Pharmacy Medical Necessity Guidelines: Opioid Analgesics

Effective: August 13, 2024

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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

OVERVIEW

Short-acting opioid analgesics are indicated for the management of moderate to severe pain for which use of an opioid analgesic is appropriate. Long-acting opioid analgesics are indicated for the management of pain severe enough to require daily, around-the-clock, long- term opioid treatment and for which alternative treatment options are inadequate; long-acting opioids should not be used for as needed treatment. Per the 2022 Centers for Disease Control and Prevention (CDC), nonopioid therapies are preferred for the treatment of subacute pain and chronic 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. When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescriber short-acting/immediate-release opioids instead of extended-release and long-acting opioids.

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).

Once opioids are initiated, providers should prescribe the lowest effective dose. Caution should be exercised when prescribing opioids at any dose, and clinicians should carefully reassess the evidence of individual benefits and risks when considering increasing the opioid dosage above 50 morphine milligram equivalents (MME) per day. Per the CDC, few trials have evaluated dosages of 90 MME/day or greater, opioid dosages 50-90 MME/day are associated with minimally greater improvement in mean pain intensity compared to doses less than 50 MME/day. If benefits do not outweigh the risks of continued therapy, a gradual taper should be employed.

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.

Methadone oral tablets (5 mg and 10 mg), Intensol oral concentrate, and oral solution are approved for the treatment of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. They are also approved for the detoxification of and maintenance of treatment of opioid addiction. However, outpatient pharmacies are only legally allowed to dispense methadone for the treatment of pain; they cannot dispense methadone for the treatment of opioid addiction. Methadose soluble oral tablet and Methadose oral concentrate are only approved for treatment of opioid addiction and are therefore not covered under the Tufts Health RITogether pharmacy benefit.

COVERAGE GUIDELINES

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

Short-acting opioid analgesics without drug-specific criteria

1. The Member is diagnosed with sickle cell-related, cancer-related, or end-of-life pain

OR

2. All of the following:
   a) The Member has a diagnosis of pain

AND

b) The Member tried and failed therapy with at least three alternative short-acting opioid analgesics, one of which must contain the same active ingredient as the requested product, if available

AND

c) The Member signed a pain management agreement consistent with the American Academy of Pain Management guidelines

AND

d) The risks of opioid analgesics (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the Member

AND

e) The provider has a plan in place to monitor the Member for misuse, abuse, and addiction during therapy

AND

f) **For dosage forms that exceed 90 MME/day with one unit dose or as prescribed per the FDA-approved package labeling:**

i. Clinical rational why the member requires a higher opioid dose

AND

ii. The analgesic is prescribed by or in consultation with a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or hematologist/oncologist OR there is a plan in place for the member to be referred to a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or hematologist/oncologist

AND

a) The provider has a taper plan in place or has a rationale as to why a dose taper is not appropriate at this time.

<u>Long-acting opioid analgesics without drug-specific criteria</u>

1. The Member is diagnosed with sickle cell-related, cancer-related, or end-of-life pain

OR

2. All of the following:

a) The Member has had an inadequate response or adverse reaction to an immediate-release opioid

AND

b) The Member has a diagnosis of chronic pain

AND

c) **If the request is for a brand agent:** The Member had an inadequate response or adverse reaction with at least two alternative generic long-acting opioid analgesics, one of which must contain the same active ingredient as the requested product, if available

AND

d) The Member signed a pain management agreement consistent with the American Academy of Pain Management guidelines

AND

e) The risks of opioid analgesics (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the Member

AND

f) The provider has a plan in place to monitor the Member for misuse, abuse, and addiction during therapy

AND

g) **For dosage forms that exceed 90 MME/day with one unit dose or as prescribed per the FDA-approved package labeling:**

i. Clinical rational why the member requires a higher opioid dose**AND**

ii. The analgesic is prescribed by or in consultation with a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or hematologist/oncologist OR there is a plan in place for the member to be referred to a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or hematologist/oncologist

AND

iii. The provider has a taper plan in place or has a rationale as to why a dose taper is not appropriate at this time.

Fentanyl 50, 75, 100 mcg/hr (Duragesic) patch, Morphine sulfate extended-release (MS Contin) 60, 100, 200 mg tablet, Oxycodone abuse deterrent (Oxycontin) 40, 60, 80 mg tablet

1. The Member is diagnosed with sickle cell-related, cancer-related or end-of-life pain

OR

2. All of the following:
   a) The Member has had an inadequate response or adverse reaction to an immediate release opioid

   AND

   b) The Member has a diagnosis of chronic pain

   AND

   c) The Member signed a pain management agreement consistent with the American Academy of Pain Management guidelines

   AND

   d) The risks of opioid analgesics (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the Member

   AND

   e) The provider has a plan in place to monitor the member for misuse, abuse, and addiction during therapy

   AND

   f) Clinical rationale why the member requires a higher opioid dose

   AND

   g) The analgesic is prescribed by or in consultation with a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or hematologist/oncologist OR there is a plan for the member to be referred to a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or hematologist/oncologist

   AND

   h) The provider has a taper plan in place or has a rationale as to why a dose taper is not appropriate at this time.

Benzhydrocodone/Acetaminophen (Apadaz)

1. The member has a diagnosis of acute pain severe enough to require an opioid analgesic

AND

2. The member has tried and failed therapy with at least three alternative short-acting opioid analgesics

AND

3. The Member signed a pain management agreement consistent with the American Academy of Pain Management guidelines

AND

4. The risks of opioid analgesics (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the Member

AND

5. The Provider has a plan in place to monitor the Member for misuse, abuse, and addiction during therapy

AND

6. The Member's treatment with benzhydrocodone/APAP will be limited to 14 days

AND

7. **For benzhydrocodone/APAP requests in which the member will exceed 90 MME/day:**
   1. Clinical rationale why the member requires a higher opioid dose

   AND

   2. The analgesic is prescribed by or in consultation with a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or hematologist/oncologist OR there is a plan in place for the member to be referred to a pain specialist, palliative care specialist, rheumatologist, headache specialist, addiction specialist, physiatrist, or hematologist/oncologist

Buprenorphine sublingual (Belbuca)

1. The Member is diagnosed with sickle cell-related, cancer-related, or end-of-life pain

OR

1. All of the following:
    a) The member has a diagnosis of severe pain requiring daily, around-the-clock, long-term opioid treatment

AND

    b) The Member meets ONE of the following:
        a. The Member has a documented swallowing disorder or is unable to administer oral analgesic agents **AND** has had an inadequate response, adverse reaction, or contraindication to transdermal buprenorphine
        i. The Member has had an inadequate response or adverse reaction to two generic analgesics
        ii. Documentation that treatment with other analgesics is not clinically appropriate for the member

AND

    c) There is a pain management agreement consistent with the American Academy of Pain Management guidelines in place for this Member

AND

    d) The risks of opioid analgesics (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the Member

AND

    e) The provider has a plan in place to monitor the Member for misuse, abuse, and addiction during therapy

Buprenorphine transdermal patch

1. The Member has a documented diagnosis of chronic pain, or end of life pain requiring around the clock, long-term opioid treatment

AND

2. All of the following:
    a) The Member meets ONE of the following:
        i. The Member has a documented swallowing disorder or is unable to administer oral analgesic agents
        ii. The Member has had an inadequate response or adverse reaction to two generic analgesics
        iii. Documentation that treatment with other analgesics is not clinically appropriate for the Member

AND

    b) The Member signed a pain management agreement consistent with the American Academy of Pain Management guidelines

AND

    c) The risks of opioid analgesics (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the Member

AND

    d) The provider has a plan in place to monitor the Member for misuse, abuse, and addiction during therapy

Immediate-release fentanyl products (Actiq, Fentora, Onsolis, Subsys, Lazanda)

1. The Member is diagnosed with cancer or terminal-illness pain

AND

2. The Member is opioid tolerant

AND

3. For requests for the buccal tablet, buccal film, sublingual spray, or nasal spray, the Member tried and failed therapy with fentanyl lozenge

Methadone 5 mg and 10 mg tablets, Intensol oral concentrate, oral solution, injection

1. The member has a documented diagnosis of moderate to severe pain requiring continuous, around-the-clock treatment with an opioid analgesic

AND

2. The member is not opioid-naïve

AND

3. **Non-cancer patients only:** The member has had ECG showing a normal QTc interval

AND

4. The Member meets ONE of the following:
    a) The member had an inadequate response, intolerance, or contraindication to two other long-acting opioid analgesics

    OR

    b) The provider submits a clinical rationale for the use of oral methadone over other long-acting opioid analgesics

AND

5. The Member signed a pain management agreement consistent with the American Academy of Pain Management guidelines

AND

6. The risks of opioid analgesics (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the Member

AND

7. The provider has a plan in place to monitor the Member for misuse, abuse, and addiction during therapy

AND

8. **Injection only:** Provider submit a clinical rationale for the use of the injection over the oral formulation

Extended-release tramadol

1. The member has a diagnosis of pain

AND

2. The Member tried and failed therapy with immediate-release tramadol

AND

3. The Member signed a pain management agreement consistent with the American Academy of Pain Management guidelines

AND

4. The risks of opioid analgesics (e.g., tolerance, dependence, respiratory depression, cognitive impairment) have been discussed with the Member

AND

5. The provider has a plan in place to monitor the Member for misuse and addiction during therapy

Reauthorization

1. The Member meets ONE of the following:
    a) The Member continues to have a diagnosis of sickle cell-related, cancer-related, or end-of-life pain AND is stable on the requested agent

    OR

    b) The Member meets ALL of the following:

        i. The Member continues to require pain management

        AND

        ii. The Member has experienced an improvement in function/pain while on the prescribed opioid

        AND

        i. The provider attests that there are no concerns of substance abuse or misuse while taking the prescribed opioid

        AND

        ii. The Member has not experienced respiratory depression or cognitive impairment while taking the prescribed opioid

        AND

        iii. The prescriber confirms that a current Member-signed pain management agreement consistent with the American Academy of Pain Management guidelines is in place

AND

iv. Member's opioid has been reassessed and there is either a taper plan in place or documentation that tapering the opioid is not appropriate at this time

LIMITATIONS

1. Approvals for a diagnosis other than cancer-related, sickle cell-related, or end-of-life pain will be limited initially to a three-month duration, and upon renewal to a six-month duration.
2. Approvals for cancer-related, sickle cell-related, or end-of-life pain will be limited to one year.
3. Approvals for Apadaz (benzhydrocodone/acetaminophen) will be limited to 14 days.
4. Quantities that exceed the quantity limit will be reviewed according to the Drugs with Quantity Limitations criteria.
5. Quantity limits apply as follows:

Generic Name	Reference Brand Name	Formulary Status	Quantity Limit
Short-Acting Agents			
APAP/Codeine	Tylenol with Codeine	QL	300/15 mg tablets: 12 tablets/day 300/30 mg tablets: 12 tablets/day 300/60 mg/tablets: 6 tablets/day
Benzhydrocodone/ Acetaminophen	Apadaz	PA, QL	168 tablets/14 days
Codeine sulfate tablet	Codeine	QL	15 mg tablets: 24 tablets/day 30 mg tablets: 12 tablets/day 60 mg tablets: 6 tablets/day
Fentanyl immediate-release	Abstral, Actiq*, Fentora, Lazanda, Onsolis, Subsys	PA; QL	Four units per day
Hydrocodone/APAP tablet	Hydrocodone/APAP	QL	2.5/325 mg tablets: 12 tablets/day 5/325 mg tablets: 8 tablets/day 7.5/325, 10/325 mg tablets: 6 tablets/day
Hydrocodone/APAP solution	Hydrocodone/APAP	QL	15 mL q4-6h prn, MAX 90 mL/day
Hydrocodone/ Ibuprofen tablet	Vicoprofen*, Reprexain*	QL	5 tablets/day
Hydromorphone liquid 5 mg/5 mL	Dilaudid*	QL	90 mL/day
Hydromorphone suppository	Hydromorphone	QL	4 suppositories/day
Hydromorphone tablet	Dilaudid*	QL	2 mg: 10 tablets/day 4 mg: 5 tablets/day 8 mg: 2 tablets/day
Meperidine 50 mg/5 mL solution	Meperidone	QL	90 mL/day
Meperidine 50 mg/5 mL syrup	Meperidine	QL	90 mL/day
Meperidine tablet	Demerol*	QL	50 mg: 18 tablets/day 100 mg: 8 tablets/day
Morphine sulfate immediate release tablet	Morphine sulfate	QL	15 mg: 6 tablets/day 30 mg: 3 tablets/day
Morphine sulfate (concentrate) oral solution 20 mg/mL	Morphine sulfate	QL	4.5 mL/day

Morphine sulfate oral solution 10 mg/5mL	Morphine sulfate	QL	45 mL/day
Morphine sulfate oral solution 20 mg/5 mL	Morphine sulfate	QL	22.5 mL/day
Oxycodone 5 mg capsule	Oxycodone	QL	12 capsules/day
Oxycodone tablet	Oxycodone	QL	5 mg tablet: 12 tablets/day 10 mg tablet: 6 tablets/day 15 mg tablet: 4 tablets/day 20 mg tablet: 3 tablets/day 30 mg tablet: 2 tablets/day
Oxycodone/APAP	Percocet Prolate	Prolate solution: PA;QL All other formulations: QL	5-325 mg/5 mL solution: 60 mL/day 10-325 mg/5 mL solution: 30 mL/day 2.5/325 mg, 5/325 mg tablets: 12 tablets/day 10 mg/325 mg tablets: 6 tablets/day 7.5/325 mg tablets: 8 tablets/day
Oxycodone/Aspirin tablets	Percodan	QL	12 tablets/day
Oxycodone/ibuprofen tablets	Oxycodone/ibuprofen	PA;QL	4 tablets/day
Oxymorphone immediate release tablet	Opana*	PA; QL	5 mg: 6 tablets/day 10 mg: 3 tablets/day
Tapentadol tablet	Nucynta	PA; QL	50 mg tablet: 4 tablets/day 75 mg tablet: 3 tablets/day 100 mg tablet: 2 tablets/day
Tramadol	Ultram*	QL	50 mg tablet: 8 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	PA; QL	One patch/7 days
Fentanyl patch 12, 25, 37.5, 50, 62.5, 75, 87.5, 100 mcg/hr	Duragesic*	PA; QL	1 patch every 3 days
Hydrocodone extended-release capsule	Zohydro ER	PA; QL	2 tablets/day
Hydromorphone ER 8, 12, 16, 32 mg	Exalgo*	PA; QL	1 tablet/day
Methadone 5 mg tablet	Dolophine	PA; QL	3 tablets/day
Methadone 10 mg tablet	Dolophine	PA; QL	2 tablets/day
Methadone Intensol oral concentrate 10 mg/mL	Methadone	PA; QL	2 mL/day
Methadone oral solution 5 mg/5 mL	Methadone	PA; QL	20 mL/day
Methadone oral solution 10 mg/5 mL	Methadone	PA; QL	10 mL/day
Methadone injection 10	Methadone	PA; QL	2 mL/day

mg/mL			
Morphine extended-release capsule	Avinza	PA; QL	1 tablet/day
Morphine extended-release 10, 20, 30, 40, 50, 80, 100 mg capsule	Kadian*	PA; QL	2 capsules/day
Morphine extended-release 200 mg capsule	Kadian	PA; QL	2 capsules/day
Morphine extended-release tablet	MS Contin*	PA; QL	3 tablets/day
Morphine extended-release abuse-deterrent tablet	Arymo	PA; QL	3 tablets/day
Morphine extended-release abuse-deterrent tablet	MorphaBond ER	PA; QL	3 tablets/day
Morphine/naloxone capsule	Embeda	PA; QL	2 capsules/day
Oxycodone extended-release abuse-deterrent tablet	Oxycontin*	PA; QL	2 tablets/day
Oxymorphone extended-release abuse-deterrent tablet	Opana ER	PA; QL	2 tablets/day
Oxymorphone extended-release tablet	Oxymorphone ER tablet	PA; QL	2 tablets/day
Tapentadol extended-release	Nucynta ER	PA; QL	2 tablets/day
Tramadol extended-release tablets	Ultram ER*	PA; QL	1 tablet/day
Tramadol biphasic extended-release tablet	Tramadol biphasic ER tablet	PA; QL	1 tablet/day

*Generic only program applies to brand name products.

CODES

None

REFERENCES

1. 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.
2. Apadaz (benzhydrocodone/acetaminophen) [prescribing information]. Newtown, PA: KVK-Tech, Inc; March 2021.
3. Belbuca (buprenorphine) [prescribing information]. Raleigh, NC: BioDelivery Services International; June 2022.
4. Butrans (buprenorphine) [prescribing information]. Stamford, CT: Purdue Pharma; June 2022.
5. 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.
6. Dowell D, Ragan KR, Jones CM, et al. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2022. *MMWR*. 2022;71(3):1-95.
7. Prolate (oxycodone and acetaminophen solution) [prescribing information]. Las Vegas, NV: Forte Bio-Pharma LLC; May 2021.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. August 8, 2023: Effective November 1, 2023, updated verbiage for members exceeding 90 MME/day to require clinical rationale why member requires a higher opioid dose, removing requirement for demonstration that lower dose is clinically inappropriate. Updated verbiage for "tried and failed" to "inadequate response or adverse reaction." Updated the diagnosis criteria for Belbuca, requiring

severe pain requiring daily, around-the-clock, long-term opioid treatment, which mirrors the FDA-approved indication. Also updated Belbuca criteria to include inability to administer oral agents and inability to administer oral agents and previous trial with transdermal buprenorphine, previous trial with two generic analgesics or documentation that other analgesics is not clinically appropriate. Similar update made to the buprenorphine transdermal batch. Removed criteria for combination agonist/antagonist opioid agents, as none of these agents are on the formulary. Updated reauthorization criteria to require continued need for pain management.

2. August 13, 2024: No criteria changes. Administrative update to fax number.

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