Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCINF040.1225	**ANTI-INFECTIVE AGENTS** **LIVTENCITY®** (maribavir tablet)
Effective Date: 2/1/2026	**Review/Revised Date**: 11/22, 10/23, 10/24, 11/25 (JEF)
Original Effective Date: 06/22	**P&T Committee Meeting Date**: 04/22, 12/22, 12/23, 12/24, 12/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA)-Approved Indications

REQUIRED MEDICAL INFORMATION:
Initial authorization requires all the following criteria to be met:
1. Documentation of history of hematopoietic stem cell or solid organ transplant
2. Documentation of post-transplant cytomegalovirus (CMV) infection/disease with CMV DNA of 2730 IU/mL or greater in whole blood or 910 IU/mL or greater in plasma
3. One of the following:
    a. Documentation of CMV infection/disease refractory (with or without genotypic resistance), to previous treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet
    b. Documented intolerance or contraindication to all the above antivirals or sufficient clinical rationale why treatment with all the above therapies is not appropriate

Reauthorization:
1. Documentation is provided to support continued therapy as evidenced by incomplete resolution of clinical symptoms, incomplete virologic clearance, or relapse in CMV infection

EXCLUSION CRITERIA:
Use in combination with ganciclovir or valganciclovir

AGE RESTRICTIONS:
May be approved for patients aged 12 years and older

PRESCRIBER RESTRICTIONS:
Must be prescribed by, or in consultation with, a transplant surgeon, infectious disease specialist, oncologist, hematologist

COVERAGE DURATION:
Initial authorization and reauthorization will be approved for twelve weeks

QUANTITY LIMIT:
Twelve tablets per day

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Livtencity® is an antiviral drug against human cytomegalovirus (CMV). It is the first drug approved for refractory CMV. It is not approved in patients with human immunodeficiency virus (HIV), other nontransplant populations, for first-line treatment of CMV infection or for prophylaxis of CMV infection.

FDA APPROVED INDICATIONS:
For the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet

POSITION STATEMENT:

- The following antiviral drugs are used to treat CMV in transplant patients: ganciclovir, valganciclovir, foscarnet, or cidofovir. Treatment options are limited when these treatments are failed.
- Approval of Livtencity® was based on a Phase 3, multicenter, randomized, open-label, active-controlled superiority trial (NCT02931539, SOLSTICE trial)
    - Evaluated safety and efficacy of maribavir versus ganciclovir, valganciclovir, foscarnet, or cidofovir in hematopoietic stem cell transplant and solid organ transplant patients.
    - Primary endpoint: Percentage of participants who achieved confirmed clearance of plasma cytomegalovirus (CMV) deoxyribonucleic Acid (DNA) (CMV Viremia Clearance) at end of week eight
    - Moderate quality of evidence that maribavir is superior in CMV viremia clearance compared with conventional antiviral therapies (ganciclovir, valganciclovir, cidofovir, or foscarnet) in transplant recipients with refractory CMV infections (with or without genotypic resistance)
    - Inclusion criteria: Age greater than 12 years, recipient of hematopoietic stem cell or solid organ transplant, have a documented CMV infection in whole blood or plasma, with a screening value of greater than or equal to (>=) 2730 international units per milliliter (IU/mL) in whole blood or >= 910 IU/mL in plasma in 2 consecutive assessments, current CMV infection that is refractory to the most recently administered of the four anti-CMV treatment agents (refractory is defined as documented failure to achieve greater than (>) 1 log10 decrease in CMV DNA level in whole blood or plasma after a 14 day or longer treatment period with intravenous (IV) ganciclovir/oral valganciclovir, IV foscarnet, or IV cidofovir OR participants with documentation of 1 or more CMV genetic mutations associated with resistance to ganciclovir/valganciclovir, foscarnet, and/or cidofovir must also meet the definition of refractory CMV infection)
    - Exclusion criteria: Current CMV infection that is considered refractory or resistant due to inadequate adherence to prior anti-CMV treatment, require ganciclovir, valganciclovir, foscarnet, or cidofovir administration for conditions other than CMV when study treatment is initiated
- A CMV Disease Definitions Working Subgroup has published consensus definitions of CMV infection and disease in solid organ transplant patients for use in clinical trials. Several of these definitions are listed below[9].
    - CMV infection – virus isolation or detection of viral proteins (antigens) or nucleic acid in any body fluid or tissue specimen
    - CMV disease - consists of “end-organ disease” and “CMV syndrome”
        - CMV end-organ disease, requires the presence of appropriate clinical symptoms and/or signs with documentation of CMV in tissue. CMV syndrome is the detection of CMV in the blood

together with at least two clinical findings including fever, malaise, leukopenia, neutropenia or thrombocytopenia, atypical lymphocytes or elevated liver enzymes
    - Refractory CMV infection - CMV viremia that increases (ie, >1 log10 increase in CMV DNA levels in the same blood compartment from the peak viral load as measured in the same laboratory and/or with the same commercial assay) OR persists (≤1 log10 increase or decrease in CMV DNA levels) after at least 2 weeks of appropriate antiviral therapy
- Maribavir was compared to valganciclovir in patient with first asymptomatic CMV infection post-HCT in the AURORA trial. The primary endpoint of noninferiority in confirmed CMV viremia clearance at week 8 (noninferiority margin of 7.0%) was not met[8].
- Two previous well controlled maribavir prophylaxis trials failed to meet their primary endpoints. Maribavir has not been approved for use for CMV prophylaxis[6].
- Safety:
    - Warnings and precautions: Risk of reduced antiviral activity when co-administered with ganciclovir and valganciclovir; virologic failure during treatment and relapse post-treatment; and risk of adverse reactions or loss of virologic response due to drug interactions
    - The most common adverse reactions (all grades, > 10%) were taste disturbance, nausea, diarrhea, vomiting, and fatigue
    - The overall safety of maribavir appears comparable to or better than the conventional CMV antivirals, resulting in lower risk of neutropenia and potentially lower risk of renal impairment
- Dosing:
    - The recommended dosage in adults and pediatric patients (12 years of age and older and weighing at least 35 kg) is 400 mg (two 200 mg tablets) taken orally twice daily with or without food
    - If co-administered with carbamazepine, increase the dosage of maribavir to 800 mg twice daily
    - If co-administered with phenytoin or phenobarbital, increase the dosage of maribavir to 1,200 mg twice daily

REFERENCE/RESOURCES:

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2. Livtencity In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically. Accessed November 6, 2025.

3. Livtencity In: Lexi-Drugs Online [Internet database]. Hudson, OH: Lexi-Comp, Inc. Updated periodically. Accessed November 6, 2025.
4. Kotton, CN, Kumar, D, Caliendo, A, et al. Third International Consensus Guidelines on the Management of Cytomegalovirus in Solid-organ Transplantation. Transplantation: 2018; 102(6):900-931.
5. Razonable RR, et al. Cytomegalovirus in solid organ transplant recipients—Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9):e13512
6. Center for Drug Evaluation and Research. FDA Integrated Review. Application Number: 215596Orig1s000. Livtencity (maribavir). Accessed November 9, 2024.
7. Clinicaltrials.gov. Efficacy and Safety Study of Maribavir Treatment Compared to Investigator-assigned Treatment in Transplant Recipients With Cytomegalovirus (CMV) Infections That Are Refractory or Resistant to Treatment With Ganciclovir, Valganciclovir, Foscarnet, or Cidofovir. Efficacy and Safety Study of Maribavir Treatment Compared to Investigator-assigned Treatment in Transplant Recipients With Cytomegalovirus (CMV) Infections That Are Refractory or Resistant to Treatment With Ganciclovir, Valganciclovir, Foscarnet, or Cidofovir - Full Text View - ClinicalTrials.gov. Accessed February 15, 2022.
8. Papanicolaou GA, Avery RK, Cordonnier C, *et al*; AURORA Trial Investigators. Treatment for First Cytomegalovirus Infection Post-Hematopoietic Cell Transplant in the AURORA Trial: A Multicenter, Double-Blind, Randomized, Phase 3 Trial Comparing Maribavir With Valganciclovir. *Clin Infect Dis*. 2024 Mar 20;78(3):562-572. Erratum in: *Clin Infect Dis*. 2024 Sep 26;79(3):803.
9. Ljungman P, Chemaly RF, Khawaya F, *et al*; CMV Definitions Working Group of the Transplant Associated Virus Infections Forum. Consensus Definitions of Cytomegalovirus (CMV) Infection and Disease in Transplant Patients Including Resistant and Refractory CMV for Use in Clinical Trials: 2024 Update From the Transplant Associated Virus Infections Forum. *Clin Infect Dis*. 2024 Sep 26;79(3):787-794.
10. Chou S, Alain S, Cervera C, *et al*. Drug Resistance Assessed in a Phase 3 Clinical Trial of Maribavir Therapy for Refractory or Resistant Cytomegalovirus Infection in Transplant Recipients. J Infect Dis. 2024 Feb 14;229(2):413-421.