

BUTORPHANOL TARTRATE NASAL SPRAY UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Miscellaneous Analgesics - Opioid agonist/antagonist
BRAND NAME (Inactive):	Stadol NS
(Generic)	(butorphanol tartrate nasal spray)

FDA INDICATIONS:

Butorphanol nasal spray is indicated for the management of pain when the use of an opioid analgesic is appropriate. (Classified as a C-IV narcotic analgesic)

ICD-9 Code: Various codes may apply; any ICD-9 code that states acute pain from any origin is acceptable.

QUANTITY LIMITATIONS

Short Term:

Extended-Supply:

(QL) CRITERIA:

	per 30 days	per 90 days
Butorphanol nasal spray	4 canisters	12 canisters

- *If a patient requires additional medication, please follow the criteria developed for Butorphanol nasal spray.*

RATIONALE:

- According to the dosing section in the package insert for Stadol NS, a patient could use an entire canister of Stadol NS in one day. However, Bristol-Myers Squibb, the manufacturer of Stadol NS, admits that using the maximum dose of butorphanol for 3+ months can lead to addiction. Therefore, a more reasonable limit was sought.
- A study by Hoffert et al examined the use of butorphanol nasal spray for acute pain relief during acute migraine. This multicenter, randomized, double-blind, placebo-controlled trial involved 157 patients with a diagnosis of migraine headache. Patients were to follow the labeled directions for use, but instead of a 16 spray (16 mg) daily maximum, patients were restricted to a 12 spray (12 mg) daily maximum. The average number of migraine headaches among the population was 4 per month. The dose range used to treat a migraine was 2 to 12 mg, with 6 mg being average. This average would require 2 bottles of Butorphanol nasal spray per month.

CRITERIA FOR EXCEEDING QL:

1. Convey to physician the amount of the drug that the patient has already received (refer to QL) and ask if the patient needs more than that amount. **AND**
2. Presence of post-operative pain in patients unable to take oral medications (including liquids). **OR**
3. Patient must have diagnosis of moderate to severe migraine headache. **AND**
4. Must have tried and failed at least 2 other abortive migraine therapy agents (e.g., acetaminophen, NSAIDs, combination products such as Fioricet or Midrin, 5-HT1 agonists such as Imitrex, and/or ergotamine products such as Migranal or Cafergot). **AND**
5. If patient experiences >4 migraine headaches per month, the physician must consider prophylactic therapy (see Table 1 below). **AND**

6. Physician must consider the possibility of medication-incurred, rebound, or chronic daily headache. Some diagnostic criteria for medication-induced headache include: headache that occurs daily or almost daily for more than 6 months, headache pain that is refractory to standard medications, even though the patient is compliant with therapy, and headache present on awakening. In patients with rebound headache, the physician should consider discontinuing the medication. **AND**
7. If the patient is >65, the physician should consider underlying organic disease or other causes of headache.

BLACK BOX WARNINGS:

None

NURSING ASSESSMENT:

1. Assess onset, type, severity, location and duration of pain.
2. Migraine treatment: note onset, location, and duration of the migraine and include any possible precipitating factors.
3. Note presence of opioid dependence or tolerance.
4. Note the presence of severe hepatic or renal dysfunction. Butorphanol nasal spray is extensively metabolized in the liver and 70-80% of a dose is eliminated renally. In patients greater than 65 years of age the half-life of butorphanol nasal spray is increased by 25% (may result in increased sensitivity to side effects; e.g., dizziness, etc.)
5. Suggest that patients document improvement in pain severity and relief of symptoms.
6. Patient's who have taken butorphanol nasal spray should refrain from driving or performing potentially hazardous tasks until the drug effects are no longer present.

PROVIDER EDUCATION:

1. Tolerance and psychological and physical dependence may occur in patients receiving Butorphanol nasal spray, and unnecessary increases in dosage or frequency of administration should be avoided.
2. Abrupt discontinuance after prolonged use of Stadol may produce withdrawal symptoms such as nausea, vomiting, abdominal cramping, diarrhea, increased temperature, diaphoresis, mydriasis, rhinorrhea, etc.
3. No instances of acute toxicity have been reported, but expected symptoms would be respiratory depression, cardiovascular effects, and other CNS effects.
4. Concurrent use of butorphanol with CNS depressants (e.g., alcohol, barbiturates, tranquilizers, antihistamines, etc.) may result in increased CNS depressant effects.

ADDITIONAL INFORMATION:

Dose:

The usual recommended dose for initial nasal administration is 1 mg (1 spray in **ONE** nostril). Adherence to this dose reduces the incidence of drowsiness and dizziness. If adequate pain relief is not achieved within 60-90 minutes, an additional 1 mg dose may be given.

The initial two-dose sequence outlined above may be repeated in 3-4 hours as needed.

Depending on the severity of the pain, an initial dose of 2 mg (1 spray in EACH nostril) may be used in patients who will be able to remain recumbent in the event drowsiness or dizziness occurs. In such patients single additional 2 mg doses should not be given for 3-4 hours.

The initial dose sequence in elderly patients and patients with hepatic/renal impairment should be limited to 1mg followed by another 1mg dose in 90-120 minutes, if needed. The repeat dose sequence in these patients should be determined by a patient's response rather than at fixed times, but will generally be no less than at 6-hour intervals.

The maximum recommended dose of Butorphanol nasal spray over a 24-hour period is 16 mg (16 sprays).

Butorphanol nasal spray is supplied as a 2.5 ml metered dose bottle containing 10 mg/ml. After initial priming, the nasal solution spray pump delivers 14-15 metered doses containing 1mg of butorphanol tartrate per spray. If repriming of the pump is necessary because of intermittent use, the spray pump will deliver about 8-10 metered doses, depending on the extent of the repriming. Priming of the pump should be repeated whenever the pump has not been used for 48 hours or longer.

Migraine therapy options:

Table Prophylactic therapy for migraine headache

DRUG CLASS	NAME
• Beta Blockers	Propranolol Atenolol Metoprolol Timolol
• Antidepressants	Amitriptyline Fluoxetine
• Calcium Channel Blockers	Nifedipine Verapamil Diltiazem
• Anticonvulsants	Divalproex sodium/sodium valproate Carbamazepine Gabapentin Topiramate
• NSAIDs	Naproxen Aspirin Ketoprofen
• Other	Feverfew Magnesium Vitamin B2 (Riboflavin)

RISK FACTORS/CONTRAINDICATIONS:

Not recommended for use in patients dependent on narcotics due to butorphanol nasal spray's opioid properties.

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