

Clinical Policy Title:	lindane shampoo
Policy Number:	RxA.201
Drug(s) Applied:	Lindane Shampoo
Original Policy Date:	02/07/2020
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

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

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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Lindane Shampoo	<i>Pediculus humanus capitis</i> (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
	<i>Pthirus pubis</i> (crab lice)		

Dosage Forms

- Shampoo: 1% (supplied in 60 mL bottles).

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Head Lice (must meet all):

1. Diagnosis of *Pediculus humanus capitis* (head lice);
2. Failure of at least two (2) 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

Commercial: 14 days

Medicaid: 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, at least 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

Commercial: 14 days

Medicaid: 14 days

II. Continued Therapy Approval

A. All Indications in Section I

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

Approval Duration

Commercial: Not applicable

Medicaid: Not applicable

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
permethrin creme 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	1 application to affected area

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<p>7 days or more after the first application, a second treatment should be given.</p> <p>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.</p>	
pyrethrins/piperonyl butoxide	<p>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.</p> <p>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.</p>	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®)	<p>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.</p> <p>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.</p>	1 application (roughly 30 mL) topically as directed.
spinosad (Natroba™)	<p>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.</p>	120 mL/application

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only, and generic name when the drug is available by generic only.

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 individuals with a known sensitivity to the product or any of its components.
- *Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.
- 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.

References

1. Lindane Shampoo Prescribing Information. Morton Grove, IL: Morton Grove Pharmaceuticals, Inc.; July 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=13ddf5e6-ac0e-41e6-b95d-d5bdd6b26fcd&type=display>. Accessed January 14, 2022.
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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. Available at: <https://publications.aap.org/pediatrics/article/135/5/e1355/33653/Head-Lice>. Accessed January 14, 2022.
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Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: <ol style="list-style-type: none"> Clinical Policy Title was updated. Drug(s) Applied was updated. Line of Business Policy Applies to was updated. Commercial approval duration and Medicaid approval duration updated. References were updated. 	07/07/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> Last Review Date was updated. Clinical policy verbiage was updated to “The provision of provider samples does not guarantee....”. APPENDIX B: Therapeutic Alternatives verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance...." APPENDIX C: Contraindication was updated to include contraindicated for individuals with a known sensitivity to the product or any of its components. References were updated. 	03/03/2021	06/10/2021
Policy was reviewed: <ol style="list-style-type: none"> Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only" Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. References were reviewed and updated. 	01/14/2022	04/18/2022