adverse reaction or contraindication to ALL of the following:
   a. Fentanyl transdermal
   b. Morphine extended-release
   c. Oxycodone extended-release

**AND**

3. Clinical rationale for the use of levorphanol instead of ALL other long-acting opioids

**Meperidine (Demerol)**

1. Documented diagnosis of pain

**AND**

2. Documentation of medical necessity due to allergy (NOT adverse reaction) to morphine

**AND**

3. Documentation member has not used morphine derivatives since documented date of morphine allergy

**Methadone (oral) (Methadose)**

1. Documented diagnosis of pain

**AND**

2. Documentation the member is not opioid naïve

**AND**

3. Documentation of baseline electrocardiogram (ECG) showing a normal QTc internal

**AND**

4. Documentation of ONE of the following:
   a. Adverse reaction or contraindication to fentanyl transdermal AND morphine sulfate extended-release
   b. Clinical rationale for the use of methadone instead of other long-acting opioids

**Methadone injection**

1. Documented diagnosis of pain

**AND**

2. Documentation of medical necessity for use instead of the oral formulations of the same product (e.g., dysphagia)

**Morphine extended-release capsule**

1. Documented diagnosis of pain

**AND**

2. Inadequate response, adverse reaction, or contraindication to morphine extended-release tablets

**AND**

3. Medical necessity for once daily dosing

**Nucynta (tapentadol)†, Oxymorphone immediate-release (oral)**

1. Documented diagnosis of pain

**AND**

2. Documented adverse reaction or contraindication to ALL of the following:
    a. Hydromorphone immediate-release
    b. Morphine immediate-release
    c. Oxycodone immediate-release

**Oxaydo† (oxycodone immediate-release)**

1. Documented diagnosis of pain

**AND**

2. Medical necessity for use instead of oxycodone immediate-release 5mg tablets available without prior authorization

**OxyContin[BP] (oxycodone extended-release tablet)**

1. Documented diagnosis of pain

**AND**

2. Documentation of adverse reaction or contraindication to ONE of the following:
    a. Fentanyl transdermal
    b. Morphine sulfate extended-release

**AND**

2. **Requests for generic formulation:** Medical records documenting ONE of the following:
    a. Trial of the preferred brand formulation

**OR**

    b. Clinical rationale for prescribing the non-preferred drug generic equivalent

**Pentazocine/Naloxone**

1. Documented diagnosis of pain

**AND**

2. Documentation of adverse reaction or contraindication to ALL of the following:
    a. ONE NSAID
    b. Hydromorphone immediate-release
    c. Morphine immediate-release
    d. Oxycodone immediate-release
    e. Tramadol

**AND**

3. Requested dose is ≤ 200 mg/day of pentazocine (4 tables/day)

**RoxyBond (oxycodone immediate-release)**

1. Documented diagnosis of pain

**AND**

2. Medical necessity for use instead of oxycodone immediate-release tablets available without prior authorization

**Seglentis (tramadol/celecoxib)**

1. Documented diagnosis of management of acute pain

**AND**

2. Medical necessity for the use of the combination product instead of the commercially available separate agents

**AND**

3. Tramadol age restriction prior authorization criteria met, as applicable

**Tramadol 25 mg**

1. Documented diagnosis of pain

**AND**

2. Documentation of adverse reaction or contraindication to BOTH of the following:
    a. Tramadol 50 mg tablets
    b. tramadol/acetaminophen tablet

**AND**

3. Age restriction criteria met, if applicable

**Tramadol 100 mg**

4. Documentation diagnosis of pain

**AND**

5. Medical necessity for the use of the 100 mg tablets instead of the 50 mg tablets

**AND**

6. Medical records documenting inadequate response or adverse reaction to tramadol 50 mg tablet (two 50 mg tablets)

**AND**

7. Age restriction criteria met, if applicable

**Tramadol extended-release capsule (Conzip), Tramadol extended-release tablet**

1. Documented diagnosis of pain

**AND**

2. Medical records documenting an inadequate response or adverse reaction to tramadol immediate-release

**AND**

3. Medical necessity for an extended-release formulation

**AND**

4. Age restriction prior authorization criteria met, as applicable

**Tramadol solution (Qdolo)**

1. Diagnosis of moderate to severe pain

**AND**

2. Member is 18 years of age or older

**AND**

3. Documentation of ONE of the following:
    a. Medical necessity for oral solution formulation

    **OR**

    b. Medical records documenting inadequate response or adverse reaction to tramadol immediate-release tablets that are available without prior authorization

**Tramadol Products for Members Less Than 12 Years of Age**

1. Documentation of ONE of the following:
    a. CYP2D6 genotyping that confirms the member is not an ultra-rapid CYP2D6 metabolizer

    **OR**

    b. Member has previously utilized a tramadol-containing product without adverse effect that prevents repeat use

**Codeine Products for Members Less than 12 Years of Age**

1. Documentation of ONE of the following:
    a. CYP2D6 genotyping that confirms the member is not an ultra-rapid CYP2D6

    **OR**

    b. Member has previously utilized a codeine product without adverse effect that prevents repeat use

**REAUTHORIZATION**

**Drug-specific criteria (including tramadol and codeine age limits)**

1. Documentation that no changes have been made to the current regimen

**High-Dose (120 MME/day limit), High-Dose Short-Acting Monotherapy, High Dose Formulations (≥ 90 MME/day with one unit dose or as prescribed per the FDA-approved package labeling): Fentanyl 50 mcg/hour (Duragesic) patch, Morphine sulfate extended-release (MS Contin) 60, 100, 200 mg tablet**

1. **If the member is not in a treatment taper:** Documentation that no changes have been made to the current regimen

**OR**

2. **If the member is in a treatment taper:** Documentation of a continued treatment taper and dose reductions are taking place

**Acetaminophen > 4 grams/day, aspirin > 4 grams/day, ibuprofen > 3,200 mg/day**

1. Documentation that no changes have been made to the current regimen

**Quantity Limits**

1. Documentation that no changes have been made to the current regimen

**Duplicate Short-Acting or Duplicate Long-Acting Opioid Regimen**

1. Documentation no changes have been made to the current regimen

**Concurrent therapy with opioid dependence agents (e.g., Brixadi, buprenorphine SL tablet, buprenorphine/naloxone SL tablet/film, Sublocade, Probuphine)**

1. Clinical rationale for continued use

**AND**

2. Documented follow-up schedule

**AND**

3. Ongoing treatment plan with taper instructions as appropriate

†Drug is non-rebate

**LIMITATIONS**

- Approval lengths will be as follows:
    - **Butorphanol taper:** Initial and reauthorization requests will be approved for 1 month.
    - **All other taper requests:** Requests for ongoing taper will be approved for 3 months.
    - **Drug-specific requests (including tramadol and codeine age limits):** initial and reauthorization requests will be approved for 6 months.
    - **Acetaminophen > 4 grams/day, aspirin > 4 gram/day, ibuprofen > 3,200 mg/day:** initial requests approved for up to three months, reauthorization requests approved for 6 months.
    - **Opioid quantity limits:** initial requests approved for three months, reauthorization requests approved for 6 months.
    - **Duplicate opioid therapy:** initial requests approved for three months, reauthorization requests approved for 6 months
    - **Concurrent therapy with opioid dependence agents:** requests approved for 14 days
    - **Concomitant Opioid and Benzodiazepine (COBI):**
        - **All criteria met:** 1 year
        - **Continued taper or documented failed taper:** 6 months (less if requested)
        - **Provisional approval:** 1 month
    - **High-Dose (exceeding 120 MME/day), and High-Dose Short-Acting Monotherapy, and High Dose Formulations (≥ 90 MME/day with one unit dose or as prescribed per the FDA-approved package labeling): Fentanyl 50 mcg/hour (Duragesic) patch, Morphine sulfate extended-release (MS Contin) 60, 100, 200 mg tablet:**
        - **Initial:** approved for 3 months. If there is documentation of a pain consult/referral, the request can be approved two weeks beyond the appointment date. If the provider has documented that the member has been referred for a pain consult, the request may be approved for one month. Subsequent submissions may be approved for one month for

up to three months in total. If after three one-month approvals the member has not had a consult then the request will be denied.
    - **Journavx**: 14 days. Subsequent requests will be reviewed against initial criteria
    - **Reauthorization:** 6 months, unless there is documentation of a continued taper which will be approved for 3 months.
    - **All other requests:** may be approved for 6 months.
- The following agents do not participate in the federal rebate program. These products are reviewed against the non-rebate medications criteria: Nucynta, Nucynta ER, Oxaydo, Prialt, Primlev, tramadol ER 150 mg capsule, Trezix, Xtampza ER and Zohydro ER (brand only).
- Oxycontin and Butrans are brand preferred. For all other opioids, if a generic is available then the generic is preferred over the brand formulation.
- Requests for brand name (no substitution) drugs with A-rated generics or therapeutically equivalent generics require documentation of an allergic response or adverse reaction to the generic product or history of allergic reaction to the inactive ingredients used in the manufacturing process of the product OR documentation of an inadequate response to the generic product.
- Requests for non-preferred generics with A-rated or therapeutically equivalent brand and MassHealth prefers the brand require documentation of an allergic response or adverse reaction to the brand name product or history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain product, OR an inadequate response to the brand name product.

- Quantity limits apply as follows:

| Generic Name | Reference Brand Name | Formulary Status | Quantity Limit |
|---|---|---|---|
| **Short-Acting Agents** | | | |
| Acetaminophen/codeine | Tylenol with Codeine | PA (< 12 y.o.), QL | **120/12 mg per 5 mL solution:** 150 mL/day<br>**300/15 mg tablets:** 12 tablets/day<br>**300/30 mg tablets:** 12 tablets/day<br>**300/60 mg tablets:** 6 tablets/day |
| Acetaminophen/caffeine/ dihydrocodeine | Trezix† | PA, QL | **320.2/30/16 mg capsules:** 10 capsules/day<br>**325/30/16 mg capsules:** 10 capsules/day |
| Benzhydrocodone/ Acetaminophen | Apadaz | PA, QL | 12 tablets/day |
| Butorphanol nasal spray | | PA, QL | 2 canisters per 30 days |
| Codeine sulfate tablet | | PA (< 12 y.o), QL | **15 mg tablets:** 24 tablets/day<br>**30 mg tablets:** 12 tablets/day<br>**60 mg tablets:** 6 tablets/day |
| Fentanyl immediate-release | Fentora, | PA, QL | Four units per day |
| Hydrocodone/APAP tablet | | QL | **2.5/325 mg tablets**: 12 tablets/day<br>**5/325 mg tablets:** 8 tablets/day<br>**7.5/325, 10/325 mg tablets:** 6 tablets/day |
| Hydrocodone/APAP 5-300 mg, 7.5-300 mg, 10-300 mg tablet | Vicodin, Vicodin ES, Vicodin HP, Xodol | PA, QL | 6 tablets/day |
| Hydrocodone/APAP 100/300 mg elixir | | QL | 67 mL/day |

| Generic Name | Reference Brand Name | Formulary Status | Quantity Limit |
|---|---|---|---|
| **Short-Acting Agents** | | | |
| Hydrocodone/APAP 7.5-325 mg/15 mL, 10-325 mg/15mL oral solution | | QL | 90 mL/day |
| Hydrocodone/ Ibuprofen 7.5-200 mg tablet | Vicoprofen, Reprexain | QL | 5 tablets/day |
| Hydrocodone/ibuprofen 5-200 mg, 10-200 mg tablet | | PA, QL | 5 tablets/day |
| Hydromorphone liquid 5 mg/5 mL | Dilaudid | QL | 20 mL/day |
| Hydromorphone 3 mg suppository | | QL | 4 suppositories/day |
| Hydromorphone tablet | Dilaudid | QL | **2 mg tablet:** 10 tablets/day<br>**4 mg tablet:** 5 tablets/day<br>**8 mg tablet:** 2 tablets/day |
| Journavx PD | | PA (<18 y.o), QL | 29 units/60 days |
| Levorphanol tablet | | PA, QL | 2 tablets/day |
| Meperidine 50 mg/5 mL solution | | PA, QL | 90 mL/day |
| Meperidine 50 mg tablet | Demerol | PA, QL | 18 tablets/day |
| Morphine sulfate (concentrate) oral solution 20 mg/mL | | QL | 4.5 mL/day |
| Morphine sulfate immediate release tablet | | QL | **15 mg tablet:** 6 tablets/day<br>**30 mg tablet:** 3 tablets/day |
| Morphine sulfate oral solution 10 mg/5 mL | | QL | 45 mL/day |
| Morphine sulfate oral solution 20 mg/5 mL | | QL | 22.5 mL/day |
| Oxycodone 5 mg capsule | | QL | **5 mg capsule:** 12 capsules/day |
| Oxycodone tablet | | QL | **5 mg tablet:** 12 tablets/day<br>**10 mg tablet:** 6 tablets/day<br>**15 mg tablet:** 4 tablets/day<br>**20 mg tablet:** 3 tablets/day<br>**30 mg tablet:** 2 tablets/day |
| Oxycodone tablet | Oxaydo† | PA, QL | **5 mg tablet:** 12 tablets/day<br>**7.5 mg tablet:** 8 tablets/day |
| Oxycodone 100 mg/5 mL concentrate | | QL | 3 mL/day |
| Oxycodone 5 mg/5 mL solution | | QL | 60 mL/day |
| Oxycodone/APAP 325 mg tablet, 300 mg solution | Percocet<br>Prolate† | Prolate solution: PA, QL<br><br>All other formulations: QL | **5-325 mg/5mL solution:** 60 mL/day<br><br>**10-300 mg/5 mL solution:** 30 mL/day<br><br>**2.5/325 mg tablet:** |

| Generic Name | Reference Brand Name | Formulary Status | Quantity Limit |
|---|---|---|---|
| **Short-Acting Agents** | | | |
| | | | 12 tablets/day<br>**5/325 mg tablet:**<br>12 tablets/day<br>**10 mg/325 mg tablet:**<br>6 tablets/day<br>**7.5/325 mg tablet:**<br>8 tablets/day |
| Oxycodone/APAP 300 mg tablet | Nalocet†, Primlev† | PA, QL | **5/300 mg tablet:** 12 tablets/day<br>**7.5/300 mg tablet:** 8 tablets/day<br>**10/300 mg tablet:** 6 tablets/day |
| Oxymorphone immediate release tablet | Opana | PA, QL | **5 mg tablet:** 6 tablets/day<br>**10 mg tablet:** 3 tablets/day |
| Pentazocine/naloxone | | PA, QL | 4 tablets/day |
| Tapentadol tablet | Nucynta† | PA, QL | **50 mg tablet:** 4 tablets/day<br>**75 mg tablet:** 3 tablets/day<br>**100 mg tablet:** 2 tablets/day |
| Tramadol oral solution | Qdolo | PA, QL | **5 mg/mL:** 80 mL/day |
| Tramadol tablet | | **50 mg:** QL<br>**100 mg:** PA, QL | **50 mg tablet:** 8 tablets/day<br>**100 mg tablet:** 4 tablets/day |
| Tramadol/acetaminophen | | PA, QL | **37.5/325 mg tablet:** 8 tablets/day |
| Tramadol/celecoxib | Seglentis | PA, QL | 4 tablets/day |

| Generic Name | Reference Brand Name | Formulary Status | Quantity Limit |
|---|---|---|---|
| **Long-Acting Agents** | | | |
| Buprenorphine buccal film | Belbuca | PA, QL | 2 films/day |
| Buprenorphine patch | Butrans | BP, QL | 1 patch every 7 days |
| Fentanyl patch 12, 25 mcg/hr | Duragesic | QL | 1 patch every 3 days |
| Fentanyl patch 50 mcg/hr | Duragesic patch 50 mcg/hr | PA, QL | 1 patch every 3 days |
| Fentanyl patch 75, 100 mcg/hr | Duragesic patch 75, 100 mcg/hr | PA, QL | 1 patch every 3 days |
| Fentanyl patch 37.5, 62.5, and 87.5 mcg/hr | | PA, QL | 1 patch every 3 days |
| Hydrocodone ER 10, 15, 20, 30, 40, 50 mg capsule | Zohydro ER† | PA, QL | 2 capsules/day |
| Hydrocodone ER 20, 30, 40, 60, 80, 100, 120 mg tablet | Hysingla ER | PA, QL | 2 tablets/day |
| Hydromorphone ER 8, 12, 16, 32 mg tablet | Exalgo | PA, QL | 1 tablet/day |
| Methadone 5 mg tablet | | PA, QL | 3 tablets/day |
| Methadone 10 mg tablet | | PA, QL | 2 tablets/day |
| Methadone Intensol oral concentrate 10 mg/mL | | PA, QL | 2 mL/day |

| | | | |
|---|---|---|---|
| Methadone oral solution 5 mg/5 mL | | PA, QL | 20 mL/day |
| Methadone oral solution 10 mg/5 mL | | PA, QL | 10 mL/day |
| Methadone injection 10 mg/mL | | PA, QL | 2 mL/day |
| Morphine extended-release 30, 45, 60, 75, 90, 120 mg capsule | Avinza | PA, QL | 1 capsule/day |
| Morphine extended-release 10, 20, 30, 40, 50, 60, 80, 100 mg capsule | Kadian | PA, QL | 1 capsule/day |
| Morphine extended-release 15 mg, 30 mg tablet | MS Contin 15 mg, 30 mg tablet | QL | 3 tablets/day |
| Morphine extended-release 60 mg, 100 mg, 200 mg tablet | MS Contin 60 mg, 100 mg, 200 mg tablet | PA, QL | 3 tablets/day |
| Oxycodone extended-release abuse-deterrent 10 mg, 15, 20, 30, 40, 60, 80 mg tablet | Oxycontin 10 mg, 15 mg, 20 mg, 30 mg tablet | PA, BP, QL | 2 tablets/day |
| Oxycodone extended-release abuse-deterrent 9, 13.5, 18, 27, 36 mg capsule | Xtampza ER† | PA, QL | 2 capsules/day |
| Oxymorphone extended-release tablet | | PA, QL | 2 tablets/day |
| Tapentadol ER | Nucynta ER† | PA, QL | 2 tablets/day |
| Tramadol extended release biphasic capsule | Conzip | PA, QL | 1 capsule/day |
| Tramadol extended-release tablets | | PA, QL | 1 tablet/day |

†Drug is non-rebate

BP = Brand Preferred; PA = Prior Authorization; QL = Quantity Limit

## CODES

None

## REFERENCES


1. Apadaz (benzhydrocodone/acetaminophen) [prescribing information]. Newtown, PA: KVK-Tech, Inc; March 2021.
2. Belbuca (buprenorphine) [prescribing information]. Raleigh, NC: BioDelivery Services International; July 2020.
3. Butrans (buprenorphine) [prescribing information]. Stamford, CT: Purdue Pharma; October 2019.
4. Centers for Disease Control and Prevention (CDC). Injury prevention & control: opioid overdose. URL: http://www.cdc.gov/drugoverdose/pubs/index.html#tabs-760094-4. March 16, 2016. Accessed 2016 March 28.
5. The American Academy of Pain Management. Prescribing issue. Opioid agreement & contracts. URL: http://www.naddi.org/aws/NADDI/asset_manager/get_file/32898/opioidagreements.pdf Accessed 2016 March 28.
6. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Guideline for Prescribing Opioids for Pain – United States, 2022. *MMWR Recomm Rep*. 2022;71(RR-3):1-95.
7. Journavx [prescribing information]. Boston (MA): Vertex Pharmaceuticals, Inc.; 2025 Jan.
8. Prolate (oxycodone and acetaminophen solution) [prescribing information]. Las Vegas, NV: Forte Bio-Pharma LLC; September 2019.


## APPROVAL HISTORY

March 20, 2023: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2023: Effective June 5, 2023, in accordance with the MassHealth Unified Formulary, updated the high dose criteria to allow approval if the member has sickle cell disease, active cancer pain, is in palliative care, or is in or transitioning to hospice care.
2. August 8, 2023: Effective October 2, 2023, in accordance with the MassHealth Unified Formulary, updated initial approval criteria for high dose regimens (120 MME/day) to include upcoming consult visit. Updated approval lengths for high-dose regimens and high-dose short-acting monotherapy regimens to include three one-month approvals if member has not had a consult visit. Updated reauthorization criteria for high-dose (120 MME/day) and high-dose short-acting monotherapy regimens to include tapering. Initial high-dose and high-dose short-acting monotherapy requests will be approved for three months. Additionally, all non-butorphanol tapering requests will be approved for three months. Removed opioid powders from the guideline, as they will be managed through the pharmaceutical compounding program.
3. November 14, 2023: Effective December 4, 2023, in accordance with the MassHealth Unified Formulary, updated concurrent opioid/opioid dependence program to include Brixadi in the lookback. Updated MNG to indicate that brand Zohydro ER is now non-rebate. Updated fax number for Pharmacy Utilization Management.
4. January 9, 2024: Effective March 4, 2024, in accordance with the MassHealth Unified Formulary, added a requirement for documented diagnosis of pain for the following agents: fentanyl transdermal, Oxycontin, Nucynta, oxymorphone IR, hydromorphone ER, Hysingla ER, Nucynta ER, oxymorphone ER, Xtampza ER, Zohydro ER, meperidine, morphine ER capsule, pentazocine/naloxone, methadone injection, Conzip, tramadol ER tablet, Ultracet, tramadol 100 mg, Apadaz, hydrocodone/ibuprofen, oxycodone/APAP 300 mg, dihydrocodone/APAP/caffeine, hydrocodone/APAP 300 mg, Buprenex, and levorphanol tablet. Added COBI criteria for opioids. Removed brand-name approval language for Apadaz, Conzip, Fentora, and Qdolo and updated language in the limitations section to account for requests for brand-name drugs with therapeutically equivalent generics.
5. May 14, 2024: Effective May 6, 2024, in accordance with the MassHealth Unified Formulary, updated MNG to reflect that brand Qdolo is no longer non-rebate.
6. November 12, 2024: Effective November 12, 2024, in accordance with the MassHealth Unified Formulary, added PA criteria: hydromorphone suppository, RoxyBond, and tramadol 25 mg. Removed PA requirement for Nucynta, Nucynta ER, Xtampza, tramadol/acetaminophen, Vicodin, Vicodin ES, Vicodin HP and Xodol. Updated hydrocodone high dose limit from 80mg/day to 120mg/day. Added requirement for co-prescribing of naloxone to high dose criteria. Removed obsolete agents: Subsys, brand Actiq, Buprenex., brand Dolophine, brand Ultracet and brand Ultram.
7. March 11, 2025: Effective April 1, 2025, in accordance with the MassHealth Unified Formulary, updated Belbuca criteria to allow for buprenorphine microdose with intent to taper off full agonist opioid. Added PA requirement for Nucynta, Nucynta ER and Xtampza ER. Updated MNG limitation section to indicate that Nucynta, Nucynta ER and Xtampza ER is now non-rebate. Updated non-rebate flags (†) for Nucynta, Nucynta ER and Xtampza ER.
8. May 12, 2025: Effective May 12, 2025, in accordance with the MassHealth Unified Formulary, added Journavx to Medical Necessity Guideline

## BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services