PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE:	**3/17/2016**
LAST REVIEW DATE:	**2/17/2022**
LAST CRITERIA REVISION DATE:	**2/17/2022**
ARCHIVE DATE:	

PEDICULICIDE AND SCABICIDE AGENTS:
CROTAN™ (crotamiton) 10% lotion
ELIMITE™ (permethrin) 5% cream
Ivermectin 0.5% lotion
Ivermectin 3 mg tablet
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

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.

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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.**

Criteria:

Ivermectin 3 mg tablet

[Note: See below for Ivermectin 0.5% lotion and brand Stromectol (ivermectin) 3 mg tablet criteria]

- **Criteria for initial therapy**: **Ivermectin 3 mg tablet** 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:
     a. Pediculosis
     b. Scabies

  3. Individual has failure, contraindication per FDA label or intolerance to **ONE** 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 prescription strength permethrin 5% cream

  4. Absence of **ALL** of the following exclusions:
     a. Pediatric individual weighing < 15 kg
     b. Woman of childbearing age who is pregnant or not currently using effective contraception

  5. There are **NO** FDA-label contraindications. such as:
     a. Hypersensitivity to any component of the product

Initial approval duration: 1 month

- **Criteria for continuation of coverage (renewal request): Ivermectin 3mg tablet** is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

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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 adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section

Renewal duration: 1 month

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

    1. **Off-Label Use of Non-cancer Medications**

    2. **Off-Label Use of Cancer Medications**

CROTAN (crotamiton) 10% lotion
ELIMITE (permethrin) 5% cream
Ivermectin 0.5% lotion
NATROBA (spinosad) 0.9% topical suspension
OVIDE (malathion) 0.5% lotion
SKLICE (ivermectin) 0.5% lotion
Spinosad 0.9% topical suspension

- **Criteria for initial therapy**: **Crotan, Sklice, Ivermectin lotion, Ovide, Elimite, Natroba, and Spinosad** 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:
        a. Pediculosis
        b. Scabies

    3. Individual has failure, contraindication per FDA label 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** FDA-label contraindications. such as:
    a. Hypersensitivity to any component of the product

Initial approval duration: 1 month

- **Criteria for continuation of coverage (renewal request): Crotan, Sklice, Ivermectin lotion, Ovide, Elimite, Natroba, and Spinosad** 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 adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section

Renewal duration: 1 month

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-cancer Medications**

2. **Off-Label Use of Cancer Medications**

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 per FDA label, or intolerance to generic oral ivermectin

3. Absence of **ALL** of the following exclusions:
    a. Pediatric individual weighing < 15 kg

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b. Woman of childbearing 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 adverse drug effects that may exclude continued use

  Renewal duration: 1 month

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of Non-cancer Medications**

  2. **Off-Label Use of Cancer Medications**

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.*

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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.

Resources:

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. **Discontinued 04-02-20.** Accessed January 11, 2022.

Crotan (crotamiton) 10% lotion product information, revised by manufacturer Marnel Pharmaceuticals, Inc. 12-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 11, 2022.

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. **Discontinued 01-20-20.** Accessed January 11, 2022.

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. **Discontinued 03-30-21.** Accessed January 11, 2022.

Ivermectin 0.5% lotion product information, revised by manufacturer Taro Pharmaceuticals U.S.A., Inc. 11-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 11, 2022.

Stromectol (ivermectin) 3mg tab product information, revised by manufacturer Merck Sharp & Dohme Corp. 02-2018. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 11, 2022.

Ivermectin 3mg tab product information, revised by manufacturer Edenbridge Pharmaceuticals, Inc. 03-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 11, 2022.

Lindane 1% shampoo product information, revised by manufacturer Morton Grove Pharmaceuticals Inc. 07-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 11, 2022.

Ovide (malathion) 0.5% lotion product information, revised by manufacturer Taro Pharmaceuticals U.S.A., Inc. 07-2018. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 11, 2022.

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Malathion 0.5% lotion product information, revised by manufacturer Taro Pharmaceuticals U.S.A., Inc. 03-2017. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 11, 2022.

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. **Discontinued 06-30-21.** Accessed January 11, 2022.

Permethrin 5% cream product information, revised by manufacturer Actavis Pharma, Inc. 12-2019. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 11, 2022.

Natroba (spinosad) 0.9% suspension product information, revised by manufacturer ParaPRO LLC 04-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 11, 2022.

Spinosad 0.9% suspension product information, revised by manufacturer Allegis Pharmaceuticals, LLC. 04-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed January 11, 2022.

Goldstein AO, Goldstein BG. Pediculosis capitis. In: UpToDate, Dellavalle RP, Levy ML, Rosen T, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Topic last updated March 25, 2021. Accessed January 13, 2022.

Goldstein AO, Goldstein BG. Pediculosis corporis. In: UpToDate, Dellavalle RP, Rosen T, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Topic last updated April 27, 2020. Accessed January 13, 2022.

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. Topic last updated March 24, 2021. Accessed January 13, 2022.

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. Topic last updated November 17, 2021. Accessed January 13, 2022.

Workowski KA, Bolan GA. Sexually Transmitted Diseases Treatment Guidelines, 2015. MMWR Recomm Rep. 2015 June 05; 64(RR-03): 1. Accessed January 20, 2022.