



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: butorphanol

Brand Name: Stadol NS

Medication Class: Opioid agonist/antagonist

FDA Approved Uses: Management of pain when the use of an opioid analgesic is appropriate

Usual Doses: 1mg dose= One spray into one nostril. A second spray may be taken in 60-90 minutes after the first if needed. This may be repeated every 3-4 hours as needed.
Or
2mg dose= One spray into each nostril. May be repeated every 3-4 hours if needed.

Duration of Therapy: Indefinite

Quantity Limit per month: 2 canisters per month

Criteria for Use: Migraine Headaches (*bullet points below are all inclusive unless otherwise noted*)

- Failed / intolerant to 2 FCHP preferred Triptans (Relpax, Zomig, Maxalt, Frova).
- Prophylactic therapy is currently being used at a sufficient dose.

Or

- Prophylaxis with at least two different therapy classes was either ineffective or not tolerated.

Criteria for Use: Pain (*bullet points below are all inclusive unless otherwise noted*)

- Evaluation of chronic pain has been documented.
- Failed / intolerant to 2 long acting narcotic analgesics

Criteria for use for greater than 2 canisters per month

- Clinical documentation and/ or treatment plan to support the need for greater than 2 canisters per month.

Contraindications:

- Hypersensitivity to butorphanol or benzethonium chloride.

Not approved if:

- Patient does not meet the above stated guidelines for approval.
- Patient has any contraindications to the use of butorphanol.



Rationale for Criteria:

Medical literature suggest that preventative therapy should be considered when patients experience greater than two migraine attacks per month.¹⁻³ About two-thirds of patients on prophylactic therapy will have a 50% reduction in frequency of migraines even though less than 10% of patients become headache-free on prophylactic therapy.^{1,4} Stadol NS is not indicated for prophylaxis of migraine.⁵

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.⁶

P&T Approval: _____ Date: _____