STADOL NS (BUTORPHANOL) UTILIZATION MANAGEMENT CRITERIA

| DRUG CLASS: | Opioid agonist/antagonists | HICL = 0000000001777 |
| BRAND NAME: | Stadol NS |
| (Generic): | (butorphanol tartrate nasal spray) |

FDA INDICATIONS: Stadol NS 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 (QL) CRITERIA:

| SHORT TERM: | EXTENDED SUPPLY: |
| per 30 days | per 90 days |
| Stadol NS | 2 canisters | 6 canisters |

If a patient requires additional medication, please follow the criteria developed for Stadol NS.

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, 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 Stadol NS 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 Stadol 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 agonist such as Imitrex, and/or ergotamine products such as Migranal or Cafergot). **AND**
5. If patient experiences > 4 migraine headaches per month, prophylactic therapy should have been given an adequate trial (see table below). **AND**
6. Physician must consider the possibility of medication-incurred, rebound or chronic headache. Some diagnostic criteria for medication 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. **AND**

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. Stadol NS 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 Stadol NS is increased by 25% (may result in increased sensitivity to side effects; e.g., dizziness, etc.).
5. The initial dose sequence in elderly patients and patients with hepatic/renal impairment should be limited to 1 mg followed by another 1 mg dose in 90-120 minutes, if needed.
6. Suggest that patients document improvement in pain severity and relief of symptoms.
7. Patients who have taken Stadol NS 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 Stadol, and unnecessary increases in dosage or frequency of administration should be avoided. (Bristol-Myers Squibb, the manufacturer of Stadol, admits that using the maximum dose of butorphanol for 3+ months can lead to addiction.)
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 maximum recommended dose of Stadol NS over a 24 hour period is 16 mg (16 sprays).

Stadol NS 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 1 mg 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:
Examples of Prophylactic therapy for migraine headache (this list may not be complete). An adequate trial of 2-3 months of treatment should be given before drug considered ineffective:

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<tr>
<th>DRUG CLASS</th>
<th>NAME</th>
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<tbody>
<tr>
<td>• Beta Blockers</td>
<td>Propranolol</td>
</tr>
<tr>
<td></td>
<td>Atenolol</td>
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<tr>
<td></td>
<td>Metoprolol</td>
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<td>Timolol</td>
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<td>• Antidepressants</td>
<td>Amitriptyline</td>
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<td></td>
<td>Fluoxetine</td>
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<td>DRUG CLASS</td>
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| 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 Stadol’s opioid properties.

**REFERENCES:**