Clinical Policy: Abametapir (Xeglyze)

Reference Number: CP.PMN.253
Effective Date: 12.01.20
Last Review Date: 11.23
Line of Business: Commercial, HIM, 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.

It is the policy of health plans affiliated with Centene Corporation® 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 ≥ 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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business:

CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, 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 for all relevant lines of business 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 nit comb to remove the dead lice and the nits (eggs) from the hair. Retreatment is not frequently required. A second treatment may	1 application (roughly 30 mL)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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; January 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/206966Orig1s002lbl.pdf. Accessed August 11, 2023.
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 August 11, 2023.
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; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	07.16.21	11.21
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications.	06.16.22	11.22
4Q 2023 annual review: no significant changes; references reviewed and updated.	08.14.23	11.23

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

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.