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.

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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. Scabies is a condition caused by mites, which are tiny, insect-like parasites that dig under the skin. Both conditions cause itching.
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 mites usually dig into the skin between the fingers, or around the ankles and wrists. The areas where they dig may look like wavy, red, raised lines on the skin. 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 to 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. 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. Post-market cases of neurotoxicity with lindane have been reported. The FDA has released a drug safety communication and revised the prescribing information. Due to safety concerns, guidelines recommend that lindane should 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. Some products can be used in children as young as 6 months of age. Permethrin lotion (OTC) and cream (Rx only) is the only product 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)

<table>
<thead>
<tr>
<th>Active agent</th>
<th>Examples – not all inclusive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoyl alcohol</td>
<td>Olesfia 5% lotion</td>
</tr>
<tr>
<td>Crotamiton</td>
<td>Eurax 10% cream, lotion</td>
</tr>
<tr>
<td>Gamma benzene hexachloride</td>
<td>Lindane 1% lotion, shampoo</td>
</tr>
<tr>
<td>Malathion</td>
<td>Ovide 0.5% lotion</td>
</tr>
<tr>
<td>Permethrin</td>
<td>Elimite 5% cream</td>
</tr>
<tr>
<td></td>
<td>Generic 5% cream</td>
</tr>
<tr>
<td></td>
<td>OTC Nix 1% liquid</td>
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</tbody>
</table>
PEDICULICIDE AND SCABICIDE AGENTS (cont.)

<table>
<thead>
<tr>
<th>Drug</th>
<th>OTC generic 1% liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pyrethrin-piperonyl butoxide</td>
<td>A-200</td>
</tr>
<tr>
<td>(4%-0.33%) all OTC</td>
<td>Lice killing max strength</td>
</tr>
<tr>
<td></td>
<td>LiceMD</td>
</tr>
<tr>
<td></td>
<td>Licide</td>
</tr>
<tr>
<td></td>
<td>Pronto</td>
</tr>
<tr>
<td></td>
<td>RID</td>
</tr>
<tr>
<td>Spinosad</td>
<td>Natroba 0.9% suspension</td>
</tr>
<tr>
<td></td>
<td>Generic 0.9% suspension</td>
</tr>
<tr>
<td></td>
<td>OTC</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>Stromectol 3 mg tab (off-label)</td>
</tr>
<tr>
<td></td>
<td>Generic 3 mg tab (off-label)</td>
</tr>
<tr>
<td></td>
<td>Sklice 0.5% lotion</td>
</tr>
</tbody>
</table>

Drug related events:

**Ineffective / failure**

Use of a drug employing optimal doses (FDA-recommended doses) for optimal duration; where the condition being treated has not improved or worsened

A request for branded agent due to generic drug failure or ineffectiveness will be assessed for potential approval with documentation of use of optimal dose / duration of the generic product and meeting other criteria within the coverage guideline. When the drug in question is a combination product, there must be documentation of failure / ineffectiveness of concurrent use (each ingredient used at the same time) of individual generic components. When the drug in question is a low dose formulation, there must be documentation of failure / ineffectiveness of low dose generic formulation.

**Adverse Drug Event:** Allergic reaction / Hypersensitivity / Intolerance

Use of a drug produced a significant reaction where continued use of the drug places the individual at risk for either lack of improvement or worsening of the condition being treated or at risk for harm and the concern is documented in medical record. A significant adverse drug event is when an individual’s outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals’ body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.

**Allergic reaction / hypersensitivity** – may or may not involve the active ingredient. When the active ingredient is involved, use of same or a chemically similar agent places the individual at risk for harm when the same or chemically similar agent is used. The subsequent reaction may be the same as the original reaction or a more exaggerated response may be seen, potentially placing the individual at even greater risk for harm.

If the reaction occurred from the active/main generic ingredient; request for branded agent with same active ingredient will not be considered unless it is proven (documented) that active ingredient did not cause reaction and the request meets other criteria within the coverage guideline

**Intolerance** – these events represent circumstance(s) where use of a drug produced a significant reaction and continued use may result in non-adherence to proposed therapy and this concern is documented in medical record
Contraindication
Use of a drug that is not recommended by the manufacturer or FDA labelling

Use of any drug in the face of a contraindication is outside of the FDA and manufacturer’s labelled recommendation and is considered investigational or experimental

Non-adherence
Individual does not follow prescribe regimen that places the individual at risk for lack of improvement or worsening of the condition being treated and this concern is documented in medical record

Precertification:
Precertification (Prior Authorization) is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) pharmacy benefit for medication(s) or product(s) indicated in this guideline.

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.

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

Criteria:
See “Resources” section for FDA-approved dosage.

- Precertification for Elimite, Eurax, Natroba, Ovide, Sklice, Spinosad, Stromectol, and Ulesfia requires completion of the specific request form in its entirety. 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 will be returned.

- FDA-approved product labeling (indication, age, dosage, testing, contraindications, exclusions, etc.) of Elimite, Eurax, Natroba, Ovide, Sklice, Spinosad, and Ulesfia is considered medically necessary when ALL of the following criteria are met:
  1. Request will follow FDA approve age limitation
  2. Individual has medical record documentation of a confirmed diagnosis of ONE of the following:
     - Pediculosis
     - Scabies
3. Individual is unable to use preferred products due to previous use failed, experienced a significant adverse event from previous use, has a contraindication to its use, OR known resistance:
   - 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. Absence of **ALL** of the following contraindications:
   - Hypersensitivity to any component of the product
   - For Ovide: Use in neonates and infants

FDA-approved product labeling (indication, age, dosage, testing, contraindications, exclusions, etc.) of Stromectol is considered **medically necessary** when **ALL** of the following criteria are met:

1. Individual has medical record documentation of a confirmed diagnosis of **ONE** of the following:
   - Intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite *Strongyloides stercoralis*
   - Onchocerciasis due to the nematode parasite *Onchocerca volvulus*

2. Individual is unable to use generic oral ivermectin due to **EITHER** of the following (documentation must be submitted with the request):
   - Experienced a significant intolerant reaction to generic oral ivermectin
   - Experienced an allergic or hypersensitivity reaction that was due to an excipient in generic ivermectin that has been identified
   - Has a contraindication to an excipient in generic ivermectin formulation that has been identified

3. Absence of **ALL** of the following exclusions:
   - Use in pediatric individuals weighing < 15 kg
   - Woman who is pregnant

**Continuation of coverage (renewal request):** Elimite, Eurax, Natroba, Ovide, Sklice, Spinosad, Stromectol, and Ulesfia is considered **medically necessary** with documentation of **ALL** of the following:

1. The individual has benefited from therapy but remains at high risk
2. The condition has not progressed or worsened while on therapy
3. Individual has not developed any contraindications or other exclusions to its continued use

**Elimite, Eurax, Natroba, Ovide, Sklice, Spinosad, Stromectol, and Ulesfia** for all other indications not previously listed is considered **experimental or investigational** based upon:

1. Lack of final approval from the Food and Drug Administration, and
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
PEDICULICIDE AND SCABICIDE AGENTS (cont.)

3. Insufficient evidence to support improvement of the net health outcome, and
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
5. Insufficient evidence to support improvement outside the investigational setting.

Resources:


### PEDICULICIDE AND SCABICIDE AGENTS (cont.)

**FDA-approved indication and dosage:**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ELIMITE™ (permethrin) 5% Cream</strong> is indicated for the treatment of infestation with <em>Sarcoptes scabiei</em> (scabies).</td>
<td><strong>Adults and children</strong> – Thoroughly massage ELIMITE™ (permethrin) 5% Cream into the skin from the head to the soles of the feet. Scabies rarely infest the scalp of adults, although the hairline, neck, temple, and forehead may be infested in infants and geriatric patients. Usually 30 grams is sufficient for an average adult. The cream should be removed by washing (shower or bath) after 8 to 14 hours. Infants should be treated on the scalp, temple, and forehead. <strong>ONE APPLICATION IS GENERALLY CURATIVE.</strong> Patients may experience persistent pruritus after treatment. This is rarely a sign of treatment failure and is not an indication for retreatment. Demonstrable living mites after 14 days indicate that treatment is necessary.</td>
</tr>
</tbody>
</table>
| **EURAX:** For eradication of scabies (*Sarcoptes scabiei*) and for symptomatic treatment of pruritic skin. | In *Scabies*: Thoroughly massage into the skin of the whole body from the chin down, paying particular attention to all folds and creases. A second application is advisable 24 hours later. Clothing and bed linen should be changed the next morning. A cleansing bath should be taken 48 hours after the last application.  
In *Pruritus*: Massage gently into affected areas until medication is completely absorbed. Repeat as needed.  
**Lotion:** Shake well before using. |
| **NATROBA Topical Suspension** is a pediculicide indicated for the topical treatment of head lice infestations in patients six (6) months of age and older. | - For topical use only. Not for oral, ophthalmic, or intravaginal use.  
- Shake bottle well.  
- Apply product to dry scalp and hair using only the amount needed to cover the scalp and hair.  
- Rinse off with warm water after 10 minutes.  
**Repeat treatment only** if live lice are seen 7 days after first treatment. |
**PEDICULICIDE AND SCABICIDE AGENTS (cont.)**

<table>
<thead>
<tr>
<th>OVIDE</th>
<th>SKLICE Lotion</th>
</tr>
</thead>
<tbody>
<tr>
<td>OVIDE is indicated for patients infected with <em>Pediculis humanus capitis</em> (head lice and their ova) of the scalp hair.</td>
<td>SKLICE Lotion is a pediculicide indicated for the topical treatment of head lice infestations in patients 6 months of age and older.</td>
</tr>
</tbody>
</table>
| 1. Apply Ovide lotion on DRY hair in amount just sufficient to thoroughly wet hair and scalp. Pay particular attention to the back of the head and neck while applying Ovide lotion. Wash hands after applying to scalp.  
2. Allow hair to dry naturally – use no electric heat source, and allow hair to remain uncovered.  
3. After 8 to 12 hours, the hair should be shampooed.  
4. Rinse and use a fine-toothed (nit) comb to remove dead lice and eggs.  
5. If lice are still present after 7 – 9 days, repeat with a second application of Ovide lotion. Further treatment is generally not necessary. Other family members should be evaluated by a physician to determine if infested, and if so, receive treatment. | - For topical use only. Not for oral, ophthalmic or intravaginal use.  
- Apply SKLICE Lotion to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp.  
- After 10 minutes, rinse off with water.  
- For single use. Discard any unused portion. |
STRONDECTOL is indicated for the treatment of the following infections:

**Strongyloidiasis** of the intestinal tract. STRONDECTOL is indicated for the treatment of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite *Strongyloides stercoralis*.

**Onchocerciasis.** STRONDECTOL is indicated for the treatment of onchocerciasis due to the nematode parasite *Onchocerca volvulus*.

NOTE: STRONDECTOL has no activity against adult *Onchocerca volvulus* parasites. The adult parasites reside in subcutaneous nodules which are infrequently palpable. Surgical excision of these nodules (nodulectomy) may be considered in the management of patients with onchocerciasis, since this procedure will eliminate the microfilariae-producing adult parasites.

**Strongyloidiasis**
The recommended dosage of STRONDECTOL for the treatment of strongyloidiasis is a single oral dose designed to provide approximately 200 mcg of ivermectin per kg of body weight. See Table 1 for dosage guidelines. Patients should take tablets on an empty stomach with water. In general, additional doses are not necessary. However, follow-up stool examinations should be performed to verify eradication of infection.

<table>
<thead>
<tr>
<th>Body Weight (kg)</th>
<th>Single Oral Dose</th>
<th>Number of 3-mg Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-24</td>
<td>1 tablet</td>
<td>1</td>
</tr>
<tr>
<td>25-35</td>
<td>2 tablets</td>
<td>2</td>
</tr>
<tr>
<td>36-50</td>
<td>3 tablets</td>
<td>3</td>
</tr>
<tr>
<td>51-65</td>
<td>4 tablets</td>
<td>4</td>
</tr>
<tr>
<td>66-79</td>
<td>5 tablets</td>
<td>5</td>
</tr>
<tr>
<td>≥80</td>
<td>200 mcg/kg</td>
<td>200 mcg/kg</td>
</tr>
</tbody>
</table>

**Onchocerciasis**
The recommended dosage of STRONDECTOL for the treatment of onchocerciasis is a single oral dose designed to provide approximately 150 mcg of ivermectin per kg of body weight. See Table 2 for dosage guidelines. Patients should take tablets on an empty stomach with water. In mass distribution campaigns in international treatment programs, the most commonly used dose interval is 12 months. For the treatment of individual patients, retreatment may be considered at intervals as short as 3 months.

<table>
<thead>
<tr>
<th>Body Weight (kg)</th>
<th>Single Oral Dose</th>
<th>Number of 3-mg Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-25</td>
<td>1 tablet</td>
<td>1</td>
</tr>
<tr>
<td>26-44</td>
<td>2 tablets</td>
<td>2</td>
</tr>
<tr>
<td>45-64</td>
<td>3 tablets</td>
<td>3</td>
</tr>
<tr>
<td>65-84</td>
<td>4 tablets</td>
<td>4</td>
</tr>
<tr>
<td>≥85</td>
<td>150 mcg/kg</td>
<td>150 mcg/kg</td>
</tr>
</tbody>
</table>
**ULESFIA Lotion** is a pediculicide indicated for the topical treatment of head lice infestation in patients 6 months of age and older. ULESFIA Lotion does not have ovocidal activity.

- Apply ULESFIA Lotion to dry hair, using enough to completely saturate the scalp and hair.
- Rinse off with water after 10 minutes.
- Repeat application in 7 days.

**SPINOSAD Topical Suspension** is a pediculicide indicated for the topical treatment of head lice infestations in patients six (6) months of age and older.

- For topical use only. Not for oral, ophthalmic, or intravaginal use.
- Shake bottle well.
- Apply product to dry scalp and hair using only the amount needed to cover the scalp and hair.
- Rinse off with warm water after 10 minutes.

Repeat treatment only if live lice are seen 7 days after first treatment.