BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

PEDICULICIDE AND SCABICIDE AGENTS: CROTAN™ (crotamiton) 10% lotion Ivermectin tablet NATROBA™ (spinosad) 0.9% topical suspension Spinosad 0.9% topical suspension STROMECTOL® (ivermectin) 3 mg tablet Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

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

- **Criteria for initial therapy:** Ivermectin tablet is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

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1. Request will follow FDA-label for age and weight

2. Individual has a confirmed diagnosis of **ONE** of the following:
    a. Pediculosis
    b. Scabies
    c. Intestinal (non-disseminated) strongyloidiasis due to the nematode parasite *Strongyloides stercoralis*
    d. Onchocerciasis due to the nematode parasite *Onchocerca volvulus*

3. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following:
    a. **For Pediculosis** individual is unable to use **BOTH** of the following**:**
        i. Over the counter topical permethrin 1% (or topical pyrethrin plus piperonyl butoxide)
        ii. Topical ivermectin 0.5% lotion
    b. **For Scabies** individual is unable to use prescription strength topical permethrin 5% cream

4. **For ivermectin 6mg**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **ivermectin 3mg**

5. Will not be used in a woman of childbearing age who is pregnant or not using effective contraception

6. There are **NO** FDA-label contraindications such as: hypersensitivity to any component of the product

Initial approval duration: 1 month

- **Criteria for continuation of coverage (renewal request):** Ivermectin tablet is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

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. **For ivermectin 6mg**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **ivermectin 3mg**

4. Individual has not developed any contraindications as listed in the criteria for initial therapy section above 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**

CROTAN (crotamiton) 10% lotion
NATROBA (spinosad) 0.9% topical suspension
Spinosad 0.9% topical suspension

- **Criteria for initial therapy**: **Crotan, Natroba, and Spinosad** and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Request will follow FDA-label for age and weight

2. Individual has a confirmed diagnosis of **ONE** of the following:
    a. Pediculosis
    b. Scabies

3. Individual has failure, contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
    a. **For Pediculosis** individual is unable to use **BOTH** of the following**:**
        i. Over the-counter topical permethrin 1% (or topical pyrethrin plus piperonyl butoxide)
        ii. Topical ivermectin 0.5% lotion
    b. **For Scabies** individual is unable to use the combination of **BOTH** of the following**:**
        i. Prescription strength topical permethrin 5% cream
        ii. Generic oral ivermectin 3 mg

4. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

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

Initial approval duration: 1 month

- **Criteria for continuation of coverage (renewal request): Crotan, Natroba, and Spinosad** and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

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. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

4. Individual has not developed any contraindications as listed in the criteria for initial therapy section above 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**

STROMECTOL (ivermectin) 3 mg tablet

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

1. Request will follow FDA-label for age and weight
2. Individual has 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*
3. Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **generic oral ivermectin** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)
4. Will not be used in a woman of childbearing age who is pregnant or not 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 **(samples are not considered for continuation of therapy)**:

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 failure after adequate trial, contraindication per FDA label, intolerance or, is not a candidate for **generic oral ivermectin** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)
4. Individual has not developed any significant adverse drug effects that may exclude continued use

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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. Classic scabies is characterized by an intensely pruritic eruption with small, often excoriated, papules in sites such as the fingers, wrists, axillae, areolae, waist, genitalia, and buttocks. Crusted scabies is a less common variant, usually presents with scaly, crusted, fissured plaques and primarily occurs in immunocompromised individuals.

Pharmacologic treatment of lice infestation is focused on use of topical agents that work by a neurotoxic action in the parasite. Agents include 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.

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Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Crotan (crotamiton) 10% lotion product information, revised by manufacturer Marnel Pharmaceuticals, Inc. 04-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 27, 2024.

Natroba (spinosad) 0.9% suspension product information, revised by manufacturer ParaPRO LLC 04-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 27, 2024.

Spinosad 0.9% suspension product information, revised by manufacturer Allegis Pharmaceuticals, LLC. 05-2023. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 27, 2024.

Stromectol (ivermectin) 3mg tab product information, revised by manufacturer Merck Sharp & Dohme LLC. 11-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 27, 2024.

Ivermectin 3mg tab product information, revised by manufacturer NuCare Pharmaceuticals Inc. 07-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 27, 2024.

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. Literature current through November 2024. Topic last updated October 12, 2022. Accessed December 27, 2024.

Goldstein AO, Goldstein BG. Pediculosis corporis. In: UpToDate, Dellavalle RP, Rosen T, Ofori AO (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Literature current through November 2024. Topic last updated September 06, 2024. Accessed December 27, 2024.

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. Literature current through November 2024. Topic last updated January 25, 2023. Accessed December 27, 2024.

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. Literature current through November 2024. Topic last updated October 31, 2022. Accessed December 27, 2024.