



Clinical Policy: Lindane Shampoo  
Reference Number: CP.PMN.09  
Effective Date: 11/06  
Last Review Date: 08/17  
Line of Business: Medicaid

[Coding Implications](#)  
[Revision Log](#)

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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

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 (~~including which may include~~ office chart notes and lab results) 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  $\geq 2$  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: ~~Treatment duration~~ One treatment (-of 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: ~~Treatment duration~~ One treatment (-of one 60 mL) bottle

### C. Other diagnoses/indications

1. Refer to 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):

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

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**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 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 – 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.

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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.
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
Under Criteria for Approval B: Deleted the note section and listed out the 3 diagnosis addressed along with FDA approved PDL medications for each condition; deleted criteria C and added it to the relevant diagnosis; updated references and added a new reference.	11/12	11/12
Under approval criteria: specified the number first line medications that have to be trialed for head lice, crab lice & scabies. Removed the requirement for failure of benzyl alcohol (non-PDL) after a malathion treatment failure because this is not supported by the literature or in any of the references. Removed Lindane lotion 30 ml bottle size. Updated references and added a new reference.	11/13	11/13
Updated references. Removed specific agents from preferred agent list.	12/14	12/14
Converted to new template Added that at least one PDL medication must have been used in the last 60 days for all indications; Provided the indicated PDL medications for all indications	08/15	08/15
Removed lindane lotion from the clinical policy as it has been permanently discontinued per 3 manufacturers and is off the market; Removed criteria for scabies following discontinuation of lindane lotion as the shampoo is not indicated for use; Added trial and failure of permethrin 1% cream to criteria for crab lice as it is recommended as one of the first line-regimens per CDC for pubic lice; Modified requirement for time frame of trial to include permethrin.	05/16	08/16

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Clarified continued approval based on PI and boxed warnings. Updated background to reflect discontinuation of lindane lotion; Updated references to reflect current literature search.		
<u>Converted to new template.</u> <u>Updated references.</u>	<u>03/17</u>	<u>08/17</u>

**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

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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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**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.

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