

Clinical Policy: Topical Agents: Anti-Parasitics

Reference Number: OH.PHAR.PPA.91

Effective Date: 01/01/2020

Last Review Date:

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

ANTI-PARASITICS, TREATMENT OF SCABIES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
PERMETHRIN cream (generic of Elimate®)	EURAX® cream, lotion (crotamiton)

ANTI-PARASITICS, TREATMENT OF LICE

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
LICE kit [piperonyl butoxide-pyrethrins shampoo, comb, permethrin home spray] (generic of Rid® complete kit) NATROBA® (spinosad) PERMETHRIN lotion (generic of Nix® cream rinse) PIPERONYL BUTOXIDE-PYRETHRINS lotion PIPERONYL BUTOXIDE-PYRETHRINS shampoo (generic of Rid® shampoo)	MALATHION lotion (generic of Ovide®) SPINOSAD (generic of Natroba®) SKLICE® lotion (ivermectin)

FDA approved indication(s)

Eurax is indicated for:

- Treatment of scabies caused by *Sarcoptes scabiei* in adults.
- Treatment of pruritus in adults.

Lice kit [piperonyl butoxide-pyrethrins shampoo, comb, permethrin home spray] (generic of Rid® complete kit) is indicated for:

- Treatment of pediculosis (lice) infestations caused by *Pediculus corporis* (body louse), *Pediculus capitis* (head louse), and *Phthirus pubis* (pubic or crab louse) in adults and children 2 years of age and older.

Malathion is indicated for:

- Treatment of pediculosis including *Pediculosis capitis* and *Pediculosis pubis* in adults and children 6 years of age and older.

Permethrin is indicated for:

- Treatment of scabies infection (adults and children 2 months of age and older) and crusted (Norwegian) scabies (adults).
- Treatment of pediculosis capitis (head lice infestation) due to *Pediculus capitis* (adults and children 2 months of age and older) and pediculosis pubis (adults).
- Pediculosis prophylaxis in adults and children 2 months of age and older.

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Sklice is indicated for:

- Treatment of pediculosis including pediculosis capitis, pediculosis corporis, and pediculosis pubis in adults and children 6 months of age and older.

Spinosad (Natroba®) is indicated for:

- Treatment of pediculosis capitis (head lice infestation) due to *Pediculus capitis* in adults and children 6 months of age and older.

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 Buckeye Health Plan, an affiliate of Centene Corporation® that Topical Agents: Anti-Parasitics are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. If request is for Sklice® or Spinosad (Natroba®), age \geq 6 months;
3. If request is for Eurax®, age \geq 18 years;
4. If request is for Malathion (Ovide®), age \geq 6 years;
5. Failure of \geq 30 days of one preferred medication, unless member meets one of the following (a, b, or c):
 - a. Allergy to medication not requiring prior approval;
 - b. Contraindication to or drug interaction with medications not requiring prior approval;
 - c. History of unacceptable/toxic side effects to medications not requiring prior approval.

Approval Duration: 14 days

II. 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.

III. Appendices/General Information

Appendix A: Abbreviation 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
Lice kit [piperonyl butoxide-pyrethrins shampoo, comb,	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	2 topical treatments applied 7 to 10 days apart;

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
permethrin home spray] (Rid® complete kit)	entire hair shaft. Allow product to remain on for 10 minutes, but no longer. Rinse thoroughly and dry 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.	if first treatment is applied to wet hair, repeat treatment should be applied in 24 hours (see Dosage).
Natroba (spinosad)	Apply a sufficient amount to cover dry scalp and hair; up to 1 bottle (120 ml). Leave on for 10 minutes and then rinse thoroughly with warm water. If live lice are still seen 7 days after first treatment, apply a second treatment.	120ml/application
Permethrin cream (Elimite®)	<p>Treatment of scabies infection: massage cream into skin from the head to the soles of the feet. Wash cream off after 8 to 15 hours. Retreatment is indicated if living mites persist after 7 to 14 days of initial treatment.</p> <p>Treatment of crusted (Norwegian) scabies: The CDC recommends ivermectin oral dosing along with the use of a topical scabicide. CDC recommends a full body application (all body parts from neck down) topically daily for 7 days and then 2 times weekly until release from care or cure in combination with oral ivermectin. Retreatment 2 weeks after the initial treatment regimen can be considered for those persons who are still symptomatic or when live mites are observed.</p>	One application to affected area; do not repeat for ≥ 7 days
Permethrin lotion (Nix® cream rinse)	Treatment of pediculosis capitis (head lice infestation): 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; do not repeat for ≥ 7 days

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<p>Treatment of pediculosis pubis: Apply 1% cream rinse topically to affected areas and washed off after 10 minutes. Patients should be evaluated 1 week after therapy and retreatment may be necessary.</p> <p>Pediculosis prophylaxis: 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. In epidemic settings, a second prophylactic application is recommended 2 weeks after the first since the life cycle of head louse is approximately 4 weeks.</p>	

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

- Contraindications(s):
 - Infants and neonates (Malathion)
- Boxed warning(s): none reported

IV. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Eurax	<p>Treatment of scabies: After routine bath, apply topically over the entire body from the chin to the toes. Repeat in 24 hours.</p> <p>Treatment of pruritus: Apply topically by massaging gently into affected area until medication is completely absorbed. Repeat if needed.</p>	<p>Scabies: 1 applications/day for 2 days, given 24 hours apart</p> <p>Pruritis: 1 application/day, then as needed</p>
Malathion	Treatment of pediculosis capitis: Apply to dry hair and scalp. Apply as a single topical application in a sufficient amount (roughly 30 mL) to saturate hair and scalp. Include behind the ears and on the nape of the neck. Let hair dry naturally. Leave on hair for 8 to 12 hours but no longer. Then, rinse thoroughly and shampoo	1 application (roughly 30 mL) topically as directed

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Drug	Dosing Regimen	Maximum Dose
	with a non-medicated shampoo. After rinsing, use a nit comb to remove the dead lice and the nits (eggs) from the hair. A second treatment may be given if live lice are seen 7 to 9 days or more after the first application. Treatment of pediculosis pubis: Apply for 8 to 12 hours and then wash off.	
Spinosad	Apply a sufficient amount to cover dry scalp and hair; up to 1 bottle (120 ml). Leave on for 10 minutes and then rinse thoroughly with warm water. If live lice are still seen 7 days after first treatment, apply a second treatment.	120ml/application
Sklice	Apply a sufficient amount (up to 1 tube) to thoroughly coat dry hair and scalp. Leave on for 10 minutes then rinse off with water. A fine-tooth comb or special nit comb may be used to remove dead lice and nits. Wait 24 hours before applying shampoo to hair and scalp after use.	4 oz/topical application

For preferred agents please see Appendix B

V. Product Availability

Drug	Availability
Eurax	Topical cream: 10% Topical lotion: 10%
Lice kit	Topical shampoo: piperonyl butoxide 4%, pyrethrum extract 0.33%
Malathion	Topical lotion: 0.5%
Permethrin	Topical cream: 5% Topical lotion: 1%
Sklice	Topical lotion: 0.5%
Spinosad	Topical suspension: 0.9%

VI. References

Refer to package inserts.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10/19	

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

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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.

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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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