Clinical Policy: Spinosad (Natroba)

Reference Number: HIM.PA.134
Effective Date: 12.01.17
Last Review Date: 08.22
Line of Business: HIM

Revision Log

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

Description

Spinosad topical suspension (Natroba®) is a pediculicide and scabicide.

FDA Approved Indication(s)

Natroba is indicated for the topical treatment of:

- Head lice infestations in patients 6 months of age and older
- Scabies infestations in adult and pediatric patients 4 years of age and older.

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

I. Initial Approval Criteria

A. Head Lice (must meet all)**:**

1. Diagnosis of head lice;
2. Age ≥ 6 months;
3. Failure of permethrin 1% cream in the last 60 days, unless contraindicated or clinically significant adverse effects are experienced;
4. Request does not exceed 2 bottles (8 oz).

Approval duration: 14 days

B. Scabies Infestation (must meet all)**:**

1. Diagnosis of scabies infestation;
2. Age ≥ 4 years;
3. Failure of permethrin 5% cream, unless contraindicated or clinically significant adverse effects are experienced;
4. Request does not exceed 4 bottles (16 oz).

Approval duration: one time

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

Approval duration: Not applicable

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

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

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
permethrin 1% creme rinse/lotion	Adults, adolescents, children, and infants ≥ 2 months: Shampoo hair with regular shampoo, rinse and towel dry. Then, apply permethrin 1% lotion sufficient to saturate the hair and scalp (usually 25 to 30 mL), especially behind the ears and on the nape of the neck. Leave on hair for 10 minutes but no longer. Then, rinse thoroughly with water. If live lice are seen 7 days or more after the first application, a second treatment should be given.	One application to affected area
permethrin 5% cream	Thoroughly massage permethrin 5% cream into the skin from the head to the soles of the feet. Scabies rarely infests the scalp of adults, although the hairline, neck, temple, and forehead may be infested in infants and geriatric patients. Usually 30 grams is sufficient for an average adult. The cream should be removed by washing (shower or bath) after 8 to 14 hours. Infants should be treated on the scalp, temple, and forehead. One application is generally curative. Patients may experience persistent pruritus after treatment. This is rarely a sign of treatment failure and is not an indication for retreatment. Demonstrable living mites after 14 days indicate that retreatment is necessary.	One application to affected area

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
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Head lice	Apply a sufficient amount to cover dry scalp, then apply to dry hair. Depending on hair length, apply up to 120 mL (one bottle) to adequately cover scalp and hair. Leave on for 10 minutes, then thoroughly rinse off with warm water. If live lice are seen 7 days after the first treatment, a second treatment should be applied.	120 mL/application
Scabies infestation	Apply a sufficient amount of Natroba to skin to completely cover the body from the neck to the toes (including the soles of the feet). For patients with balding scalp, also apply product to the scalp,	Varies per body surface area

Indication	Dosing Regimen	Maximum Dose
	hairline, temples, and forehead. Allow to absorb into the skin and dry for 10 minutes before getting dressed. Leave on the skin for at least 6 hours before showering or bathing.	

VI. Product Availability

Suspension: 9 mg of spinosad per gram of Natroba topical suspension in 120 mL bottles

VII. References

1. Natroba Prescribing Information. Carmel, IN: ParaPRO LLC; April 2021. Available at: http://www.natroba.com. Accessed March 22, 2022.
2. Centers for Disease Control and Prevention. Parasites-Lice-Head Lice. Available at: https://www.cdc.gov/parasites/lice/head/treatment.html. Updated October 15, 2019. Accessed March 22, 2022.
3. Centers for Disease Control and Prevention. Parasites - Scabies. Suggested General Guidelines. Available at: http://www.cdc.gov/parasites/scabies/treatment.html. September 3, 2015; Accessed March 22, 2022.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/. Accessed March 22, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2018 annual review: modified timeframe of trial of permethrin from within the last 6 months to last 60 days; shortened approval duration from 1 month to 14 days (aligns with other pediculicide policies); continued therapy: removed requirement that 6 months should have elapsed since previous claim for Natroba; references reviewed and updated.	08.08.18	11.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.31.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	08.08.20	08.20
3Q 2021 annual review: added criteria for newly approved indication for scabies infestation; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	05.08.21	08.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	03.22.22	08.22
Template changes applied to other diagnoses/indications.	10.11.22	

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.

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