TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Prevymis™ (letermovir)

Effective: November 10, 2020

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

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[SM] – 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:
Oral formulation
RXUM: 617-673-0988

Intravenous Formulation
All plans except Tufts Health Direct - Health Connector
PRECERT:617.972.9409
Tufts Health Direct - Health Connector Only
MM: 888.415.9055

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

OVERVIEW

Prevymis™ is a cytomegalovirus (CMV) DNA terminase complex inhibitor indicated for prophylaxis of CMV infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

Prevymis™ is available as tablets for oral administration and solution for intravenous use. Prevymis™ injection should be used only in patients unable to take oral therapy. Patients should be switched to oral Prevymis ™ as soon as they are able to take oral medications.

COVERAGE GUIDELINES

The plan may authorize coverage of Prevymis™ (letermovir) for Members, when the following criteria are met:

1. Documentation that patient has received, or is scheduled to receive, an allogeneic hematopoietic stem cell transplant (HSCT)

   Note: Date of HSCT must be submitted on the request

   AND
2. Patient is at high risk of CMV infection (e.g. CMV-seropositive recipients, seronegative recipients who receive a graft from seropositive donor)

   AND
3. If the request is for the IV formulation, documentation that the member cannot tolerate or have contraindications to the oral formulation

LIMITATIONS

1. Coverage of Prevymis™ (letermovir) is limited to maximum of 100 days post-transplant.
2. The plan does not provide coverage of Prevymis™ (letermovir) for any condition not listed above in the "Pharmacy Coverage Guidelines."

CODES

None

REFERENCES

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accessdata.fda.gov/drugsatfda_docs/nda/2017/209939Orig1s000,209940Orig1s000SumR.pdf. Accessed 2018 January 9.
3. Food and Drug Administration. Developing products for rare diseases & conditions. 2017b December. URL: fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm. Accessed 2018 January 30.
4. Food and Drug Administration. Drugs@FDA. URL: accessdata.fda.gov/scripts/cder/drugsatfda. Available from Internet. Accessed 2018a January 9.
5. Food and Drug Administration. Fact sheet: breakthrough therapies. 2018b. URL: fda.gov/forpatients/approvals/fast/ucm405397.htm. Available from Internet. Accessed 2018 January.
6. Food and Drug Administration. Fast track. 2018c January. URL: fda.gov/ForPatients/Approvals/Fast/ucm405399.htm. Accessed 2018 January 30.
7. Ljungman P, Hakki M, and Boeckh M. Cytomegalovirus in hematopoietic stem cell transplant recipients. *Hematol Oncol Clin North Am*. 2011; 25(1):151–69.
8. Marty FM, Ljungman P, Chemaly RF, et al. Letermovir prophylaxis for cytomegalovirus in hematopoietic-cell transplantation. *N Engl J Med*. 2017; 377(25):2433-44.
9. National Comprehensive Cancer Network. Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prevention and Treatment of Cancer-Related Infections, V.1.2018. © National Comprehensive Cancer Network, Inc. 2017. All rights reserved. Accessed January 2018. To view the most recent and complete version of the guideline, go online to NCCN.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc.
10. Prevymis prescribing information. Whitehouse Station, NJ: Merck & Co., Inc.; 2017 November.
11. RxPipeline. Available with subscription at caremark.com/wps/portal/client. Accessed 2018 January 12.

APPROVAL HISTORY

March 13, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- January 8, 2019: No changes
- October 15, 2019: Removed the age restrictions, allowing coverage for all ages when medically necessary.
- November 10, 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.