Pharmacy Management Drug Policy

SUBJECT: Cytomegalovirus (CMV)
POLICY NUMBER: PHARMACY-136
EFFECTIVE DATE: 01/2026
LAST REVIEW DATE: 08/13/2026

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Cytomegalovirus (CMV) is a common herpes virus that infects 1 in 3 children in the US and over half of adults by age 40 years. Infected individuals with a competent immune system typically do not require treatment but certain groups are at high risk for CMV infection: infants infected in utero (congenital CMV), very low birth weight and premature infants, and immunocompromised individuals (such as transplant patients and people infected with HIV). While infection of healthy individuals may be asymptomatic or present mild symptoms such as fatigue and sore throat, infection of patients with compromised immune systems may lead to severe clinical manifestations such as retinitis, colitis, esophagitis, pneumonia, and neurologic defects like dementia and central nervous system vasculitis.

Diagnosis of CMV in individuals at least 12 months of age is primarily done via serologic tests to detect CMV antibodies (IgM and IgG). Newborns may be tested through PCR testing of their saliva and a confirmatory urine test to verify the presence of CMV-specific IgM and or four-fold rise in CMV-specific IgG.

Initial management of CMV involves antiviral therapy with intravenous (IV) ganciclovir or oral valganciclovir as the preferred agents for both treatment and prophylaxis. For patients with resistant or refractory disease, IV foscarnet, IV cidofovir, and oral maribavir are alternative agents that may be used.

Livtencity (maribavir) is a CMV pUL97 kinase inhibitor that impedes protein phosphorylation to stop viral DNA replication and nuclear egress. It is indicated for treatment of post-transplant CMV infection or disease that is refractory to treatment, regardless of genotypic resistance, with ganciclovir, valganciclovir, cidofovir, or foscarnet in adults and pediatric patients 12 years of age and older weighing at least 35 kg.

Specific populations may be indicated for CMV prophylaxis or preemptive therapy due to their risk of developing CMV-disease related complications (e.g. hematopoietic stem cell transplantation [HSCT] recipients). Prophylactic therapy is administration of a drug to prevent infection in patients at increased risk whereas preemptive therapy is defined as administration of antiviral therapy to asymptomatic patients with laboratory markers of viremia to avoid disease progression, in which

case valganciclovir, ganciclovir, or foscarnet are recommended. Medications for CMV prophylaxis include ganciclovir, foscarnet, acyclovir, valacyclovir, valganciclovir, and letermovir. Of note, foscarnet, acyclovir, and valacyclovir are not FDA-approved for this indication.

Prevymis (letermovir) is a non-nucleoside CMV inhibitor that targets the CMV DNA terminase complex which is required for viral DNA processing and packaging. It is indicated for prevention of CMV infection and disease in adults and pediatric patients 6 months of age and older weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant, as well as the prophylaxis of CMV disease in adults and pediatric patients 12 years of age and older who are kidney transplant recipients at high risk (donor CMV seropositive/recipient seronegative [D+/R-]). The NCCN guidelines for the Prevention and Treatment of Cancer-Related Infections include consideration of letermovir for primary prophylaxis in allogeneic HCT recipients who are CMV seropositive.

DRUG SPECIFIC POLICIES/CRITERIA:

Livtencity – maribavir (Rx)
1. Must be 12 years of age or older and weigh at least 35 kg **AND** 2. Must be prescribed by, or in consultation with, a hematologist, infectious disease specialist, oncologist, or a physician affiliated with a transplant center **AND** 3. Must have a diagnosis of cytomegalovirus (CMV) infection/disease following a hematopoietic stem cell transplant (HSCT) or a solid organ transplant (SOT) **AND** 4. Must have post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) to at least one of the following therapies: a. Ganciclovir b. Valganciclovir c. Cidofovir d. Foscarnet 5. Refractory infection/disease is defined below (a or b): a. Definition of Refractory CMV infection: CMV viremia (DNAemia or antigenemia) that increases (> 1 $\log_{10}$) or persists (< 1 $\log_{10}$ increase or decrease) after at least 2 weeks of antiviral therapy b. Definition of Refractory CMV end-organ disease: Worsening in signs and symptoms or progression into end- organ disease (for a patient not previously diagnosed with CMV end-organ disease) OR lack of improvement in signs and symptoms after at least two weeks of appropriately dosed antiviral therapy 6. Must not have CMV disease involving the central nervous system, including the retina **AND** 7. Livtencity will not be authorized for use in combination with ganciclovir or valganciclovir **AND** 8. Livtencity will not be approved for non-FDA approved diagnoses (such as for the prevention of CMV infection/disease). 9. Approval will be provided for a total of 8 weeks. a. As therapy with Livtencity has not been studied for longer than 8 weeks, recertification will not be authorized. 10. Refer to the Livtencity prescribing information for approved dosing. 11. Quantity Limit: 120 tablets per 30-day supply. a. An increase in the quantity limit in accordance with the prescribing information may be provided with documentation Livtencity is being co-administered with certain anticonvulsants

Prevymis – letermovir (Rx and Medical)
1. Member must meet **ONE** of the following criteria (a or b): a. Member is a recipient of an allogenic hematopoietic stem cell transplant (HSCT) **AND** i. Member must be 6 months of age or older and weigh least 6 kg **AND** ii. Member is CMV-seropositive (R+) **AND** iii. Prevymis is being requested for CMV prophylaxis **AND** iv. Member will initiate therapy with Prevymis between Day 0 and Day 28 post transplantation (documentation of date of transplant is required) **OR** b. Member is a recipient of a kidney transplant **AND** i. Member must be 12 years of age or older and weigh at least 40 kg **AND** ii. Member is CMV-seronegative **AND** iii. Member must have received a primary or secondary allograft kidney from a seropositive [D+] donor **AND** iv. Prevymis is being requested for CMV prophylaxis **AND** v. Member will initiate Prevymis between Day 0 and Day 7 post transplantation (documentation of date of transplant is required). 2. Prescriber attests member is not concurrently using medications that are contraindicated with Prevymis (i.e., pimozide, ergot alkaloids, pitavastatin and simvastatin when co-administered with cyclosporine) **AND** 3. All requests for Prevymis IV will require clinical justification why the oral formulation cannot be used. 4. For kidney transplant recipients, authorization will be provided for 7 months to allow for 200 days of treatment post-transplant. Reauthorization will not be permitted. 5. For allogenic HSCT recipients, initial authorization will be provided for 4 months to allow for 100 days post-transplant. a. Recertification for an additional 4 months to allow an additional 100 days of therapy (maximum 200 days of treatment post-transplant) may be authorized with documentation of the following: i. Member is high-risk for late CMV infection and disease with one or more of the following risk factors: 1. HLA-related (sibling) donor with at least one mismatch at one of the following three HLA-gene loci: HLA-A, -B or –DR; or 2. Unrelated donor with at least one mismatch at one of the following four HLA-gene loci: HLA-A, -B, -C and -DRB1; or 3. Haploidentical donor; or 4. Use of umbilical cord blood as stem cell source; or 5. Use of ex vivo T-cell-depleted grafts; or 6. Receipt of anti-thymocyte globulin; or 7. Receipt of alemtuzumab; or 8. Use of systemic prednisone (or equivalent) at a dose of ≥1 mg/kg of body weight per day. 6. Refer to the Prevymis prescribing information for approved dosing. 7. Quantity Limits: a. Prevymis 240 mg or 480 mg tablets: 30 per 30 days b. Prevymis 20 mg or 120 mg oral pellet packets: 120 per 30 days

POLICY GUIDELINES:

1. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusions.
    a. Coverage criteria may be dependent on the contract renewal date.
    b. Coverage of drugs listed in this policy are contract dependent.
    c. Not of drugs listed in this policy are contract dependent.
    d. Not all contracts/benefits cover all medical infusible drugs.
2. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging, and other objective or subjective measures of clinical benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in the disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue to align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (e.g., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
5. This policy is applicable to drugs that are included on a specific drug formulary (Pharmacy benefit only). If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
6. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
7. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
8. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
9. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed

Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html

10. The requested site of care may impact approval timeframe and subject to review.
11. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
12. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
13. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key:
Experimental/Investigational = (E/I),
Not medically necessary/ appropriate = (NMN).
Copyright © 2006 American Medical Association, Chicago, IL

HCPCS:

J3490 Prevymis injection - for intravenous use

UPDATES:

Date:	Revision:
08/13/2026	Reviewed & Approved P&T Committee
07/13/2026	Revised
06/01/2026	Revised
01/01/2026	Effective & Posted
10/31/2025	Created
08/14/2025	Reviewed & Approved P&T Committee

REFERENCES:

1. Prevymis [package insert]. Whitehouse Station, NJ. Merck & Co., Inc., 2025.
2. Livtencity [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; 2024
3. Dalton M. Cytomegalovirus (CMV). NFID. August 26, 2025. Accessed September 16, 2025. https://www.nfid.org/infectious-disease/cytomegalovirus-cmv/

4. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV. Hiv.gov. July 14, 2025. Accessed September 16, 2025. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/cytomegalovirus
5. CDC. Laboratory testing for CMV and congenital CMV. Cytomegalovirus (CMV) and Congenital CMV Infection. April 15, 2024. Accessed September 16, 2025. https://www.cdc.gov/cytomegalovirus/php/laboratories/index.html
6. Raglow Z, Kaul DR. A New Antiviral Option for Cytomegalovirus Prevention After Kidney Transplant. Jamanetwork.com. doi:10.1001/jama.2023.910
7. Razonable RR, Humar A. Cytomegalovirus in solid organ transplant recipients—Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant*. 2019; 33:e13512. https://doi-org.gate.lib.buffalo.edu/10.1111/ctr.13512
8. Marty FM, Ljungman P, Chemaly RF, et al. Letermovir Prophylaxis for Cytomegalovirus in Hematopoietic-Cell Transplantation. *N Engl J Med*. 2017;377(25):2433-2444. doi:10.1056/NEJMoa1706640
9. National Comprehensive Cancer Network®. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) prevention and treatment of cancer-related infections V.1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed [September 19, 2025]. To view the most recent and complete version of the guideline, go online to NCCN.org.
10. 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
11. Yong MK, Shigle TL, Kim Y, et-al. American Society for Transplantation and Cellular Therapy Series: #4 - Cytomegalovirus treatment and management of resistant or refractory infections after hematopoietic cell transplantation. Transplant Cell Ther. 2021;27(12):957-967. https://doi.org/10.1016/j.jtct.2021.09.010.