

PRIOR AUTHORIZATION CRITERIA

BRAND NAME

(generic)

butorphanol tartrate nasal spray

Status: *CVS Caremark Criteria*

Type: *Post Limit Prior Authorization*

POLICY

FDA-APPROVED INDICATIONS

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

COVERAGE CRITERIA

Butorphanol nasal spray will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of migraine headache.
AND
- Medication overuse headache has been ruled out.
AND
- The patient has experienced an inadequate treatment response, contraindication or intolerance to abortive migraine therapy.
AND
The patient is currently using migraine prophylactic therapy or has experienced an inadequate treatment response, contraindication or intolerance to migraine prophylactic therapy
AND
- The patient has experienced an inadequate treatment response, contraindication or intolerance to at least 2 oral opioids
OR
- The patient is unable to take oral medications, including liquids

Quantity Limit may apply.

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Butorphanol tartrate nasal solution is indicated for the management of pain when the use of an opioid analgesic is appropriate. In the clinical trials, butorphanol was evaluated for several types of pain, including postoperative pain, post-cesarean section related pain, and migraine headache pain.

The American Academy of Neurology (AAN) and Institute for Clinical Systems Improvement (ICSI) guidelines recommend rescue medication for migraine that includes nonsteroidal anti-inflammatory drugs (NSAIDs), migraine-specific medications (i.e., triptans, ergot derivatives), combination analgesics containing caffeine, isometheptene or butalbital, or opiate analgesics. The compendia and AAN Management of Acute Attacks guideline state that butorphanol tartrate nasal spray may be considered alternative therapy for migraine headache pain when other antimigraine drugs cannot be used or as rescue therapy when sedative effects will not place the patient at risk. The ICSI Diagnosis and Treatment of Headache guideline does not recommend the use of butorphanol because of its high potential for abuse and adverse side-effects. Butorphanol has been associated with episodes of abuse. Proper patient selection, dose, prescribing limitations, appropriate directions for use and frequent monitoring are important to minimize the risk of abuse, physical dependence and adverse effects.¹⁻⁷ Therefore, patients with migraine headache must be unable to take other migraine treatments and have had an inadequate response, intolerance, or contraindication to at least two oral opioids (or unable to take oral medications) prior to butorphanol nasal spray.

Frequent use of acute medications is generally thought to cause medication-overuse headache. To decrease the risk of medication-overuse headache (“rebound headache” or “drug-induced headache”) many experts limit acute therapy to two

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headache days per week on a regular basis.^{4,5} Therefore, the prescriber must have considered and ruled out the diagnosis of medication overuse headache.

Prophylactic therapy currently can be considered in patients with recurring migraine attacks when the attacks substantially interfere with daily routines; the frequency of migraine attacks and reliance on acute therapy would increase the potential for drug-induced (rebound) headache; acute therapy is ineffective, contraindicated, or not tolerated; in patients who prefer prophylactic therapy; in those with uncommon migraine conditions, and in patients with medication overuse.¹⁷⁻²² For prevention of migraine headache, the AAN and the American Headache Society 2012 guideline update recommendations state that the following medications are established as effective and should be offered for migraine prevention: β -adrenergic blocking agents, metoprolol, propranolol, timolol; and antiepileptic drugs (AEDs), divalproex sodium, topiramate, sodium valproate. Additionally the following medications are probably effective: antidepressants, amitriptyline, venlafaxine; and β -adrenergic blocking agents, atenolol, nadolol and should be considered for migraine prevention. Efficacy and safety of individual agents, even within the same class of drugs, may vary among patients therefore, if the patient fails one preventive medication, others should be tried as failure of one agent does not preclude success with another one.^{4,6,7} Therefore, patients with migraine headache must be currently taking or had inadequate response, intolerance, or contraindication to prophylactic therapies.

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 1mg 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. However, the incidence of adverse experiences (nausea, vomiting, dizziness) was higher with the 2mg dose in the clinical trials for migraine headache pain. Additional doses should not be given for 3 to 4 hours.

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.

REFERENCES

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