Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Prevymis® (letermovir)

Effective: January 1, 2026

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

Applies to:

Commercial Products

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

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

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

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

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

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 (FDA) Approved Indications:

- Prevymis (letermovir) is a cytomegalovirus (CMV) DNA terminase complex inhibitor indicated for:
  - Prophylaxis of CMV infection and disease in adult and pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)
  - Prophylaxis of CMV disease in adult and pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])
- Prevymis (letermovir) is available as tablets and pellets for oral administration and solution for intravenous use. Prevymis (letermovir) injection should be used only in patients unable to take oral therapy. Patients should be switched to oral Prevymis (letermovir) as soon as they are able to take oral medications.
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Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Prevymis (letermovir) injection for infusion for Members when the following criteria are met:

Prophylaxis of CMV infection and disease in CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant (HSCT)

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 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. The prescribing physician is a hematologist, infectious disease specialist, oncologist or transplant specialist

   AND

4. If the request is for the IV formulation, documentation that the member is unable to take or tolerate oral Prevymis (letermovir) tablets.

Prophylaxis of CMV disease in kidney transplant recipients at high risk

1. Documentation that patient has received, or is scheduled to receive, a kidney transplant
   Note: Date of kidney transplant must be submitted on request

AND

2. Patient is at high risk of CMV infection (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])

AND

3. The prescribing physician is a hematologist, infectious disease specialist, nephrologist, oncologist or transplant specialist

AND

4. If the request is for the IV formulation, documentation that the member is unable to take or tolerate oral Prevymis (letermovir) tablets.

Limitations

- Coverage of Prevymis (letermovir) is limited to maximum of:
  - HSCT: 100 days post-HSCT. Members at risk for late CMV infection and disease may be continued through 200 days post-HSCT (provider documentation of risk and medical necessity required).
  - Kidney transplant: 200 days post-kidney transplant.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3490	Unclassified drug

References:

1. Centers for Disease Control and Prevention. Cytomegalovirus (CMV) and congenital CMV infection. 2017 December. URL: https://www.cdc.gov/cmv/clinical/features.html. Available from Internet. Accessed 2018 January 23.
2. Food and Drug Administration. Center for drug evaluation and research summary review. 2017a. URL: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209939Orig1s000,209940Orig1s000S umR.pdf. Accessed 2018 January 9.
3. Food and Drug Administration. Developing products for rare diseases & conditions. 2017b December. URL: https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm. Accessed 2018 January 30.
4. Food and Drug Administration. Drugs@FDA. URL: http://www.accessdata.fda.gov/scripts/cder/drugsatfda. Available from Internet. Accessed 2018a January 9.
5. Food and Drug Administration. Fact sheet: breakthrough therapies. 2018b. URL: https://www.fda.gov/forpatients/approvals/fast/ucm405397.htm. Available from Internet. Accessed 2018 January.
6. Food and Drug Administration. Fast track. 2018c January. URL: https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm. Accessed 2018 January 30.
7. Hakki M, Aitken SL, Danziger-Isakov L, et al. American Society for Transplantation and Cellular Therapy series: #3—prevention of cytomegalovirus infection and disease after hematopoietic cell transplantation. Transplant Cell Ther. 2021;27(9):707-719. https://doi.org/10.1016/j.jtct.2021.05.001.
8. Ljungman P, Hakki M, and Boeckh M. Cytomegalovirus in hematopoietic stem cell transplant recipients. Hematol Oncol Clin North Am. 2011; 25(1):151–69.
9. 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.
10. 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.
11. Prevymis prescribing information. Whitehouse Station, NJ: Merck & Co., Inc.; January 2025.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Added coverage for the supplemental indication for Prevymis in prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]). Updated duration post-HSCT that members at risk for late CMV infection and disease may be continued through 200 days post-HSCT (provider documentation of risk and medical necessity required). Administrative updates to add Medical Benefit Drugs to title and update MATogether and RITogether fax numbers to 617-673-0939. Removed the Limitation that members should be switched to oral Prevymis as soon as they are able to take oral medications. Removed the Limitation Coverage will be limited to FDA-approved indications (effective 12/1/23).
- November 12, 2024: Administrative updates to overview to include Prevymis's expanded indications in pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT), pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]), and availability of pellet formulation.
- November 2024: Administrative Update: Update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 2025 E-Vote: no changes (effective 1/1/26)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.