

Clinical Policy: Lindane Shampoo

Reference Number: PA.CP.PMN.09

Effective Date: 01/18

Last Review Date: 08/17

Line of Business: Medicaid

[Revision Log](#)

Description

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

FDA approved indication

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 (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness 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 ≥ 2 PDL agents indicated for head lice, one of which was used within the past 60 days, unless ALL PDL agents for head lice are contraindicated or clinically significant adverse effects are experienced.

Approval duration: One treatment (one 60 mL bottle)

B. Crab Lice (must meet all):

1. Diagnosis of *Phthirus pubis* (crab lice);
2. Failure of pyrethrins/piperonyl butoxide AND permethrin 1% cream, one of which was used within the past 60 days, unless both agents are contraindicated or clinically significant adverse effects are experienced.

Approval duration: One treatment (one 60 mL bottle)

C. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications (must meet all):

1. Continuation of therapy will not be granted per manufacturer labeling. New cases of lice must be evaluated against the initial approval criteria.

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

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: Treatment duration of one 60 ml bottle

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

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

PDL: preferred drug list

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
Phthirus pubis (crab lice)		

VI. Product Availability

Shampoo: 1% (supplied in 60 mL bottles)

VII. Workflow Document

N/A

VIII. References

1. Lindane Shampoo Prescribing Information. Morton Grove, IL: Morton Grove Pharmaceuticals, Inc.; June 2010. Available at: <https://dailymed.nlm.nih.gov/dailymed/>. Accessed March 23, 2017.
2. Centers for Disease Control and Prevention. Parasites-Lice-Head Lice. Available at: <https://www.cdc.gov/parasites/lice/head/treatment.html>. Updated August 19, 2016. Accessed March 23, 2017.

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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.
4. Centers for Disease Control and Prevention. Parasites-Lice-Pubic “Crab” Lice. Available at: <https://www.cdc.gov/parasites/lice/pubic/treatment.html>. Updated August 17, 2015. Accessed March 23, 2017.
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 March 23, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date