Pharmacy Medical Necessity Guidelines: Pediculicide Medications

Effective: May 12, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM:
617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Pediculicides are indicated for the topical treatment of head lice (pediculus capitis) infestation.

Spinosad topical suspension is a pediculicide indicated for the topical treatment of head lice infestations in patients 6 months of age and older. Per the American Academy of Pediatrics, safety and effectiveness of spinosad has not been established in children less than 4 years of age.

Sklice (ivermectin) lotion is a pediculicide indicated for the topical treatment of head lice infestations in patients 6 months of age and older.

Ulesfia (benzyl alcohol) lotion is a pediculicide indicated for the topical treatment of head lice infestation in patients 6 months of age and older.

COVERAGE GUIDELINES

The plan may authorize coverage of for Members when the following criteria for a particular regimen are met and limitations do not apply:

Spinosad Suspension

1. The Member is at least 6 months of age

AND

2. The Member tried and failed two treatment cycles (e.g., 0 and 9 days) in the last 30 days with, or the provider documents concern with the efficacy or safety of an over-the-counter product (examples include permethrin, piperonyl butoxide/pyrethrins and piperonyl butoxide/pyrethrins/permethrin).

Sklice (ivermectin) lotion, Ulesfia (benzyl alcohol) lotion

1. The Member is at least 6 months of age

AND

2. The Member tried and failed two treatment cycles (e.g., 0 and 9 days) with, or the provider documents concern with the efficacy or safety of an over-the-counter product (examples include permethrin, piperonyl butoxide/pyrethrins, and piperonyl butoxide/pyrethrins/permethrin).

AND

3. **For members at least 4 years of age:** The member has tried and failed one treatment cycle with spinosad suspension within the last 30 days

LIMITATIONS

1. Quantities for Sklice and spinosad are limited to one package size per Rx, i.e. Sklice 117 gm/Rx or Spinosad 120 ml/Rx, providing one complete course of therapy per prescription.
2. Requests for brand-name products, which have AB-rated generics, will also be reviewed according to Brand Name Medications criteria.

CODES

None

REFERENCES

1. Frankowski BL, Bocchini JA, and Council on School Health and Committee on Infectious Diseases. Head Lice. Pediatrics 2010; 126: 392-402.
2. Stough D, et al. Efficacy and safety of spinosad and permethrin creme rinses for pediculosis capitis (head lice). Pediatrics. 2009;124(3):e389-95.
3. Spinosad (Natroba) Topical Suspension for Head Lice. The Medical Letter on Drugs and Therapeutics. 2011; 53: 50-51.
4. Sklice (Ivermectin) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals; June 2017.
5. Natroba (Spinosad) [prescribing information]. Carmel, IN: ParaPRO; December 2014.
6. Devore CD, Schutze GE. Head lice. *Pediatrics*. 2015;135:e1355-1365.
7. Ulesfia (benzyl alcohol) [prescribing information]. Mississauga, ON: Contract Pharmaceuticals Limited; June 2015.
8. Devore CD, Schutza GE and the Council on School Health and Committee on Infectious Diseases. Head lice. *Pediatrics.* 2015;135:e1355-e1365.

APPROVAL HISTORY

January 13, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2016: Administrative change to rebranded template.
2. January 12, 2016: Added piperonyl butoxide/pyrethrins to examples of OTC products and clarified provider consideration to any of the OTC products is sufficient.
3. January 10, 2017: Removed "requests for quantities that exceed the quantity limit will also be reviewed according to the Drugs with Quantity Limitation criteria" from the limitations section of the MNG. Effective 4/1/17, added criteria for Ulesfia. Effective 7/1/17, specified for all products that OTC trial must be within the previous 30 days.
4. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Updated criteria for Sklice and Ulesfia to require a trial and failure of spinosad within the last 30 days. For all agents specified that member must try and fail two treatment cycles of an over-the-counter product.
5. July 10, 2018: No changes.
6. June 11, 2019: Reduced the minimum age for approval of spinosad from 4 years of age to 6 months of age. Administrative changes made to template.
7. May 12, 2020: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.