Clinical Policy: Naproxen Oral Suspension (Naprosyn)

Reference Number: HIM.PA.130
Effective Date: 12.01.17
Last Review Date: 11.24
Line of Business: HIM

Revision Log

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

Description

Naproxen oral suspension (Naprosyn®) is a non-steroidal anti-inflammatory drug (NSAID).

FDA Approved Indication(s)

Naprosyn suspension is indicated:

- For the relief of the signs and symptoms of:
  - Rheumatoid arthritis
  - Osteoarthritis
  - Ankylosing spondylitis
  - Polyarticular juvenile idiopathic arthritis
  - Tendonitis
  - Bursitis
  - Acute gout
- For the management of:
  - Pain
  - Primary dysmenorrhea

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 Naprosyn oral suspension and naproxen oral suspension is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for Naprosyn or Naproxen Oral Suspension (must meet all)**:**

1. Age ≥ 2 years;
2. Documentation supports inability to use generic naproxen oral tablets;
3. If request is for brand Naprosyn oral suspension, member must use generic naproxen oral suspension, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed any of the following (a or b):
   a. Adults: 1,500 mg per day (60 mL per day);
   b. Pediatrics: 15 mg/kg per day.

Approval duration: 12 months

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: HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; 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: HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. If request is for brand Naprosyn oral suspension, member must use generic naproxen oral suspension, unless contraindicated or clinically significant adverse effects are experienced;
3. If request is for a dose increase, new dose does not exceed any of the following (a or b):
   a. Adults: 1,500 mg per day (60 mL per day);
   b. Pediatrics: 15 mg/kg per day.

Approval duration: 12 months

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: HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; 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: HIM.PA.154 for health insurance marketplace.

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 – HIM.PA.154 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CABG: coronary artery bypass graft
FDA: Food and Drug Administration
NSAID: non-steroidal 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
naproxen (Naprosyn®) oral tablets	Ankylosing Spondylitis, Osteoarthritis, Rheumatoid Arthritis 250-500 mg PO BID Bursitis, Pain, Primary Dysmenorrhea, Acute Tendonitis 500 mg PO followed by 250 mg Q6-8 hrs Acute Gout 750 mg PO followed by 250 mg PO Q8 hrs until attack has subsided Juvenile Idiopathic Arthritis 10 mg/kg/day PO in two divided doses	1,500 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 to naproxen or any components of the drug product; history of asthma, urticarial, or other allergic-type reactions after taking aspirin or other NSAIDs; in the setting of coronary artery bypass graft (CABG) surgery
- Boxed warning(s): cardiovascular thrombotic events; gastrointestinal bleeding, ulceration, and perforation

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Ankylosing spondylitis, osteoarthritis, rheumatoid arthritis	250-500 mg PO BID	1,500 mg/day
Bursitis, pain, primary dysmenorrhea, acute tendonitis	500 mg PO followed by 250 mg Q6-8 hrs as required	1,250 mg/day
Acute gout	750 mg PO followed by 250 mg PO Q8 hrs until attack has subsided	1,250 mg/day
Polyarticular juvenile idiopathic arthritis	10 mg/kg/day PO in two divided doses	15 mg/kg/day

VI. Product Availability

Oral suspension: 125 mg/5 mL

VII. References

1. Naprosyn Prescribing Information. Alpharetta, GA: Canton Laboratories, LLC; April 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/018965s027lbl.pdf. Accessed July 15, 2024.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 1, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2020 annual review: no significant changes; references reviewed and updated.	08.21.20	11.20
4Q 2021 annual review: no significant changes; HIM.PHAR.21 changed to HIM.PA.154; references reviewed and updated.	06.25.21	11.21
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.28.22	11.22
4Q 2023 annual review: added requirement for use of generic formulation for brand Naprosyn; references reviewed and updated.	06.30.23	11.23
4Q 2024 annual review: clarified PA criteria also applies to generic naproxen oral suspension; references reviewed and updated.	07.15.24	11.24

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.