# Clinical Policy: Anthelmintics (albendazole, ivermectin lotion, ivermectin tablets, spinosad suspension)

Reference Number: AZ.CP.PHAR.403
Effective Date: 11.16.16
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Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
The following are anthelmintics requiring prior authorization: albendazole (Albenza®), ivermectin lotion (Sklice®), ivermectin tablets (Stromectol®), spinodad (Natroba®).

**FDA approved indication**
Albendazole (Albenza®) is indicated:
- For the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, *Taenia solium*.
- For the treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, *Echinococcus granulosus*.

Sklice® (ivermectin lotion) is indicated:
- For the treatment of head lice infestation in patients 6 months of age and older

Ivermectin tablets (Stromectol®) are indicated:
- For the treatment of intestinal (i.e., non-disseminated) strongyloidiasis due to the nematode parasite *Strongyloides stercoralis*
- For the treatment of onchocerciasis due to the nematode parasite *Onchocerca volvulus*

Spinosad topical suspension (Natroba®) is indicated for:
- Head lice infestations in patients 6 months of age and older
- Scabies infestations in adult and pediatric patients 4 years of age and older.

**Policy/Criteria**
*Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria*

It is the policy of Arizona Complete Health-Complete Care Plan and Care1st that albendazole, ivermectin tablets, and Sklice are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**
**A. Head Lice Infestation** (must meet all)**:**
1. Diagnosis of pediculosis capitis (head lice);
2. If request is for Sklice or Natroba, both of the following are required (a and b):

a. Age ≥ 6 months;
b. Documentation supports failure of at least two applications of either permethrin cream 1% OR pyrethins-piperonyl butoxide (e.g., A-200), unless contraindicated or clinically significant adverse effects experienced;

3. If request is for ivermectin (Stromectol), all of the following (a, b and c):
   a. Age ≥ 18 years;
   b. Documentation supports failure of at least two applications of either permethrin cream 1% OR pyrethins-piperonyl butoxide (e.g., A-200), unless contraindicated or clinically significant adverse effects experienced;
   c. Documentation supports failure of Sklice, unless contraindicated or clinically significant adverse effects experienced;
4. Dose does not exceed the following:
   a. Sklice: 4oz tube administered as single application;
   b. Natroba: 2 bottles (8oz)
   c. Ivermectin (Stromectol): 200 mcg/kg for 2 doses.

**Approval duration: 1 month (Sklice, Ivermectin); 14 days (Natroba)**

**B. Pubic Lice Infestation (off-label)** (must meet all)**:**
1. Diagnosis of pediculosis pubis (pubic lice);
2. If request is for Sklice, age ≥ 6 months;
3. If request is for ivermectin (Stromectol), age ≥ 18 years;
4. Documentation supports failure of at least two applications of either permethrin cream 1% OR pyrethins-piperonyl butoxide (e.g., A-200), unless contraindicated or clinically significant adverse effects experienced;
5. Dose does not exceed the following:
   a. Sklice: 4oz tube administered as single application;
   b. Ivermectin (Stromectol): 250 mcg/kg for 2 doses.

**Approval duration: 2 months**

**C. Scabies Infestation** (must meet all)**:**
1. Diagnosis of scabies infestation;
2. Age ≥ 4 years;
3. Failure of permethrin 5% cream, unless contraindicated or clinically significant adverse effects are experienced;
4. Request does not exceed 4 bottles (16 oz).

**Approval duration: one time**

**D. Scabies (off-label)** (must meet all)**:**
1. Diagnosis of scabies;
2. Request is for ivermectin (Stromectol);
3. Age ≥ 18 years;
4. Member is currently not pregnant;

5. If member has classic scabies: Documentation supports failure of at least two applications of permethrin cream 5% unless contraindicated or clinically significant adverse effects experienced;
6. If member has crusted scabies: Documentation supports ivermectin is prescribed concurrently with permethrin cream 5%;
7. Dose does not exceed the following:
   a. Classic scabies: 200 mcg/kg for 2 doses;
   b. Crusted scabies: 200 mcg/kg for 7 doses.

**Approval duration: 2 months**

**E. Intestinal Strongyloidiasis** (must meet all)**:**
1. Diagnosis of strongyloidiasis due to the nematode parasite *Strongyloides stercoralis;*
2. Request is for ivermectin (Stromectol);
3. Weight ≥ 15kg;
4. Dose does not exceed 200mcg/kg for single dose.

**Approval duration: 1 month**

**F. Intestinal Onchocerciasis** (must meet all)**:**
1. Diagnosis of onchocerciasis due to the nematode parasite *Onchocerca volvulus- non adult stage;*
2. Request is for ivermectin (Stromectol);
3. Weight ≥ 15kg;
4. Dose does not exceed 150mcg/kg for single dose.

**Approval duration: 1 month**

**G. Parenchymal Neurocysticercosis** (must meet all)**:**
1. Diagnosis of penchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm *Taenia solium;*
2. Patient is receiving appropriate corticosteroid (plus anticonvulsant therapy if with seizures) to prevent cerebral hypertensive episodes;
3. Request is for albendazole;
4. Dose does not exceed 800mg per day.

**Approval duration: 1 month**

**H. Cystic Hydatid Disease** (must meet all)**:**
1. Diagnosis of cystic hydatid disease of the liver, lung and peritoneum, caused by the larval form of the dog tapeworm *Echinococcus granulosus;*
2. Request is for albendazole;
3. Dose does not exceed 800mg per day.

**Approval duration: 18 weeks**

**I. Other off-label infections caused by helminths** (must meet all):
1. Diagnosis is one of the following (a – g):

a. Ascariasis
b. Capillariasis;
c. Cutaneous larva migrans (zoonotic hookworm);
d. Hookworm infection;
e. Pinworm infection (Enterobiasis);
f. Whipworm infection (Trichuriasis);
g. Other off-label infections caused by helminths*;
*If non-FDA approved, the indication is supported by Micromedex® with strength of recommendation of Class I or IIa, Clinical Pharmacology®, CDC guidelines, evidence from at least two high-quality, published studies in reputable peer-reviewed journals, or evidence-based clinical practice guidelines

2. Request is for albendazole;
3. Documentation supports failure of a FDA-approved medication (provided that such agent is commercially available), unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 400mg per day.

**Approval duration: 10 days or duration are within dosing guidelines recommended by clinical practice guidelines and/or medical literature**

**J. Other diagnoses/indications**

1. Refer to AZ.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. Head Lice Infestation** (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. If request is for a dose increase, new dose does not exceed the following:
   a. Sklice: 4oz tube administered as single application;
   b. Ivermectin (Stromectol): 200 mcg/kg for 2 doses.
   c. Spinosad topical suspension (Natroba®): Re-authorization is not permitted. Members must meet the initial approval criteria.

**Approval duration: 1 month**

**B. Pubic Lice Infestation (off-label)** (must meet all):

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. If request is for a dose increase, new dose does not exceed the following:
   a. Sklice: 4oz tube administered as single application;
   b. Ivermectin (Stromectol): 200 mcg/kg for 2 doses.

**Approval duration: 2 months**

**C. Scabies**:
1. Re-authorization is not permitted. Members must meet the initial approval criteria.

**Approval duration: Not applicable**

**D. Scabies (off-label)** (must meet all):
1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. If request is for a dose increase, new dose does not exceed the following:
   a. Classic scabies: 200 mcg/kg for 2 doses;
   b. Crusted scabies: 200 mcg/kg for 7 doses.

**Approval duration: 2 months**

**E. Intestinal Strongyloidiasis** (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Request is for ivermectin (Stromectol);
3. Re-treatment interval has been at least 3 months;
4. If request is for a dose increase, new dose does not exceed 200mcg/kg.

**Approval duration: 1 month**

**F. Intestinal Onchocerciasis** (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Request is for ivermectin (Stromectol);
3. Evidence of larvae still present 3 months following initial therapy;
4. If request is for a dose increase, new dose does not exceed 150mcg/kg.

**Approval duration: 1 month**

**G. Parenchymal Neurocysticercosis (must meet all):**
1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Request is for albendazole;
3. Evidence of cysts still present after initial treatment;
4. If request is for a dose increase, new dose does not exceed 800mg per day.

**Approval duration: 1 month**

**H. Cystic Hydatid Disease (must meet all):**
1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Request is for albendazole;
3. Evidence of larvae still present after initial treatment;
4. If request is for a dose increase, new dose does not exceed 800mg per day.

**Approval duration: Up to a total of 18 weeks**

**I. Other off-label infections caused by helminths** (must meet all):
1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Evidence of larvae still present after initial treatment;
3. If request is for a dose increase, new dose does not exceed 400mg per day.

**Approval duration: 10 days**

**J. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Centene Corporation and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to AZ.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – AZ.CP.PMN.53.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
N/A

*Appendix B: General Information*

- The safety of Sklice has not been established in pediatric patients below the age of 6 months. Sklice is not recommended in patients under six months of age because of the potential increased systemic absorption due to a high ratio of skin surface area to body mass and the potential for an immature skin barrier and risk of ivermectin toxicity.
- The American Academy of Pediatrics (AAP) 2015 guidelines, recommend permethrin 1% (Nix®) as the initial treatment of choice for head lice, with a second treatment in 7 to 10 days after the first. Nix is FDA approved for children as young as 2 months old.
- Pyrethrins plus piperonyl butoxide can be used in children as young as 2 years of age.
- Malathion should be used in children 6 years and older and is generally reserved for treatment after pyrethrins plus piperonyl butoxide or permethrin.
- The AAP no longer recommends lindane 1% shampoo as first line treatment of head lice. Overuse, misuse, and accidentally swallowing can be toxic to the nervous system. The Centers for Disease Control (CDC) recommends against the use of lindane in pregnant or breast-feeding women, patients with HIV or irritated skin/sores on the scalp, individuals with a history of seizure disorders, infants, children, the elderly, or persons who weigh less than 110 lbs.

- If hepatic enzymes exceed 2 times the upper limit of normal, consider discontinuation of Albenza.
- CDC guidelines for the treatment of enterobiasis (pinworms) or hookworms recommend mebendazole, albendazole or pyrantel pamoate (OTC).
- CDC guidelines for the treatment of clonorchis recommend praziquantel or albendazole.
- Examples of off-label conditions that are recommended by Micromedex (at least Class IIa) for use of albendazole in adult and pediatric patients:
  - Ascariasis
  - Capillaria
  - Cutaneous larva migrans (zoonotic hookworm)
  - HIV (Infection by Microsporidia)
  - Infection by Gnathostoma
  - Trichuriasis

*Appendix C: Therapeutic Alternatives*

| Drug | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **OTC Medications**** | | |
| permethrin (Nix®) cream rinse | Apply to hair. After 10 minutes, rinse off with water. Repeat in 7 to 10 days if live lice are seen | One application to affected area; do not repeat for ≥ 7days |
| pyrethrins plus piperonyl butoxide (RID®, A-200®, Pronto®) Shampoo and Spray Kit | Apply to dry hair. After 10 minutes, rinse off with water | 2 topical treatments, applied 7 to 10days apart |
| **Prescription Medications** | | |
| | | |
| malathion 0.5% (Ovide®)* topical lotion | Apply 30 ml to dry hair and scalp. After 8 to 12 hours rinse with water. Repeat in 7-9 days if lice are seen | One application (roughly 30 mL) topically as directed |
| Ulesfia® (benzyl alcohol 5%) topical lotion | Apply to dry hair. After 10 minutes, rinse off with water. Repeat in 7 days | One application per week |

**May require prior authorization ** Over the counter products may not be a covered benefit*
*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

## V. Dosage and Administration

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Anthelmintics (Albendazole, Ivermectin cream, Ivermectin tablets)

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| Ivermectin (Sklice) | Head Lice/ Pubic Lice (off-label) | Apply lotion to dry hair (up to one 4 oz tube). After 10 minutes, rinse off with water. Repeat in 7 days if live lice are seen. | 4oz per application |
| Ivermectin (Stromectol) | Head Lice (off-label) | Single oral dose to provide 200 mcg/kg body weight | 200mcg/kg/day |
| Ivermectin (Stromectol) | Pubic Lice (off-label) | Single oral dose to provide 250 mcg/kg body weight, repeat in 14 days | 250mcg/kg/day |
| Ivermectin (Stromectol) | Scabies (off-label) | Classic scabies:<br>Single oral dose to provide 200 mcg/kg body weight. Repeat in 14 days<br><br>Crusted scabies:<br>Oral ivermectin (200 mcg/kg/dose) Depending on infection severity, ivermectin should be taken in three doses (approximately days 1, 2, and 8), five doses (approximately days 1, 2, 8, 9, and 15), or seven doses (approximately days 1, 2, 8, 9, 15, 22, and 29). | 200mcg/kg/day |
| Ivermectin (Stromectol) | Intestinal Strongyloidiasis | Single oral dose to provide 200mcg/kg body weight | 200mcg/kg/day |
| Ivermectin (Stromectol) | Intestinal Onchocerciasis | Single oral dose to provide 150mcg/kg body weight | 150mcg/kg/day |
| albendazole (Albenza) | Neurocysticercosis | <60kg: 15mg/kg/day in 2 divided doses with food for 8-30 days<br><br>≥60kg: 400mg PO BID with food for 8-30 days | 800mg per day |
| albendazole (Albenza) | Echinococcosis | <60kg: 15mg/kg/day in 2 divided doses with food for | 800mg per day |

| | | | |
|---|---|---|---|
| | | 28 days followed by a 14 day albendazole free interval, repeat cycle 2 times<br><br>≥60kg: 400mg PO BID with food for 28 days followed by a 14 day albendazole free interval, repeat cycle 2 times | |
| albendazole (Albenza) | Ascariasis (off-label) | 400mg PO as a single dose on am empty stomach | 400mg per day |
| albendazole (Albenza) | Capillaria infection (off label) | 400mg PO once daily with food (fatty meal) for 10 days | 400mg per day |
| albendazole (Albenza) | Cutaneous larva migrans (zoonotic hookworm) (off label) | 400 mg PO once daily with food for 3 to 7 days | 400mg per day |
| albendazole (Albenza) | Hookworm infection (off label) | 400 mg PO once daily on an empty stomach | 400mg per day |
| albendazole (Albenza) | Pinworm infection (Enterobiasis) (off label) | 400 mg PO once daily on an empty stomach | 400mg per day |
| albendazole (Albenza) | Whipworm infection (Trichuriasis) (off label) | 400 mg PO once daily on an empty stomach for 3 days | 400mg per day |
| Natroba™* (spinosad 0.9%) topical suspension | Head Lice | Apply suspension to dry hair (up to one 4 oz bottle). After 10 minutes, rinse off with water. Repeat in 7 days if lice are seen | 120ml per application |
| Natroba™* (spinosad 0.9%) topical suspension | Scabies infestation | Apply a sufficient amount of Natroba to skin to completely cover the body from the neck to the toes (including the soles of the feet). For patients with balding scalp, also apply | Varies per body surface area |

| | | | |
|---|---|---|---|
| | | product to the scalp, hairline, temples, and forehead. Allow to absorb into the skin and dry for 10 minutes before getting dressed. Leave on the skin for at least 6 hours before showering or bathing. | |

## VI. Product Availability

| Drug | Availability |
|---|---|
| Albendazole (Albenza) | Tablets: 200mg |
| Ivermectin (Sklice) | Topical Lotion: 0.5%, 117 gram tube |
| Ivermectin (Stromectol) | Tablets: 3mg |
| Spinosad (Natroba) topical suspension | Suspension: 9 mg of spinosad per gram of Natroba topical suspension in 120 mL bottles |

## VII. References

1. Sklice [prescribing information]. Arbor Pharmaceuticals, LLC. June 2017.
2. Stromectol [prescribing information]. Merck and Co., Inc. Whitehouse Station, NJ., December 2009.
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10. CDC Guidelines for the Treatment of Enterobiasis. Available at https://cdc.gov/parasites/pinworm/treatment.html. Accessed February 21, 2020.
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12. CDC Guidelines for the Treatment of Hookworm. Available at https://www.cdc.gov/parasites/hookworm/treatment.html. Accessed February 21, 2020.
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| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Converted to new template. Annual Review: Added interval history for ivermectin for continuation of therapy. Added Albenza to criteria, including off-label use for Ascariasis and Capillaria infection. | 06.17 | 11.17 |
| Annual Review: Added additional Micromedex Class IIa recommendations for use of albendazole to General Information section. Also added CDC recommendation for use of albendazole for enterobiasis. | 09.12.18 | 09.18 |
| 1Q2020 Annual Review. Changed drug name format of Albenza to albendazole (albenza); Changed drug name format of Stromectol to ivermectin tablets (Stromectol); Added approval criteria for public lice, scabies, and other off-label infection caused by helminths that are treated with albendazole; Changed approval duration from one time to 1 month for intestinal Strongyloidiasis and intestinal Onchocerciasis; Updated I.D.2: anticonvulsant therapy is not required concurrently unless member has seizures; Added hookworms and Clonorchis as CDC treatment recommendations examples in the General Information section. Added Cutaneous larva migrans (zoonotic hookworm) Echinococcosis and Infection by Gnathostoma as examples of Micromedex strength Class IIa examples in the General Information section; Updated References. | 02.21.20 | 03.20 |
| 1Q2021 Annual Review; No significant changes made. | 02.21 | 02.21 |
| Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st. | 5.10.21 | 04.21 |
| Added spinosad (Natroba) to criteria using HIM.PA.134 as template. Natroba is indicated for lice and scabies. References added and updated. | 6.25.21 | 07.21 |

**Important Reminder**

## CLINICAL POLICY
Anthelmintics (Albendazole, Ivermectin cream, Ivermectin tablets)

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.