Clinical Policy: Ketorolac Nasal Spray (Sprix)

Reference Number: DE.PMN.282
Effective Date: 01.23
Last Review Date: 01.23 Revision Log
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Ketorolac Nasal Spray (Sprix®) is nonsteroidal anti-inflammatory drug (NSAID).

FDA Approved Indication(s)

Sprix is indicated in adult patients for the short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the opioid level.

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 Sprix is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Pain Management (must meet all)**:**

1. Prescribed for the short term management of pain;
2. Age ≥ 18 years;
3. Failure of generic ketorolac tablets, unless contraindicated, clinically significant adverse effects are experienced, or inability to swallow tablets (e.g. dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting);
4. Failure of an adequate trial of at least two preferred* FDA-approved drugs for the indication and/or drugs that are considered the standard of care within the same drug class on the PDL, when such agents exist, at maximum indicated doses, unless clinically significant adverse effect are experienced, or all are contraindicated;
   ** Generic is preferred, if available, and brand is not the preferred agent;*
5. Total prescribed ketorolac treatment duration, including other formulations (i.e., intramuscular, intravenous, or oral), will not exceed 5 days;
6. Dose does not exceed both of the following (a and b):
   a. 8 sprays (4 in each nostril) per day;
   b. 5 bottles total.

Approval duration: 14 days (5 days total ketorolac treatment duration)

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255; or
b. For drugs NOT on the formulary or PDL, the non-formulary policy for the relevant line of business: CP.PMN.16; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53.

II. Continued Therapy

A. Pain Management

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1, 2, or 3):

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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary or PDL, the no coverage criteria policy for the relevant line of business: CP.PMN.255; or
   b. For drugs NOT on the formulary or PDL, the non-formulary policy for the relevant line of business: CP.PMN.16; or
3. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53.

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 policies – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NSAID: nonsteroidal anti-inflammatory drug

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 a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Ketorolac tromethamine tablet	20 mg once, followed by 10 mg every 4 to 6 hours as needed; maximum daily dose: 40 mg/day; maximum duration: 5 days combined (parenteral, oral, and nasal)	40 mg/day

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):
  - Hypersensitivity
  - History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs
  - In the setting of CABG surgery
  - Use in patients with active peptic ulcer disease or with recent GI bleeding or perforation
  - Use as a prophylactic analgesic before any major surgery
  - Use in patients with advanced renal disease or patients at risk for renal failure due to volume depletion
  - Use in patients with suspected or confirmed cerebrovascular bleeding, patients with hemorrhagic diathesis, incomplete hemostasis, and those at high risk of bleeding
  - Use in labor and delivery
- Boxed warning(s): risk of serious cardiovascular and gastrointestinal events

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Pain management	31.5 mg (one 15.75 mg spray in each nostril) every 6 to 8 hours.	126 mg (8 sprays) per day

VI. Product Availability

Nasal Spray: 1.7 g bottle (8 sprays delivering 15.75 mg ketorolac tromethamine each)

VII. References

1. Sprix Prescribing Information. Wayne, PA: Zyla Life Sciences US Inc.; April 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022382s021lbl.pdf. Accessed August 23, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.22	01.23

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 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.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.