Clinical Policy: Maribavir (Livtencity)

Reference Number: CP.PMN.271
Effective Date: 03.01.22
Last Review Date: 02.25
Line of Business: Commercial, HIM, 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 one of the following: ganciclovir, valganciclovir, cidofovir, foscarnet;
5. Member does not have CMV disease involving the central nervous system (including the retina);
6. Livtencity is not prescribed concurrently with ganciclovir or valganciclovir;
7. 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 (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Post-Transplant CMV Infection (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Livtencity for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. Member has not received ≥ 8 weeks of therapy;
4. Livtencity is not prescribed concurrently with ganciclovir or valganciclovir;
5. 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 • If co-administered with carbamazepine: 1,600 mg (8 tablets) per day • 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.; March 2024. Available at http://www.livtencity.com. Accessed October 22, 2024.

2. Clinical Pharmacology [database online]. Elsevier, Inc. Updated periodically. Available at: https://www.clinicalkey.com/pharmacology/. Accessed November 14, 2024.
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.
4. Antimicrobial Drugs Advisory Committee briefing document on maribavir. Published October 7, 2021. Available at: https://www.fda.gov/media/152715/download. Accessed November 14, 2024.
5. Avery RK, Alain S, Alexander BD, et al. Maribavir for refractory cytomegalovirus infections with or without resistance post-transplant: Results from a phase 3 randomized clinical trial. Clin Infect Dis. 2022 Sep 10;75(4):690-701.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.01.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.07.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	10.24.22	02.23
COC applied to continued therapy section	07.10.23	
1Q 2024 annual review: added requirement that Livtencity is not prescribed concurrently with ganciclovir or valganciclovir; references reviewed and updated.	10.23.23	02.24
1Q 2025 annual review: no significant changes; references reviewed and updated.	10.22.24	02.25

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.