



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/17/2016
LAST REVIEW DATE: 2/18/2021
LAST CRITERIA REVISION DATE: 2/18/2021
ARCHIVE DATE:

PEDICULICIDE AND SCABICIDE AGENTS:

CROTAN™ (crotamiton) 10% lotion
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
Ivermectin 0.5% lotion
SPINOSAD 0.9% topical suspension
STROMEKTOL® (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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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.

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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.

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.**

Crotan (crotamiton) 10% lotion
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
Ivermectin 0.5%
Spinosad 0.9% topical suspension
Ulesfia (benzoyl alcohol) 5% lotion

Criteria:

- **Criteria for initial therapy:** Crotan, Elimite, Eurax, Natroba, Ovide, Sklice, Ivermectin, Spinosad, and Ulesfia is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
 1. Request will follow FDA-approved age limitation
 2. A confirmed diagnosis of **ONE** of the following:
 - a. Pediculosis
 - b. Scabies
 3. Individual has failure, contraindication or intolerance to **ALL** of the following:
 - a. **For Pediculosis:** unable to use **BOTH**:
 - i. Over-the-counter permethrin 1%
 - ii. Over-the-counter pyrethrin plus piperonyl butoxide
 - b. **For Scabies:** unable to use **BOTH**:
 - i. Prescription permethrin 5% cream
 - ii. Generic oral ivermectin 3 mg
 4. There are **NO** contraindications:
 - a. Contraindication include:
 - i. Hypersensitivity to any component of the product

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- ii. **For Ovide:** Use in neonates and infants

Initial approval duration: 1 month

- **Criteria for continuation of coverage (renewal request):** Crotan, Elimite, Eurax, Natroba, Ovide, Sklice, Ivermectin, 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
 3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
 - a. Contraindications as listed in the criteria for initial therapy section

Renewal duration: 1 month

Stromectol (ivermectin) 3 mg tablet

- **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:
 - a. Intestinal (non-disseminated) strongyloidiasis due to the nematode parasite *Strongyloides stercoralis*
 - b. 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:
 - a. Use in pediatric individuals weighing < 15 kg
 - b. 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

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- Individual has been adherent with the medication
- Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use

Renewal duration: 1 month

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. 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.

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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	Crotan 10% lotion Eurax 10% cream, lotion
Gamma benzene hexachloride	Lindane 1% lotion, shampoo
Malathion	Ovide 0.5% lotion Malathion 0.5% lotion
Permethrin	Elimite 5% cream Permethrin 5% cream OTC Nix lotion, spray, rinse, shampoo
Pyrethrin-piperonyl butoxide (4%-0.33%) all OTC	Lice Killing Maximum Strength Shampoo LiceMD Complete Kit Licide Shampoo Licide Maximum Strength Liquid Licide Treatment Kit RID Essential Lice Elimination Kit RID Lice Killing Shampoo
Spinosad	Natroba 0.9% suspension Spinosad 0.9% suspension
Ivermectin	Stromectol 3 mg tab (off-label use) Ivermectin 3 mg tab (off-label use) Sklice 0.5% lotion

Resources:

Crotan (crotamiton) 10% lotion product information, revised by manufacturer Marnel Pharmaceuticals, Inc. 01-2020, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-20.

Elimite (permethrin) 5% cream product information, revised by manufacturer Prestium Pharma, Inc. 01-2016, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-20.

Eurax (crotamiton) 10% cream & lotion product information, revised by manufacturer Ranbaxy Laboratories, Inc. 09-2012, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-20.

Ivermectin 3mg tab product information, revised by manufacturer Edenbridge Pharmaceuticals, Inc. 03-2017, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-20.

Lindane 1% shampoo product information, revised by manufacturer Olta Pharmaceuticals Corporation 03-2009, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-20.

Natroba (spinosad) 0.9% suspension product information, revised by manufacturer ParaPRO LLC 10-2018, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-20.

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Nix (permethrin) 1% shampoo product information, revised by manufacturer Insight Pharmaceuticals 06-2009, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-2020.

Ovide (malathion) 0.5% lotion product information, revised by manufacturer Taro Pharmaceuticals U.S.A., Inc. 07-2018, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-2020.

Permethrin 1% lotion product information, revised by manufacturer Walgreen Company 12-2019, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-2020.

Permethrin 5% cream product information, revised by manufacturer Encube Ethicals Private Limited 04-2019, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-2020.

KI-Tapiox Lice Treatment (pyrethrum & piperonyl butoxide) product information, revised by manufacturer Certus Pharma 08-2019, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-2020

Sklice (ivermectin) 0.5% lotion product information, revised by manufacturer Arbor Pharmaceuticals 11-2017, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-2020.

Spinosad 0.9% suspension product information, revised by manufacturer Allegis Pharmaceuticals, LLC. 12-2018, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-2020.

Stromectol (ivermectin) 3mg tab product information, revised by manufacturer Merck Sharp & Dohme Corp. 12-2019, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-2020.

Ulesfia (benzyl alcohol) 5% lotion product information, revised by manufacturer Cerecor, Inc. 04-2019, at DailyMed <http://dailymed.nlm.nih.gov> accessed 11-25-2020.

Goldstein AO, Goldstein BG. Pediculosis capitis. In: UpToDate, Dellavalle RP, Levy ML, Rosen T, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Accessed on 11-30-2020.

Goldstein AO, Goldstein BG. Pediculosis corporis. In: UpToDate, Dellavalle RP, Rosen T, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Accessed on 11-30-2020.

Goldstein AO, Goldstein BG. Pediculosis pubis and pediculosis ciliaris. In: UpToDate, Dellavalle RP, Levy ML, Rosen T, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Accessed on 11-30-2020.

Goldstein BG, Goldstein AO. Scabies: Management. In: UpToDate, Dellavalle RP, Levy ML, Rosen T, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. <http://uptodate.com>. Accessed on 11-30-2020.