MEDICAL MUTUAL®

Drug Policy

Policy:	Livtencity (maribavir)	Annual Review Date: 01/18/2024 Last Revised Date: 01/18/2024

OVERVIEW

Livtencity, a protein kinase inhibitor, is indicated for the treatment of patients ≥ 12 years of age (weighing ≥ 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.[1] Coadministration of Livtencity with ganciclovir or valganciclovir is not recommended; Livtencity may antagonize the antiviral activity of these agents. In the pivotal study (SOLSTICE), patients were treated with Livtencity (or another medication) for up to 8 weeks.

CMV infection is a common complication of hematopoietic-cell and solid-organ transplantation and is associated with increased morbidity and mortality.[2] The available antiviral agents (valganciclovir tablets or oral solution, ganciclovir injection, cidofovir injection, and foscarnet injection) are effective but use is limited by their toxic effects. In addition, approximately 5 to 14% of transplant recipients develop infection with drug-resistant CMV, which is associated with poor outcomes.

POLICY STATEMENT

This policy involves the use of Livtencity. Prior authorization is recommended for pharmacy benefit coverage of Livtencity. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Livtencity as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Livtencity be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Livtencity is recommended in those who meet the following criteria:

1. <u>Cytomegaloviris Infection - Treatment</u>

Criteria. *Patient must meet the following criteria (A, B, C, D, E, <u>and</u> F):*

A) Patient is ≥ 12 years of age; AND

B) Patient weighs ≥ 35 kg; AND
C) Patient is post-transplant; AND
Note: This includes patients who are post hematopoietic stem cell transplant or solid organ transplant.
D) Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir; AND
E) The medication is not prescribed in conjunction with ganciclovir or valganciclovir; AND
F) The medication is prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 months (60 days)
B) *Extended Approval:* Extended approval is not recommended

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Livtencity has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Livtencity™ tablets [prescribing information]. Lexington, MA: Takeda; November 2021.
2. Maertens J, Cordonnier C, Jaksch P, et al. Maribavir for preemptive treatment of cytomegalovirus reactivation. *N Engl J Med*. 2019;381:1136-1147.