QUANTITY LIMIT CRITERIA

<table>
<thead>
<tr>
<th>BRAND NAME (generic)</th>
<th>butorphanol tartrate nasal spray</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status:</td>
<td>CVS Caremark Criteria</td>
</tr>
<tr>
<td>Type:</td>
<td>Quantity Limit</td>
</tr>
</tbody>
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POLICY

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

RATIONALE
Butorphanol tartrate nasal solution is indicated for the management of pain when the use of an opioid analgesic is appropriate.

Butorphanol is used to relieve moderate to severe pain. In clinical trials, butorphanol was evaluated for several types of pain, including postoperative pain, post-cesarean section related pain, and migraine headache pain. Butorphanol nasal spray may be appropriate for use as alternative therapy for migraine headache pain that has not responded to other abortive agents. Butorphanol has been associated with episodes of abuse. Of the cases received, there were more reports of abuse with the nasal spray formulation than with the injectable formulation. Proper patient selection, dose, prescribing limitations, appropriate directions for use and frequent monitoring are important to minimize the risk of abuse and physical dependence.

The usual recommended dose for initial nasal administration of butorphanol tartrate nasal solution is 1mg (1 spray in one nostril). If adequate pain relief is not achieved within 60 to 90 minutes, an additional 1 mg dose may be given. Depending on the severity of the pain, an initial dose of 2mg (1 spray in each nostril) may be used in patients who will be able to remain recumbent in the event drowsiness or dizziness occurs. Additional doses should not be given for 3 to 4 hours.

The initial limit criteria are intended to meet the immediate need of the patient being discharged from the hospital with moderate to severe postoperative pain, or the migraine patient in acute need of rescue therapy.

Butorphanol Tartrate Nasal Solution USP, 10mg/mL is supplied in a 2.5mL bottle nasal solution with a metered-dose spray pump. On average, one bottle will deliver 14 to 15 doses if no repriming is necessary.

If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required.

REFERENCES

LIMIT CRITERIA

<table>
<thead>
<tr>
<th>Drug</th>
<th>1 Month Limit*</th>
<th>3 Month Limit*</th>
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<tbody>
<tr>
<td>butorphanol nasal spray</td>
<td>2 bottles / 25 days</td>
<td>6 bottles / 75 days</td>
</tr>
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</table>

*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.