Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Xerese (acyclovir and hydrocortisone)**

Effective: January 1, 2027

Guideline Type	☒ Prior Authorization ☒ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care 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

Xerese (acyclovir and hydrocortisone), a combination of acyclovir, a herpes simplex virus deoxynucleoside analog DNA polymerase inhibitor, and hydrocortisone, a corticosteroid, is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and children (6 years of age and older).

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Xerese (acyclovir and hydrocortisone) for patients when all of the following criteria are met:

1. Documented diagnosis of recurrent herpes labialis

AND

2. Patient is 6 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. For patients 12 years of age and older, documentation of both of the following:
    a. The patient has had a trial and failure, inadequate response or intolerance to topical acyclovir
    b. The patient has had a trial and failure, inadequate response or intolerance to Denavir (penciclovir) cream

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.
- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.

Codes

None

References

1. Xerese (acyclovir and hydrocortisone) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; August 2020.

Approval And Revision History

September 15, 2026: Reviewed by the Pharmacy & Therapeutics Committee. Medical Necessity Guideline effective January 1, 2025.

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.