BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/17/16**
SECTION: DRUGS	**LAST REVIEW DATE: 2/21/19**
	LAST CRITERIA REVISION DATE: 2/21/19
	ARCHIVE DATE:

PEDICULICIDE AND SCABICIDE AGENTS:
ELIMITE™ (permethrin) 5% cream
EURAX® (crotamiton) 10% cream & lotion
NATROBA™ (spinosad) 0.9% topical suspension
OVIDE® (malathion) 0.5% lotion
SKLICE® (ivermectin) 0.5% lotion
SPINOSAD 0.9% topical suspension
STROMECTOL® (ivermectin) 3 mg tablet
ULESFIA® (benzoyl alcohol) 5% lotion

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

PEDICULICIDE AND SCABICIDE AGENTS (cont.)

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Criteria:

- **Criteria for initial therapy**: **Elimite, Eurax, Natroba, Ovide, Sklice, Spinosad, and Ulesfia** is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Request will follow FDA-approve age limitation

  2. A confirmed diagnosis of **ONE** of the following:
     - Pediculosis
     - Scabies

  3. Individual has failure, contraindication or intolerance to **ALL** of the following:
     - **For Pediculosis:** unable to use **BOTH:**
       - Over-the-counter permethrin 1%
       - Over-the-counter pyrethrin plus piperonyl butoxide
     - **For Scabies:** unable to use **BOTH:**
       - Prescription permethrin 5% cream
       - Generic oral ivermectin 3 mg

  4. There are **NO** contraindications:
     - Contraindication include:
       - Hypersensitivity to any component of the product
       - **For Ovide:** Use in neonates and infants

  Initial approval duration: 1 month

- **Criteria for continuation of coverage (renewal request): Elimite, Eurax, Natroba, Ovide, Sklice, Spinosad, and Ulesfia** is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. A renewal request will be considered a re-infection and will follow the criteria as listed in Criteria for Initial Therapy section

  2. Individual has been adherent with the medication

PEDICULICIDE AND SCABICIDE AGENTS (cont.)

3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    - Contraindications as listed in the criteria for initial therapy section

Renewal duration: 1 month

- **Criteria for initial therapy: Stromectol (ivermectin)** tablet is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. A confirmed diagnosis of **ONE** of the following:
    - Intestinal (non-disseminated) strongyloidiasis due to the nematode parasite *Strongyloides stercoralis*
    - Onchocerciasis due to the nematode parasite *Onchocerca volvulus*

2. Individual has failure, contraindication or intolerance to generic oral ivermectin

3. Absence of **ALL** of the following exclusions:
    - Use in pediatric individuals weighing < 15 kg
    - Woman of child bearing age who is pregnant or not currently using effective contraception

Initial approval duration: 1 month

- **Criteria for continuation of coverage (renewal request): Stromectol (ivermectin)** tablet is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. A renewal request will be considered a re-infection and will follow the criteria as listed in Criteria for Initial Therapy section

2. Individual has been adherent with the medication

3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use

Renewal duration: 1 month

PEDICULICIDE AND SCABICIDE AGENTS (cont.)

Description:

- Pediculosis (lice) and scabies are caused by ectoparasites.
  - Lice are small insects that live on the skin
    - They are often connected to hair on the scalp or in the pubic area
    - Lice eggs (nits), are attached to the hair shaft next to the scalp, often behind the ears or on the back of the neck
  - Scabies is a condition caused by tiny mites, insect-like parasites that dig under the skin
    - Scabies mites usually dig into the skin between the fingers, or around the ankles & wrists
    - The areas where they dig may look like wavy, red, raised lines on the skin
  - Both conditions cause itching.
    - With scabies the itching is often worse at night

- Pharmacologic treatment of lice infestation is focused on use of topical agents that work by a neurotoxic action in the parasite
  - Agents include lindane, permethrin, pyrethrins/piperonyl butoxide, crotamiton, and malathion
  - Permethrin is recommended as first-line treatment for pediculosis
  - Repeat treatment is typically required for complete eradication and it is timed on the life cycle of the louse.
    - Initial treatment is followed by a second treatment 7-10 days later to eradicate most nonresistant lice
  - Resistance to permethrin and pyrethrins/piperonyl butoxide can be significant in various communities, necessitating the use of other agents

- Scabies is treated with permethrin cream as a first line agent
  - It should be applied to all areas of the body and reapplied in 1 week
  - Itching may continue for up to 2 weeks after appropriate and effective treatment
  - Off-label use of oral ivermectin may also be considered if permethrin cannot be used or was unsuccessful
  - Oral ivermectin is FDA-approved for treatment of nematode parasites *strongyloides stercoralis* and *onchocera volvulus*

- There are no known differences in safety or efficacy for all products except lindane
  - Post-market cases of neurotoxicity with lindane have been reported
  - Lindane may be associated with higher rates of neurotoxicity in infants, children, those who weigh less than 110 pounds (50 kilograms), individuals with other skin conditions, elderly patients or patients with uncontrolled seizure disorder or at increased risk for seizures
  - The FDA released a drug safety communication and revised the prescribing information
  - Due to safety concerns, guidelines recommend that lindane not be used for head lice but may be used as an alternative agent for scabies if treatment with permethrin or oral ivermectin are not options
  - Overall, most products are well tolerated and have sufficient records of clinical experience
  - All products are associated with dermatologic adverse events (such as skin irritation, redness, and itching)

- Products used for lice and scabies vary in their FDA-approved age range

PEDICULICIDE AND SCABICIDE AGENTS (cont.)

- Some products can be used in children as young as 6 months of age
- Permethrin lotion (OTC) and cream (Rx only) are the only products FDA-approved for use in children 2 months of age and older

Definitions:

Products used for Pediculosis and Scabies: (listing does not imply agent is on formulary or without need for precertification)

Active agent	Examples – not all inclusive
Benzoyl alcohol	Ulesfia 5% lotion
Crotamiton	Eurax 10% cream, lotion
Gamma benzene hexachloride	Lindane 1% lotion, shampoo
Malathion	Ovide 0.5% lotion
Permethrin	Elimite 5% cream Generic 5% cream OTC Nix 1% liquid OTC generic 1% liquid
Pyrethrin-piperonyl butoxide (4%-0.33%) all OTC	A-200 Lice killing max strength LiceMD Licide Pronto RID
Spinosad	Natroba 0.9% suspension Generic 0.9% suspension OTC
Ivermectin	Generic 3 mg tab (off-label) Sklice 0.5% lotion

Resources:

Elimite. Package Insert. Revised by manufacturer 07/2012. Accessed 03-07-2016.

Elimite. Package Insert. Revised by manufacturer 08/2015. Accessed 03-02-2017.

Eurax. Package Insert. Revised by manufacturer 03/2009. Accessed 03-07-2016.

Eurax. Package Insert. Revised by manufacturer 09/2012. Accessed 03-02-2017.

Natroba. Package Insert. Revised by manufacturer 12/2014. Accessed 03-07-2016, 03-02-2017.

Ovide. Package Insert. Revised by manufacturer 12/2011. Accessed 03-08-2016, 03-02-2017.

Sklice. Package Insert. Revised by manufacturer 02/2012. Accessed 03-07-2016.

PEDICULICIDE AND SCABICIDE AGENTS (cont.)

Sklice. Package Insert. Revised by manufacturer 01/2016. Accessed 03-02-2017.

Spinosad. Package Insert. Revised by manufacturer 06/2015. Accessed 03-02-2017.

Stromectol. Package Insert. Revised by manufacturer 2007. Accessed 03-07-2016.

Stromectol. Package Insert. Revised by manufacturer 05/2010. Accessed 03-02-2017.

Ulesfia. Package Insert. Revised by manufacturer 01/2014. Accessed 03-07-2016.

Ulesfia. Package Insert. Revised by manufacturer 06/2015. Accessed 03-02-2017.

Gunning K, Pippitt K, Kiraly B, and Sayler M: Pediculosis and Scabes: A treatment Update. 2013 Indian J Clin Practice; Aug; 24(3), adapted from Am Fam Physician 2012; 86(6):535-541

Workowski, KA, Bolan, GA. Sexually transmitted diseases treatment guidelines, 2015. Centers for Disease Control and Prevention Sexually transmitted diseases treatment guidelines *MMWR Recomm Rep*. 2015;64:1-137

Devore CD, Schutze GE: Head lice. Clinical Report: Guidance for the Clinician in Rendering Pediatric Care. 2015 Pediatrics; 135(5): 1355-1365. Errata 2015 Pediatrics; 136 (4): 781-782.

Salavastru CM, Chosidow O, Boffa MJ, Janier M, and Tiplica GS. European guideline for the management of scabies. Eur Acad Dermatol Venereol 2017, 31: 1248-1253. DOI: 10.1111/jdv.14351

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.