Pharmacy Medical Necessity Guidelines: Antiviral Agents, Topical

Effective: July 1, 2017

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

This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans

☐ Tufts Health Plan Commercial Plans – large group plans

☐ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans

☐ Tufts Health Direct – Health Connector

☒ Tufts Health Together – A MassHealth Plan

Tufts Health Freedom Plan products

☐ Tufts Health Freedom Plan - large group plans

☐ Tufts Health Freedom Plan - small group plans

Fax Numbers:

RXUM: 617.673.0988

OVERVIEW

Available topical antiviral agents Food and Drug Administration (FDA)-approved for the treatment of herpes labialis (cold sores) are herpes simplex virus nucleoside analogue DNA polymerase inhibitors. Both brand and generic options are available.

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Denavir (penciclovir) 1% cream is indicated for the treatment of recurrent herpes labialis (cold sores) in adults and children 12 years of age and older.

Zovirax (acyclovir) 5% cream is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults and adolescents 12 years of age and older.

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred topical antiviral agent for Members when **all** of the following criteria are met:

1. The Member is 12 years of age or older

AND

2. Documented diagnosis of diagnosis of recurrent herpes labialis

AND

3. Documentation the Member has tried and failed, or the provider indicates inappropriateness to two different oral antiviral agents

LIMITATIONS

None

CODES

None

REFERENCES

1. Denavir (penciclovir) cream [prescribing information]. Newtown, PA 18940: Prestium Pharma, Inc.; 2013 September.
2. Zovirax (acyclovir) cream [prescribing information]. Irvine, CA: Valeant Pharmaceuticals; 2014 April.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

- January 1, 2016: Administrative change to rebranded template.
- March 8, 2016: Approval duration extended to life of plan.
- March 14, 2017: Removed requirement of trial and failure with acyclovir 5% ointment and replaced it with trial and failure of two oral antiviral agents

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. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink^{SM} Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.