Pharmacy Medical Necessity Guidelines: Opioid Analgesics

Effective: February 20, 2017

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
<th>Type of Review – Clinical Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td></td>
<td>√</td>
</tr>
<tr>
<td>Not Covered</td>
<td></td>
<td>RX Department to Review</td>
</tr>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>RXUM</td>
<td>Fax Numbers:</td>
</tr>
</tbody>
</table>

This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhode Health Partners Plan

Tufts Health Freedom Plan products
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

Fax Numbers:
RXUM: 617.673.0988

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS
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.

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve long-acting opioids for use in patients for whom alternative treatment options (e.g., nonopioid analgesics, immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Long-acting agents are not indicated as an as-needed analgesic.

Belbuca (buprenorphine) buccal film and Butrans (buprenorphine) transdermal patch 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.

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
1. The Member is diagnosed with cancer-related, malignant, or end-of-life pain and is receiving the same active opioid ingredient in a long-acting formulation

OR

2. Both of the following:
   a) 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

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

Long-acting opioid analgesics
1. The Member has been stable on the requested agent and is diagnosed with cancer-related, malignant, or end-of-life pain

OR

2. Both of the following:
   a) The Member tried and failed therapy with at least two alternative long-acting opioid analgesics, one of which must contain the same active ingredient as the requested product, if available
AND

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

Buprenorphine sublingual (Belbuca)
1. The Member has been stable on the requested agent and is diagnosed with cancer-related, malignant, or end-of-life pain

OR

2. Both of the following:
   a) The Member has a documented swallowing disorder
   AND
   b) There is a pain management agreement consistent with the American Academy of Pain Management guidelines in place for this Member

Buprenorphine transdermal (Butrans)
1. The Member has been stable on the requested agent and is diagnosed with cancer-related, malignant, or end-of-life pain

OR

2. Both of the following:
   a) The Member is unable to utilize oral analgesic agents
   AND
   b) The Member signed a pain management agreement consistent with the American Academy of Pain Management guidelines

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

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

AND

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

Combination agonist/antagonist opioid agents, such as morphine/naltrexone (Embeda)
1. Provider documentation that the Members is at risk for substance abuse or diversion

AND

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

Upon renewal
1. Provider documentation that preferred opioid analgesics, which are covered without restriction, are not sufficient for the Member

AND

2. Prescriber confirmation that a Member-signed pain management consistent with the American Academy of Pain Management guidelines is in place
LIMITATIONS

1. Approvals for a noncancer diagnosis will be limited initially to a three-month duration, and upon renewal to a six-month duration.
2. Approvals for a cancer diagnosis will be limited to one year.
3. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.
4. Quantity limits apply as follows:

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Reference Brand Name</th>
<th>Formulary Status</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Short-Acting Agents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>APAP/Codeine</td>
<td>Tylenol #3</td>
<td>QL</td>
<td>360 mg codeine /day</td>
</tr>
<tr>
<td>Codeine</td>
<td>Codeine</td>
<td>QL</td>
<td>360 mg/day</td>
</tr>
<tr>
<td>Fentanyl immediate-release</td>
<td>Abstral, Actiq*,</td>
<td>PA; QL</td>
<td>Four units per day</td>
</tr>
<tr>
<td></td>
<td>Fentora, Lazanda,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocodone/APAP</td>
<td>Hydrocodone/APAP</td>
<td>QL</td>
<td>4 gm APAP/day</td>
</tr>
<tr>
<td>Hydrocodone/ Ibuprofen</td>
<td>Vicoprofen*, Reprevain*</td>
<td>QL</td>
<td>5 tablets per day</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Dilaudid*</td>
<td>QL</td>
<td>64 mg/day</td>
</tr>
<tr>
<td>Meperidine</td>
<td>Demerol*</td>
<td>QL</td>
<td>1200 mg/day</td>
</tr>
<tr>
<td>Methadone</td>
<td>Methadose*</td>
<td>QL</td>
<td>60 mg/day</td>
</tr>
<tr>
<td>Morphine IR</td>
<td>MSIR</td>
<td>QL</td>
<td>240 mg/day</td>
</tr>
<tr>
<td>Oxycodone IR</td>
<td>Oxycodone</td>
<td>QL</td>
<td>160 mg/day</td>
</tr>
<tr>
<td>Oxycodone/APAP</td>
<td>Percocet</td>
<td>QL</td>
<td>160 mg oxycodone/day</td>
</tr>
<tr>
<td>Hydrocodone/Aspirin</td>
<td>Percodan</td>
<td>QL</td>
<td>160 mg oxycodone/day</td>
</tr>
<tr>
<td>Oxymorphone IR</td>
<td>Opana*</td>
<td>PA; QL</td>
<td>80 mg/day</td>
</tr>
<tr>
<td>Tapentadol</td>
<td>Nucynta</td>
<td>PA</td>
<td>600 mg/day</td>
</tr>
<tr>
<td>Tramadol</td>
<td>Ultram*</td>
<td>QL</td>
<td>400 mg/day</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>Quantity Limit</th>
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</thead>
<tbody>
<tr>
<td><strong>Long-Acting Agents</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buprenorphine buccal film</td>
<td>Belbuca</td>
<td>PA; QL</td>
<td>2 units per day</td>
</tr>
<tr>
<td>Buprenorphine patch</td>
<td>Butrans</td>
<td>PA; QL</td>
<td>One patch per week</td>
</tr>
<tr>
<td>Fentanyl patch 12, 25, 50, 75, 100 mcg/hr</td>
<td>Duragesic*, Fentanyl</td>
<td>QL</td>
<td>1 patch every 3 days</td>
</tr>
<tr>
<td>Fentanyl patch 37.5, 62.5, and 87.5 mcg/hr</td>
<td></td>
<td>PA; QL</td>
<td>1 patch every 3 days</td>
</tr>
<tr>
<td>Hydrocodone ER</td>
<td>Zohydro ER</td>
<td>Non-Covered</td>
<td>Should not exceed 240 mg/day</td>
</tr>
<tr>
<td>Hydromorphone ER 8, 12, and 16 mg</td>
<td>Exalgo*</td>
<td>PA; QL</td>
<td>64 mg/day</td>
</tr>
<tr>
<td>Hydromorphone ER 32 mg</td>
<td>Exalgo</td>
<td>PA; QL</td>
<td>64 mg/day</td>
</tr>
<tr>
<td>Morphine ER</td>
<td>Avinza</td>
<td>PA; QL</td>
<td>240 mg/day</td>
</tr>
<tr>
<td>Morphine ER 40, 70, 130, 150, and 200 mg</td>
<td>Kadian</td>
<td>PA; QL</td>
<td>240 mg/day</td>
</tr>
<tr>
<td>Morphine ER 10, 20, 30, 50, 80, and 100 mg</td>
<td>Kadian*</td>
<td>PA; QL</td>
<td>240 mg/day</td>
</tr>
<tr>
<td>Morphine SR</td>
<td>MS Contin*</td>
<td>QL</td>
<td>240 mg/day</td>
</tr>
<tr>
<td>Oxycodone CR</td>
<td>Oxycontin</td>
<td>QL</td>
<td>160 mg/day; 3 tablets/day</td>
</tr>
<tr>
<td>Oxymorphone ER</td>
<td>Opana ER</td>
<td>PA; QL</td>
<td>80 mg/day</td>
</tr>
<tr>
<td>Tapentadol ER</td>
<td>Nucynta ER</td>
<td>PA</td>
<td>500 mg/day</td>
</tr>
<tr>
<td>Tramadol 24HR ER</td>
<td>Ultram ER*</td>
<td>PA; QL</td>
<td>300 mg/day</td>
</tr>
</tbody>
</table>
*Generic only program applies to brand name products.

**REFERENCES**

2. Butrans (buprenorphine) [prescribing information]. Stamford, CT: Purdue Pharma; June 2014.

**APPROVAL HISTORY**

July 21, 2011: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 19, 2012: Reviewed by Pharmacy & Therapeutics Committee
- December 12, 2013: Reviewed by Pharmacy & Therapeutics Committee
- October 7, 2014: Reviewed by the Pharmacy and Therapeutics Committee. Removed criteria related to brand-name requests and quantity limit as these requests will now defer to the Brand Name and QL medical necessity guidelines, respectively. Durations of approval have changed. Pain management agreements are required.
- May 12, 2015: Reviewed by the Pharmacy and Therapeutics Committee; Incorporate fentanyl 37.5 mcg, 62.5 mcg and 87.5 mcg/hr transdermal patches.
- January 1, 2016: Administrative change to rebranded template.
- April 12, 2016: Added Belbuca (buprenorphine) buccal film to the criteria. Removed Limitation "Requests for quantities that exceed the quantity limit will be reviewed according to the Quantity Limit criteria."
- August 9, 2016: Updated the approval duration for members with cancer diagnosis.
- February 14, 2017: Administrative change to clarify the quantity limit for fentanyl patches.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template

**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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline...
and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.