# Clinical Policy: Maribavir (Livtencity)

Reference Number: DE.PMN.271
Effective Date: 01.23
Last Review Date: 01.23
Line of Business: Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Maribavir (Livtencity™) is a cytomegalovirus (CMV) pUL97 kinase inhibitor.

## FDA Approved Indication(s)

Livtencity is indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet.

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Livtencity is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Post-Transplant CMV Infection** (must meet all)**:**

1. Diagnosis of CMV infection following hematopoietic stem cell transplant or solid organ transplant (e.g., kidney, lung, heart, liver, pancreas, intestine);
2. Age ≥ 12 years;
3. Weight ≥ 35 kg;
4. Failure to achieve > 1 $\log_{10}$ decrease in CMV DNA level in whole blood or plasma after a ≥ 14-day trial of TWO of the following: ganciclovir, valganciclovir, cidofovir, foscarnet;
5. Member does not have CMV disease involving the central nervous system (including the retina);
6. Dose does not exceed (a, b, or c):
   a. 800 mg (4 tablets) per day;
   b. If co-administered with carbamazepine: 1,600 mg (8 tablets) per day;
   c. If co-administered with phenytoin or phenobarbital: 2,400 mg (12 tablets) per day.

**Approval duration: 8 weeks**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53.

## II. Continued Therapy

**A. Post-Transplant CMV Infection** (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member has not received ≥ 8 weeks of therapy;
4. If request is for a dose increase, new dose does not exceed (a, b, or c):
   a. 800 mg (4 tablets) per day;
   b. If co-administered with carbamazepine: 1,600 mg (8 tablets) per day;
   c. If co-administered with phenytoin or phenobarbital: 2,400 mg (12 tablets) per day.

**Approval duration: up to 8 weeks total**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

CMV: cytomegalovirus
FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| ganciclovir (Cytovene®)* | 5 mg/kg IV q12 hours | 10 mg/kg/day |
| valganciclovir (Valcyte®)* | 900 mg PO BID | 1,800 mg/day |
| cidofovir (Vistide®)* | 5 mg/kg IV once per week | 5 mg/kg/week |
| foscarnet (Foscavir®)* | 90 mg/kg IV q12 hours or 60 mg/kg IV q8 hours | 180 mg/kg/day |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*
**Off-label*

*Appendix C: Contraindications/Boxed Warnings*
None reported

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Post-transplant CMV infection | • 400 mg PO BID<br>or<br>• If co-administered with carbamazepine: 1,600 mg (8 tablets) per day<br>or<br>• If co-administered with phenytoin or phenobarbital: 2,400 mg (12 tablets) per day | 2,400 mg/day |

## VI. Product Availability

Tablet: 200 mg

## VII. References

1. Livtencity Prescribing Information. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; November 2021. Available at http://www.livtencity.com. Accessed December 1, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com. Accessed December 1, 2021.
3. Takeda Pharmaceuticals U.S.A., Inc. NCT02931539: 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. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT02931539. Accessed December 1, 2021.
4. Antimicrobial Drugs Advisory Committee briefing document on maribavir. Published October 7, 2021. Available at: https://www.fda.gov/media/152715/download. Accessed December 1, 2021.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 11.22 | 01.23 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.