Pharmacy Medical Necessity Guidelines:
Antiviral Agents, Topical

Effective: February 10, 2026

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. Wald A, Johnston C. Treatment and prevention of herpes simplex virus type 1 in immunocompetent adolescents and adults. UpToDate. Available at: www.uptodate.com. Accessed2 February 2026.
2. Denavir (penciclovir) cream [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc.; November 2018.
3. Zovirax (acyclovir) cream [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; February 2021.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2023: No changes.
2. February 13, 2024: Effective March 1, 2024, updating the fax number for RxUM.
3. February 11, 2025: No changes
4. February 10, 2026: 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.

Provider Services