Stadol (butorphanol tartrate nasal solution)
Policy Number: C4735-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
5/1/2013	2/1/2019	2/1/2020
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
	RxPA	Q2 2019

PRODUCTS AFFECTED:
Stadol (butorphanol tartrate)

DRUG CLASS:
Opioid Partial Agonists

ROUTE OF ADMINISTRATION:
Intranasal

PLACE OF SERVICE:
Retail Pharmacy

AVAILABLE DOSAGE FORMS:
Butorphanol Tartrate SOLN 10MG/ML

FDA-APPROVED USES: Butorphanol tartrate nasal solution is indicated for the management of pain when the use of an opioid analgesic is appropriate.

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: migraine headache or acute pain

REQUIRED MEDICAL INFORMATION:

A. MIGRAINE HEADACHE:
1. Medication overuse headache has been ruled out.
   AND
2. The patient has experienced an inadequate treatment response, contraindication or intolerance to abortive migraine therapy-2 formulary triptan products
   AND
3. Documentation the member is currently using migraine prophylactic therapy or has experienced an inadequate treatment response, contraindication or intolerance to migraine prophylactic therapy

B. ACUTE PAIN:
1. Documentation member has experienced a failure or intolerance to a trial of NSAIDs or lidocaine or capsaicin as appropriate

DURATION OF APPROVAL: Initial authorization: 12 weeks, Continuation of therapy: 12 weeks

QUANTITY: 2 canisters per 30 days

PRESCRIBER REQUIREMENTS: No requirement

AGE RESTRICTIONS: 18 years of age and older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. FOR ALL INDICATIONS:

1. Documentation that Stadol (butorphanol tartrate nasal solution) has provided improvement in the member's condition

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of Stadol (butorphanol tartrate) are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy. Contraindications to butrophanol tartrate include: acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; significant respiratory depression; GI obstruction, including paralytic ileus (known or suspected). Documentation of allergenic cross-reactivity for opioids is limited. However, because of similarities in chemical structure and/or pharmacologic actions, the possibility of cross-sensitivity cannot be ruled out with certainty.

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND: None

APPENDIX: None

REFERENCES:

1. Bennie RE, Boehringer LA, Dierdorf SF, et al, "Transnasal Butorphanol Is Effective for Postoperative Pain Relief in Children Undergoing Myringotomy," Anesthesiology, 1998, 89(2):385-90.
2. Berna C, Kulich RJ, Rathmell JP. Tapering long-term opioid therapy in chronic noncancer pain: evidence and recommendations for everyday practice. Mayo Clin Proc. 2015;90(6):828-842. doi: 10.1016/j.mayocp.2015.04.003.
3. Brennan MJ. The effect of opioid therapy on endocrine function. Am J Med. 2013;126(3)(suppl 1):S12-S18. doi: 10.1016/j.amjmed.2012.12.001.
4. Butorphanol tartrate nasal solution [prescribing information]. Eatontown, NJ: West-Ward Pharmaceuticals Corp.; August 2018.
5. Chou R, Fanciullo GJ, Fine PG, et al, "Clinical Guidelines For the Use of Chronic Opioid Therapy in Chronic Noncancer Pain," J Pain, 2009, 10(2):113-30.