



Effective Date: 5/1/2013
Last P&T Approval/Version: 01/26/2022
Next Review Due By: 01/2023
Policy Number: C4735-A

Stadol (butorphanol tartrate)

PRODUCTS AFFECTED

Stadol (butorphanol tartrate)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:

migraine headache or acute pain

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. MIGRAINE HEADACHE:

1. Medication overuse headache has been ruled out.
AND
2. Documentation the member has experienced an inadequate treatment response (after 1 month), contraindication or intolerance to TWO preferred formulary abortive migraine therapy products triptan products
AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted

Drug and Biologic Coverage Criteria

for review [Contraindications to Stadol (butorphanol tartrate) include: Hypersensitivity (e.g., anaphylaxis) To butorphanol or any component of the formulation; 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).

B. ACUTE PAIN:

1. Documentation of an Inadequate response (2 weeks), intolerance, or contraindication to TWO preferred formulary Non-Steroidal-Anti-Inflammatory-Drugs NSAIDs), lidocaine or capsaicin as appropriate for type of acute pain

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Documentation of no intolerable adverse effects or drug toxicity
AND
2. Documentation that Stadol (butorphanol tartrate nasal solution) has provided improvement in the member's condition

DURATION OF APPROVAL:

Initial authorization: 12 weeks, Continuation of therapy: 12 weeks

PRESCRIBER REQUIREMENTS:

No requirement

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

15ml per 30 days

PLACE OF ADMINISTRATION:

The recommendation is that intranasal medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Intranasal

DRUG CLASS:

Opioid Partial Agonists

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

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

None

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 butorphanol 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

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Butorphanol Tartrate SOLN 10MG/ML

REFERENCES

1. Butorphanol tartrate nasal solution [prescribing information]. Eatontown, NJ: West-Ward PharmaceuticalsCorp; August 2018.
2. Butorphanol tartrate nasal spray [prescribing information]. Weston, FL: Apotex Corp; January 2021.
3. Bennie RE, Boehringer LA, Dierdorf SF, et al, "Transnasal Butorphanol Is Effective for Postoperative PainRelief in Children Undergoing Myringotomy," Anesthesiology, 1998,89(2):385-90.
4. Berna C, Kulich RJ, Rathmell JP. Tapering long-term opioid therapy in chronic noncancer pain: evidence andrecommendations for everyday practice. Mayo Clin Proc. 2015;90(6):828-842. doi: 10.1016/j.mayocp.2015.04.003.
5. 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.
6. Butorphanol tartrate nasal solution [prescribing information]. Eatontown, NJ: West-Ward PharmaceuticalsCorp.; August 2018.
7. Chou R, Fanciullo GJ, Fine PG, et al, "Clinical Guidelines For the Use of Chronic Opioid Therapy in ChronicNoncancer Pain," J Pain, 2009, 10(2):113-30.