

<b>Clinical Policy Title:</b>	benzyl alcohol
<b>Policy Number:</b>	RxA.287
<b>Drug(s) Applied:</b>	Ulesfia®
<b>Original Policy Date:</b>	02/07/2020
<b>Last Review Date:</b>	06/10/2021
<b>Line of Business Policy Applies to:</b>	All lines of business

## Background

Benzyl alcohol (Ulesfia®) is a pediculicide. Ulesfia® is indicated for the topical treatment of head lice infestation in patients 6 months of age and older.

Limitation(s) of use: Ulesfia® does not have ovocidal activity.

## Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
benzyl Alcohol (Ulesfia®)	Head lice	<p>Apply to dry hair to completely saturate the scalp and hair; leave on for 10 minutes, then thoroughly rinse off with water. Repeat application after 7 days.</p> <p>Hair Length: Ounces (oz) = amount of 8 oz bottle per application</p> <ul style="list-style-type: none"> <li>• 0-2 inches: 4-6 oz = ½-¾ bottle</li> <li>• 2-4 inches: 6-8 oz = ¾-1 bottle</li> <li>• 4-8 inches: 8-12 oz = 1-1½ bottles</li> <li>• 8-16 inches: 12-24 oz = 1½-3 bottles</li> <li>• 16-22 inches: 24-32 oz = 3-4 bottles</li> <li>• &gt; 22 inches: 32-48 oz = 4-6 bottles</li> </ul>	1 application/week

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.

## Dosage Forms

- Lotion, 5%

## 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 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 head lice;
2. Age  $\geq$  6 months;
3. Failure of one preferred agent indicated for head lice (*see Appendix B for examples*), used in the last 60 days, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 6 bottles (48 ounces) per 7 days.

#### Approval Duration

**Commercial:** 14 days

**Medicaid:** 14 days

### II. Continued Therapy Approval

#### A. Head Lice

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 1% crème rinse/lotion	Adults, adolescents, children, and infants $\geq$ 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.	One application to affected area

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Then, rinse thoroughly with water. If live lice are seen 7 days or more after the first application, a second treatment should be given.	
pyrethrins/piperonyl butoxide	Head 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®)	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®)	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 Warning**

- Contraindication(s):

- None reported.
- Boxed Warning(s):
  - None reported.

**APPENDIX D: General Information**

- Not Applicable

**References**

1. Ulesfia Prescribing Information. Dublin, Ireland: Lachlan Pharmaceuticals; April 2020. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2020/022129s008lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022129s008lbl.pdf). Accessed April 13, 2021.
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 April 13, 2021.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: <http://www.clinicalpharmacology-ip.com/>.

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"> <li>1. Clinical Policy Title was updated</li> <li>2. Drug(s) Applied was updated</li> <li>3. Line of Business Policy Applies to was updated</li> <li>4. Commercial approval duration and Medicaid approval duration updated.</li> <li>5. References were updated</li> </ol>	07/01/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Statement about provider sample, “The provision of provider samples does not guarantee coverage...” was added to Clinical Policy.</li> <li>2. Therapeutic alternatives verbiage in Appendix B was updated to “Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements”.</li> <li>3. References were reviewed and updated.</li> </ol>	04/13/2021	06/10/2021