Prior Authorization Approval Criteria
Stadol NS (butorphanol)

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 FCHP preferred Triptans (Relpax, Zomig, Maxalt, Frova).
  • Failed / intolerant to Fioricet.
  • 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.
  • Patient has failed at least 2 non-opioid therapies
  • Patient has failed morphine extended release, methadone, or Duragesic patches.
Or
  • Patient is NPO.

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.

Criteria for continuation of therapy:
  • Patient’s pain has been recently re-assessed and there continues to be a medical need for the medication.
  • Patient is tolerating and responding to medication.
  • Patient has improved functioning and is meeting treatment goals.
  • Patient is not exhibiting addictive behaviors and is not being treated for substance abuse.

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.
- Patient is being treated for substance abuse (including treatment with buprenorphine or buprenorphine-naloxone).

Rationale for Criteria:
Medical literature suggest that preventative therapy should be considered when patients experience greater than two migraine attacks per month. 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. Stadol NS is not indicated for prophylaxis of migraine.

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.

P&T Approval: ___________________________ Date: ____________
Revised 12/16/12