

Clinical Policy: Lindane Shampoo

Reference Number: PA.CP.PMN.09

Effective Date: 01/18

Last Review Date: 07/17/19

[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(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 (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 preferred agents indicated for head lice, 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 rinse or lotion, one of which was used within the past 60 days, unless both agents 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

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):

- 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):

- Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
- 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:

- 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

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 crème rinse 1%, lotion 1%	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/pipe ronyl 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	2 topical treatments applied 7—10 days apart; if the first treatment is

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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.	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.
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

Lindane Shampoo is contraindicated for:

- 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

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
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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. References

1. Lindane Shampoo Prescribing Information. Morton Grove, IL: Morton Grove Pharmaceuticals, Inc.; June 2010. Available at: <https://dailymed.nlm.nih.gov/dailymed/>. April 12, 2018.
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 April 13, 2018.
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 April 13, 2018.
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 April 13, 2018.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 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; updated Appendices; references reviewed and updated.	08/18	

CLINICAL POLICY
Lindane Shampoo

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	