Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
# Denavir (penciclovir) cream

*Effective: March 1, 2026*

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| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

**Food and Drug Administration – Approved Indications**

**Denavir (penciclovir)** cream is a deoxynucleoside analog HSV DNA polymerase inhibitor indicated for the treatment of recurrent herpes labialis (cold sores) in adults and pediatric patients 12 years of age and older.

## Clinical Guideline Coverage Criteria

The plan may authorize coverage of penciclovir (generic Denavir) 1% cream for patients when all of the following criteria are met:

1. Documented diagnosis of recurrent herpes labialis

**AND**

2. Patient is 12 years of age or older

**AND**

3. The patient has had a trial and failure, inadequate response or intolerance to least TWO different oral antiviral agents (e.g. famciclovir and valacyclovir)

**AND**

4. The patient has had a trial and failure, inadequate response or intolerance to topical acyclovir.

## Limitations

- For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

## Codes

None

## References

1. Denavir (penciclovir) cream [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc.; November 2018.

## Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 8, 2023: no changes
- August 13, 2024: no changes
- August 12, 2025: no changes
- February 10, 2026: Effective March 1, 2026, updated criteria to indicate Member needs to have a trial and failure, inadequate response or intolerance to topical acyclovir instead of specifying that the Member use the ointment or cream formulation of acyclovir.

- February 2026: Administrative update to remove CareLink from Medical Necessity Guideline template.

## 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.