Clinical Policy: Maribavir (Livtencity)

Reference Number: ERX.NPA.163
Effective Date: 03.01.22
Last Review Date: 02.22
Line of Business: Commercial, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CMV: cytomegalovirus
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

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 or • If co-administered with carbamazepine: 1,600 mg (8 tablets) per day or • 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	12.01.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.