# DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Butorphanol Drug Quantity Management Policy – Per Days
- Butorphanol tartrate nasal spray (generic only)

**REVIEW DATE:** 09/16/2022

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## OVERVIEW

Butorphanol tartrate nasal spray, an opioid agonist-antagonist, is indicated for the **management of pain** severe enough to require an opioid analgesic and for which alternative treatments are inadequate.[1]

Limitations of Use: Because of the risks of addiction, abuse, and misuse, with opioids, even at recommended doses, reserve butorphanol tartrate nasal spray for use in patients for whom alternative treatment options (e.g., non-opioid analgesics) have not been tolerated, are not expected to be tolerated, have not provided adequate analgesia, or are not expected to provide adequate analgesia.

## Dosing

In patients using butorphanol nasal spray for pain management, the usual recommended dose for initial nasal administration is 1 mg (one spray in one nostril).[1] If adequate pain relief is not achieved within 60 to 90 minutes, an additional 1 mg dose may be given. The initial dose sequence outlined above may be repeated in 3 to 4 hours as required after the second dose of the sequence. Depending on the severity of the pain, an initial dose of 2 mg (one 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 to 4 hours.

## Availability

Butorphanol tartrate nasal spray, USP is supplied in a 2.5 mL bottle of nasal spray solution (10 mg/mL) and a metered-dose spray pump.[1]

After initial priming each metered spray delivers an average of 1.0 mg of butorphanol tartrate and the 2.5 mL bottle will deliver an average of 14 to 15 doses of butorphanol.[1] Therefore, based on availability and dosing for pain management, at the maximum dose of two sprays every 3 hours, one bottle of butorphanol nasal spray would last approximately 1 day.

## Management of Migraine Pain

Butorphanol also has established efficacy for the acute treatment of migraine headache.[2,3] However, guidelines do not recommend routine use.[3] Patients who need to use acute treatments for migraine on a regular basis should limit treatment to an average of two headache days per week and patients who exceed this limit should be offered preventive treatment.

If butorphanol nasal spray is only used occasionally, as may be the case with migraine, it needs to be reprimed with each use, therefore, the 2.5 mL bottle will deliver an average of 8 to 10 sprays. At the recommended dose (1 to 2 sprays, with another 2 sprays repeated 3 to 4 hours later if the headache persists), one bottle will treat two migraine headaches, when used intermittently.

## POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent the stockpiling, misuse, and/or overuse use of butorphanol tartrate nasal spray. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below.

**Automation:** None.

**Drug Quantity Limits**

| Product | Strength/Package Size | Retail Maximum Quantity per 28 days | Home Delivery Maximum Quantity per 84 days |
|---|---|---|---|
| Butorphanol tartrate nasal spray (generic only) | 10 mg/mL nasal spray solution in a 2.5 mL bottle | 5 mL (2 bottles)* | 15 mL (6 bottles) |

* This is a quantity sufficient to treat 2 days of pain with around-the-clock use or four headache episodes.

## CRITERIA

**1.** If the patient is requesting butorphanol for the acute treatment of migraine or cluster headache, approve a one-time override for an additional 5 mL (2 bottles), for a total of 4 bottles (10 mL) at retail and an additional 15 mL (6 bottles), for a total of 30 mL (12 bottles) home delivery, if the patient meets ONE of the following criteria (A, B, OR C):

**A)** The patient has tried abortive therapy with a triptan; OR

**B)** The patient has tried abortive therapy with an ergotamine derivative; OR

**C)** The patient has a contraindication to the above agents.

Note: This one-time override provides a quantity sufficient to treat a total of eight headaches in one 28-day period or 24 headaches in one 84-day period.

**2.** If the patient is requesting butorphanol for the treatment of acute, short-term, pain not related to migraine or cluster headache, approve a one-time override for an additional 5 mL (2 bottles), for a total of 10 mL (4 bottles) at retail and an additional 15 mL (6 bottles), for a total of 30 mL (12 bottles) at home delivery.

## REFERENCES

1. Butorphanol tartrate nasal spray [prescribing information]. Westin, FL: Apotex; January 2021.
2. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
3. Ailani J, Burch RC, Robbins MS, on behalf of the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021;61(7):1021-1039.