Clinical Policy: Benzyl Alcohol (Ulesfia)

Reference Number: ERX.NPA.81
Effective Date: 09.01.18
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Benzyl alcohol (Ulesfia®) is a pediculicide.

FDA Approved Indication(s)
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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Ulesfia is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Head Lice (must meet all)**:**
1. Diagnosis of head lice;
2. Age ≥ 6 months;
3. Failure of malathion or spinosad, used in the last 60 days, unless both are contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 6 bottles (48 ounces) per 7 days.

Approval duration: 14 days

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 14 days (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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 Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Head lice	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. Hair Length: Ounces (oz) = amount of 8 oz bottle per application • 0 – 2 inches: 4 – 6 oz = ½ – ¾ bottle • 2 – 4 inches: 6 – 8 oz = ¾ – 1 bottle • 4 – 8 inches: 8 – 12 oz = 1 – 1½ bottles • 8 – 16 inches: 12 – 24 oz = 1½ – 3 bottles • 16 – 22 inches: 24 – 32 oz = 3 – 4 bottles • > 22 inches: 32 – 48 oz = 4 – 6 bottles	1 application/week

VI. Product Availability

Lotion 5%: 8 oz bottles (2) in box

VII. References

1. Ulesfia Prescribing Information. Dublin, Ireland: Lachlan Pharmaceuticals; June 2015. Available at: https://www.accessdata.fda.gov/ . Accessed May 3, 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 May 3, 2021.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/.
4. Devore CD, Schutze GE, Council on School Health and Committee on Infectious Diseases, American Academy of Pediatrics. Head lice. Pediatrics. 2015;135(5):e1355-e1365.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from ERX.ST.25; no significant changes; added diagnosis; references reviewed and updated.	04.02.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.21.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.30.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	05.03.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.