

Clinical Policy: Butorphanol Nasal Spray

Reference Number: HIM.PA.46

Effective Date: 12.01.14

Last Review Date: 05.19

Line of Business: HIM

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Butorphanol tartrate is a synthetically derived opioid agonist-antagonist analgesic of the phenanthrene series.

FDA Approved Indication(s)

Butorphanol tartrate nasal solution is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitation(s) 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, or are not expected to be tolerated,
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that butorphanol nasal spray is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Pain Management (must meet all):

1. Prescribed for the management of pain;
2. Age \geq 18 years;
3. Failure of at least 2 non-opioid ancillary treatments (such as non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen-containing products (*see Appendix B for examples*), unless contraindicated or clinically significant adverse effect are experienced;
4. For pain related to migraine headache, failure of at least 2 anti-migraine agents (*see Appendix B for examples*), unless contraindicated or clinically significant adverse effect are experienced;
5. For chronic pain, failure of an antidepressant or anticonvulsant agent (*see Appendix B for examples*), unless contraindicated or clinically significant adverse effect are experienced;
6. Member is unable to use oral medications for pain relief.

Approval duration: 12 months

B. Other diagnoses/indications:

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Pain Management (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation Key

FDA: Food and Drug Administration

NSAID: non-steroidal anti-inflammatory disease

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be formulary agents and may require prior authorization.

Drug Class	Commonly Used Examples	Dose Limit/ Maximum Dose
Non-steroidal anti-inflammatory agents (NSAIDs)	Motrin [®] (ibuprofen), Naprosyn [®] (naproxen), Relafen [®] (nabumetone), Voltaren [®] (diclofenac), Orudis [®] (ketoprofen), Clinoril [®] (sulindac), Toradol [®] (ketorolac)	Varies according to the agent used
Non-opioid analgesics	aspirin, acetaminophen opioid combinations (APAP/codeine, APAP hydrocodone)	Varies according to the agent used
Anti-migraine agents (non-triptans)	Cafergot [®] (ergotamine/caffeine), D.H.E.-45 [®] (dihydroergotamine), Midrin [®] (isometheptene/APAP), Fiorinal [®]	Varies according to the agent used

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Drug Class	Commonly Used Examples	Dose Limit/ Maximum Dose
	(butalbital/aspirin), Fioricet [®] (butalbital/APAP)	
Anti-migraine agents (triptans)	almotriptan (Axert [®]), eletriptan (Relpax [®]), frovatriptan (Frova [®]), naratriptan (Amerge [®]), rizatriptan (Maxalt [®]), sumatriptan (Imitrex [®]), zolmitriptan (Zomig [®])	Varies according to the agent used
Anticonvulsants	Carbamazepine (Tegretol [®]), gabapentin (Neurontin [®]), divalproex (Depakote [®]), topiramate (Topamax [®])	Varies according to the agent used
Antidepressants/ Tricyclic antidepressants	amitriptyline (Elavil [®]), desipramine (Norpramin [®]), imipramine (Tofranil [®]), nortriptyline (Pamelor [®]), duloxetine (Cymbalta [®]), venlafaxine (Effexor [®])	Varies according to the agent used

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment; known or suspected gastrointestinal obstruction, including paralytic ileus; hypersensitivity to butorphanol tartrate, the preservative benzethonium chloride, or any of the formulation excipients (e.g., anaphylaxis).
- Boxed warning(s): risks of addiction, abuse, and misuse; life-threatening respiratory depression; accidental ingestion; neonatal opioid withdrawal syndrome; cytochrome P450 3A4 inducers, 3A4 interactions; concomitant use with benzodiazepines or other central nervous system depressants.

V. References

1. Butorphanol Tartrate Nasal Solution Prescribing Information. Eatontown, NJ: West-Ward Pharmaceuticals Corp.; August 2018. Available at: <https://dailymed.nlm.nih.gov/dailymed/>. Accessed February 27, 2019.
2. Butorphanol Nasal Spray Drug Monograph. Clinical Pharmacology. Accessed February 27, 2019. <http://www.clinicalpharmacology-ip.com/>
3. Micromedex[®] Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 27, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guidelines to new format	05.16	05.16
Clinical changes made to criteria: Added requirement that butorphanol is prescribed for the management of pain. Non-clinical changes: Converted to new template; Updated references.	01.17	05.17

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q18 annual review: due to the current concerns around utilization of opioid agents, replaced requirement for prior trials of 2 immediate-release opioids with the requirement for prior trials of at least 2 non-opioid ancillary treatments plus 2 anti-migraine agents (if migraine pain) plus two anticonvulsants or antidepressants (if chronic pain) plus documentation of an inability to take oral medications; added age limit; references reviewed and updated.	02.26.18	05.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.27.19	05.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not

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intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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