

Clinical Policy: Abametapir (Xeglyze)

Reference Number: ERX.NPA.150

Effective Date: 12.01.20

Last Review Date: 11.21

Line of Business: Commercial, Medicaid

[Revision Log](#)

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

Description

Abametapir (Xeglyze™) is a pediculicide.

FDA Approved Indication(s)

Xeglyze is indicated for topical treatment of head lice infestation in patients 6 months of age and older.

Xeglyze should be used in the context of an overall lice management program:

- Wash (with hot water) or dry-clean all recently worn clothing, hats, used bedding and towels;
- Wash personal care items such as combs, brushes and hair clips in hot water;
- Use a fine-tooth comb or special nit comb to remove dead lice and nits.

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 Xeglyze 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 \geq 6 months;
3. Failure of two preferred agents indicated for head lice (*see Appendix B for examples*), used in the last 60 days, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed 1 bottle for a single use.

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
pyrethrins/piperonyl butoxide*	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
permethrin 1% cream rinse/lotion*	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.	One application to affected area
benzyl alcohol 5% lotion (Ulesfia®)	Adults, adolescents, and children ≥ 6 months: 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.	1 application/week
ivermectin 0.5% lotion (Sklice®)	Adults, adolescents, and children ≥ 6 months: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp. Leave on the hair and scalp for 10 minutes, and then rinse off with water. The tube is intended for single use; discard any unused portion.	1 tube/topical application
malathion 0.5% lotion (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	1 application (roughly 30 mL)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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.	
spinosad 0.9% topical suspension (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.

*Over-the-counter

Appendix C: Contraindications/Boxed Warnings

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Head lice	Apply Xeglyze to dry hair in an amount sufficient (up to the full content of one bottle) to thoroughly coat the hair and scalp. Massage Xeglyze into the scalp and throughout the hair; leave on the hair and scalp for 10 minutes and then rinse off with warm water. Treatment with Xeglyze involves a single application. Discard any unused product.	1 application

VI. Product Availability

Bottle containing lotion (filled to a nominal 200 g [approximately 7 oz or 210 mL]): 0.74% (w/w)

VII. References

1. Xeglyze Prescribing Information. Princeton, NJ: Dr. Reddy's Laboratories; June 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/206966lbl.pdf. Accessed July 16, 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 July 16, 2021.
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-e1365.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.11.20	11.20
4Q 2021 annual review: no significant changes; references reviewed and updated.	07.16.21	11.21

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.

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