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# Clinical Policy: Anthelmintics

Reference Number: AZ.CP.PHAR.403
Effective Date: 11.16.16
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Line of Business: Arizona Medicaid

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®).

## FDA approved indication

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 is indicated:

- For the treatment of head lice infestation in patients 6 months of age and older

Ivermectin is 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*

## 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 health plans affiliated with Centene Corporation® that Albenza, Sklice and ivermectin 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. Request is for Sklice;
3. Age ≥ 6 months;
4. Dose does not exceed 4oz tube administered as single application.

**Approval duration: 12 months**

**B. 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.

**Approval duration: One time approval**

**C. 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.

**Approval duration: One time approval**

**D. 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 to prevent cerebral hypertensive episodes;
3. Request is for Albenza;
4. Dose does not exceed 800mg per day.

**Approval duration: 1 month**

**E. 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 Albenza;
3. Dose does not exceed 800mg per day.

**Approval duration: 18 weeks**

**F. Ascariasis or Capillaria infection** (off-label) (must meet all):
1. Diagnosis of Ascariasis or Capillaria infection;
2. Request is for Albenza;
3. Dose does not exceed 400mg per day
4. Documentation supports failure of or presence of clinically significant adverse effects or contraindication to an FDA-approved medication for the relevant diagnosis (provided that such agent is commercially available).

**Approval duration: 10 days**

**G. Other diagnoses/indications**
1. Refer to 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. Request is for Sklice;
3. If request is for a dose increase, new dose does not exceed 4oz tube per administration.

**Approval duration: 12 months**

**B. 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: One time approval**

**C. 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: One time approval**

**D. 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 Albenza;
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: 1 month**

**E. 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 Albenza;
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**

**F. Ascariasis, Capillaria infection** (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. Request is for Albenza;
3. Evidence of larvae still present after initial treatment;
4. If request is for a dose increase, new dose does not exceed 400mg per day.

**Approval duration: 10 days**

**G. 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 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 – CP.PMN.53 or evidence of coverage documents

## 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) 2009 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.
- CDC guidelines for the treatment of enterobiasis (pin worms) recommend mebendazole, albendazole or pyrantel pamoate (OTC). Pyrantel pamoate is on the Arizona Medicade formulary, and should be used first.
- If hepatic enzymes exceed 2 times the upper limit of normal, consider discontinuation of Albenza.
- Micromedex provides Class IIa recommendations for use of albendazole for adult and pedicatric patients with the following conditions:
  - Ascariasis
  - Capillaria
  - HIV (Infection by Microsporidia)
  - 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** | | |
| Natroba™* (spinosad 0.9%) topical suspension | 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 | 20ml per application |
| 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

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| Sklice (Ivermectin) | Head Lice | 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) | 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 |
| Albenza (albendazole) | Neurocysticercosis | <60kg: 15mg/kg/day in 2 divided doses with food for 8-30 | 800mg per day |

| | | | |
|---|---|---|---|
| | | days<br><br>≥60kg: 400mg PO BID with food for 8-30 days | |
| Albenza (albendazole) | Echinococcosis | <60kg: 15mg/kg/day in 2 divided doses with food for 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 | 800mg per day |
| Albenza (albendazole) | Ascariasis (off-label) | 400mg PO as a single dose on am empty stomach | 400mg per day |
| Albenza (albendazole) | Capillaria infection (off label) | 400mg PO once daily with food (fatty meal) for 10 days | 400mg per day |

## VI. Product Availability

| Drug | Availability |
|---|---|
| Albenza (albendazole) | Tablets: 200mg |
| Ivermectin (Sklice) | Topical Lotion: 0.5%, 117 gram tube |
| Ivermectin (Stromectol) | Tablets: 3mg, 6mg |

## VII. References

1. Sklice [prescribing information]. Sanofi Pasteur, Inc., June 2017.
2. Stromectol [prescribing information]. Merck and Co., Inc. Whitehouse Station, NJ., December 2009.
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9. Albenza [prescribing information]. Amedra Pharmaceuticals LLC. Horsham, PA., December 2017.
10. CDC Guidelines for the Treatment of Enterobiasis. Available at https://cdc.gov/parasites/pinworm/treatment.html

| 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 | |

**Important Reminder**

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.

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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

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**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.

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