Stadol (butorphanol tartrate)
Policy Number: C4735-A

CRITERIA EFFECTIVE DATES:

<table>
<thead>
<tr>
<th>ORIGINAL EFFECTIVE DATE</th>
<th>LAST REVIEWED DATE</th>
<th>NEXT REVIEW DUE BY OR BEFORE</th>
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<tr>
<td>5/1/2013</td>
<td>11/4/2020</td>
<td>1/26/2022</td>
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J CODE: J0595

PRODUCTS AFFECTED:
Stadol (butorphanol tartrate)

DRUG CLASS:
Opioid Partial Agonists

ROUTE OF ADMINISTRATION:
Intranasal

PLACE OF SERVICE:
Retail Pharmacy

AVAILABLE DOSAGE FORMS:
Butorphanol Tartrate SOLN 10MG/ML

FDA-APPROVED USES:
Butorphanol tartrate nasal solution is indicated for the management of pain when the use of an opioid analgesic is appropriate.

COMPENDIAL APPROVED OFF-LABELED USES:

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
migraine headache or acute pain

REQUIRED MEDICAL INFORMATION:
A. MIGRAINE HEADACHE:
1. Medication overuse headache has been ruled out. AND
2. The member has experienced an inadequate treatment response, contraindication or intolerance to abortive migraine therapy-2 formulary triptan products AND
3. Documentation the member is currently using migraine prophylactic therapy or has experienced an inadequate treatment response, contraindication or intolerance to migraine prophylactic therapy
B. ACUTE PAIN:
   1. Documentation member has experienced a failure or intolerance to a trial of NSAIDs or lidocaine or capsaicin as appropriate

DURATION OF APPROVAL:
Initial authorization: 12 weeks, Continuation of therapy: 12 weeks

QUANTITY:
15ml per 30 days

PRESCRIBER REQUIREMENTS:
No requirement

AGE RESTRICTIONS:
18 years of age and older

CONTINUATION OF THERAPY:
A. FOR ALL INDICATIONS:
   1. Documentation that Stadol (butorphanol tartrate nasal solution) has provided improvement in the member's condition

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Stadol (butorphanol tartrate) are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy. Contraindications to butorphanol tartrate include, acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; significant respiratory depression; GI obstruction, including paralytic ileus (known or suspected). Documentation of allergenic cross-reactivity for opioids is limited. However, because of similarities in chemical structure and/or pharmacologic actions, the possibility of cross-sensitivity cannot be ruled out with certainty.

OTHER SPECIAL CONSIDERATIONS:

BACKGROUND:

APPENDIX:
None

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.
REFERENCES:


