Clinical Policy: Lindane Shampoo

Reference Number: CP.PMN.09
Effective Date: 11.01.06
Last Review Date: 08.22
Line of Business: Medicaid

Revision Log

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

Description

Lindane is an ectoparasiticide and ovicide effective against Pediculus humanus capitis (head lice), Pthirus pubis (crab lice), and their ova.

FDA Approved Indication(s)

Lindane Shampoo is indicated for the treatment of head lice (infestations of Pediculus humanus capitis), crab lice (infestations of Pthirus pubis), and their ova only in patients who cannot tolerate other approved therapies, or have failed treatment with other approved therapies.

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 Lindane shampoo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of Pediculus capitis (head lice);
2. Failure of two preferred agents indicated for head lice (*see Appendix B for examples*), at least one of which was used within the past 60 days, unless ALL preferred agents for head lice are contraindicated or clinically significant adverse effects are experienced;
3. Request does not exceed 1 bottle (60 mL) per treatment course.

Approval duration: 14 days

B. Crab Lice (must meet all)**:**

1. Diagnosis of Pthirus pubis (crab lice);
2. Failure of pyrethrins/piperonyl butoxide AND permethrin 1% cream, used in last 60 days, unless both are contraindicated or clinically significant adverse effects are experienced;
3. Request does not exceed 1 bottle (60 mL) per treatment course.

Approval duration: 14 days

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: CP.PMN.255 for Medicaid; 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: CP.PMN.16 for Medicaid; 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 for Medicaid.

II. Continued Therapy

A. All Indications in Section I
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: CP.PMN.255 for Medicaid; 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: CP.PMN.16 for Medicaid; 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 for Medicaid.

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 for Medicaid 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% cream rinse/lotion	Head lice: 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. Pubic (crab) lice: The CDC recommends applying permethrin 1% cream rinse topically to affected areas and washed off after 10 minutes. Patients should be evaluated 1 week after therapy and retreatment may be necessary.	One application to affected area
pyrethrins/piperonyl butoxide	Head lice, pubic (crab) lice: Adults, adolescents, and children 2 to 12 years: Apply liberally to dry hair and scalp or skin. For head lice, apply first to back of neck and behind ears. Use enough product to cover entire hair shaft. Allow product to remain on affected areas for 10 minutes, but no longer. Rinse thoroughly and dry affected areas with a clean towel. Repeat application once in 7 to 10 days. If the first treatment was applied to wet hair, the hair should be rinsed, dried, and then the product should be reapplied in 24 hours. Repeat application on dry hair in 7 to 10 days.	2 topical treatments applied 7—10 days apart; if the first treatment is applied to wet hair, repeat treatment should be applied in 24 hours
malathion (Ovide®)	Head lice: Adults, adolescents, and children ≥ 6 years: Apply to dry hair and scalp. Apply as a single topical application in a sufficient amount (roughly 30 mL) to saturate hair and scalp. Leave on hair for 8-12 hours but no longer. Then, rinse thoroughly and shampoo with a non-medicated shampoo. After rinsing, use a nit comb to remove the dead lice and the nits (eggs) from the hair. Retreatment is not frequently required. A second treatment may be given if live lice are seen 7-9 days or more after the first application.	1 application (roughly 30 mL) topically as directed.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
spinosad (Natroba®)	Head lice: Adults, adolescents, children, and infants ≥ 6 months: Apply a sufficient amount of spinosad suspension to cover dry scalp and hair; up to one bottle (120 mL) may be required depending on the length of hair. Leave on for 10 minutes and then rinse thoroughly with warm water. If live lice are still seen 7 days after the first treatment, apply a second treatment.	120 mL/application

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):
  - Premature infants because their skin may be more permeable than that of full term infants and their liver enzymes may not be sufficiently developed to metabolize Lindane.
  - Patients with crusted (Norwegian) scabies and other skin conditions (e.g., atopic dermatitis, psoriasis) that may increase systemic absorption of the drug.
  - Patients with known uncontrolled seizure disorders and for individuals with known sensitivity to the product or any of its components.
- Boxed warning(s):
  - Lindane Shampoo should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications for the treatment of lice.
  - Neurologic toxicity: Seizures and deaths have been reported following Lindane Shampoo use with repeat or prolonged application, but also in rare cases following a single application according to directions. Lindane Shampoo should be used with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.
  - Lindane Shampoo is contraindicated in premature infants and individuals with known uncontrolled seizure disorders.
  - Instruct patients on proper use of Lindane Shampoo, the amount to apply, how long to leave it on, and avoiding retreatment. Inform patients that itching occurs after the successful killing of lice and is not necessarily an indication for retreatment with Lindane Shampoo.

Appendix D: General Information

Retreatment with lindane shampoo is not recommended. Seizures and deaths have been reported following use with repeat or prolonged application, but also in rare cases following a single application according to directions.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Pediculus capitis (head lice)	Apply shampoo directly to dry hair and work thoroughly into the hair for 4 minutes only. After 4 minutes, add small quantities of water to hair until a good lather forms. Immediately rinse all lather away. Avoid unnecessary contact of lather with other body surfaces. Amount of shampoo needed is based on length and density of hair; most patients will require 30 mL (maximum: 60 mL). Do not re-treat.	60 mL
Pthirus pubis (crab lice)		

VI. Product Availability

Shampoo: 1% (supplied in 60 mL bottles)

VII. References

1. Lindane Shampoo Prescribing Information. Morton Grove, IL: Morton Grove Pharmaceuticals, Inc.; December 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=13ddf5e6-ac0e-41e6-b95d-d5bdd6b26fcd. Accessed May 12, 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 May 12, 2022.
3. Devore CD, Schutze GE, Council on School Health and Committee on Infectious Diseases, American Academy of Pediatrics. Head lice. Pediatrics. 2015;135(5):e1355-e1365.
4. Centers for Disease Control and Prevention. Parasites-Lice-Pubic "Crab" Lice. Available at: https://www.cdc.gov/parasites/lice/pubic/treatment.html. Updated September 12, 2019. Accessed May 12, 2022.
5. Workowski KA, Bolan GA, Division of STD Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2015. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm. Accessed May 12, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: no significant changes; modified approval duration of one treatment (one 60 mL bottle) to 14 days and incorporated quantity limit in the criteria; added Appendix D; references reviewed and updated.	04.12.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.21.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.30.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	05.03.21	08.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2022 annual review: no significant changes; references reviewed and updated.	05.12.22	08.22
Template changes applied to other diagnoses/indications.	09.19.22	

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.

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.