Original Effective Date: 02/01/2022
Current Effective Date: 03/28/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C22246-A

Livtencity (maribavir)

PRODUCTS AFFECTED

Livtencity (maribavir)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Refractory post-transplant cytomegalovirus (CMV) infection/disease

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CYTOMEGALOVIRUS INFECTION:
1. Documentation of a diagnosis of post-transplant cytomegalovirus (CMV) infection/disease AND
2. Documentation of hematopoietic cell transplant (HSCT) OR solid organ transplant (SOT) date

AND

3. Documentation of member treatment failure (refractory) with or without resistance to ONE of the following: ganciclovir, valganciclovir, foscarnet, or cidofovir.
   AND
4. Documentation member weighs at least 35kg
   AND
5. Prescriber attests Livtencity (maribavir) will be used as antiviral monotherapy

CONTINUATION OF THERAPY: N/A

DURATION OF APPROVAL:
Initial authorization: 8 weeks, Continuation of Therapy: N/A

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with, an infectious disease specialist, hematologist, or a transplant specialist. [If prescribed in consultation, consultation notes must be submitted with initial request]

AGE RESTRICTIONS:
12 years of age and older

QUANTITY:
800 mg daily [400mg BID] for 8 weeks

Maximum Quantity Limits –
1600 mg daily [800 mg BID] is allowed with documentation Livtencity (maribavir) will be administered concurrently with carbamazepine
2400 mg daily [1200 mg BID] is allowed with documentation Livtencity (maribavir) will be administered concurrently with phenytoin or phenobarbital

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
CMV Agents

FDA-APPROVED USES:
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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Cytomegalovirus (CMV) is a common type of herpes virus that commonly causes infection in patients who are immunosuppressed after a hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT). The condition affects 16%–56% of SOT recipients and 30%–70% of HSCT recipients and can lead to CMV disease and have a major negative impact on transplant recipients, including loss of the transplanted organ and death. CMV is most often caused by a reactivation of CMV acquired long before your transplant. If you develop your first CMV infection, the virus likely came from your transplanted organ. (The donor might have been exposed to the virus.) CMV is transmitted by contact between mucous membranes (the mouth and genitals) and live virus present in the secretions of infected CMV patients.

Patients who receive bone marrow, lung, heart, heart-lung, liver, pancreas-kidney, and kidney transplants require different levels of immunosuppression. Bone marrow transplant and lung transplant recipients tend to be at the highest risk for CMV infection. The disease occurs with the highest frequency in donor-positive/recipient-negative transplant recipients. This relationship is true for all organ transplant recipients except bone marrow transplant recipients; in these patients, the highest incidence of CMV disease is in donor-negative/recipient-positive people.

The diagnosis of CMV should be suspected among transplant recipients who present with signs or symptoms compatible with CMV syndrome or disease. However, the clinical manifestations of CMV are nonspecific and overlap with many infectious and noninfectious illnesses. Thus, among all transplant recipients, laboratory confirmation is required to establish the diagnosis. Occasionally, a biopsy with histopathologic examination of tissue is necessary to diagnose tissue invasive CMV disease.

Among transplant recipients, confirming the diagnosis of CMV infection or disease with nucleic acid testing (NAT). NAT using the polymerase chain reaction (PCR) for the detection of CMV DNA is the diagnostic modality of choice for most transplant clinicians. CMV disease is defined as the presence of detectable CMV in a clinical specimen accompanied by other clinical manifestations.

To treat CMV in transplant recipients, patients are generally given one or more of the following antiviral drugs: ganciclovir, valganciclovir, foscarnet, or cidofovir. However, when these standard treatments fail, the outlook for this patient population is much worse

Livtencity
Livtencity, a CMV pUL97 kinase inhibitor, is an oral antiviral that works by preventing the phosphorylation of proteins and viral DNA replication, encapsulation, and nuclear egress. Because its mechanism of action is different than conventional antivirals used for CMV, Livtencity retains some activity against CMV that is resistant to some conventional agents.

Livtencity's safety and efficacy were evaluated in a Phase 3 SOLSTICE trial, multicenter, open-label, active-controlled trial that compared Livtencity with a treatment assigned by a researcher running the study, which could include one or two of the following antivirals used to treat CMV: ganciclovir, valganciclovir, foscarnet or cidofovir. In the study, 352 transplant recipients with CMV infections who did not respond (with or without resistance) to treatment randomly received Livtencity or treatment assigned by a researcher for up to eight weeks.

The study compared the two groups' plasma CMV DNA concentration levels at the end of the study's eighth week, with efficacy defined as having a level below what is measurable. Of the 235 patients who received Livtencity, 56% had levels of CMV DNA below what was measurable versus 24% of the 117 patients who received an investigator-assigned treatment. All-cause mortality was similar in both treatment groups; graft loss was not measured for SOTs. Treatment with maribavir was not associated with new safety signals, and maribavir was associated with lower incidence of neutropenia compared to investigator-

assigned treatment (IAT).
After the end of treatment phase, 65/131 (50%) of patients in the Livtencity group and 11/28 (39%) patients in the IAT group who achieved CMV DNA level < LLOQ, lower limit of quantification; experienced virologic relapse during the follow-up period. In both groups, most of the relapses occurred within 4 weeks after study drug discontinuation. Six percent of patients in both groups developed new-onset symptomatic CMV infection during the entire study period.

The most common side effects of Livtencity include taste disturbance, nausea, diarrhea, vomiting and fatigue. Livtencity may reduce the antiviral activity of ganciclovir and valganciclovir, so coadministration with these drugs is not recommended. Virologic failure due to resistance can occur during and after treatment with Livtencity, therefore CMV DNA levels should be monitored and Livtencity resistance should be checked if the patient is not responding to treatment or relapses.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Livtencity (maribavir) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. There are not currently any FDA labeled contraindications to Livtencity (maribavir).

OTHER SPECIAL CONSIDERATIONS:
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 Livtencity is co-administered with carbamazepine, increase the dosage of Livtencity to 800 mg twice daily. If Livtencity is co-administered with phenytoin or phenobarbital, increase the dosage of Livtencity to 1,200 mg twice daily.
Livtencity is available to healthcare providers through a network of specialty pharmacies and distributors (Amber Specialty Pharmacy and Biologics by McKesson).

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Livtencity TABS 200MG (28 per bottle or 56 per bottle)

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: References	Q1 2025
REVISION- Notable revisions: Prescriber Requirements Quantity References	Q1 2024
REVISION- Notable revisions: Required Medical Information Quantity References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file