VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Infectious Disease – Livtencity Prior Authorization Policy
- Livtencity™ (maribavir tablets – Takeda)

REVIEW DATE: 12/01/2021; selected revision 01/19/2022

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

Prior Authorization is recommended for prescription benefit coverage of Livtencity. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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, approval requires Livtencity to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Cytomegalovirus Infection – Treatment.** Approve for 2 months if the patient meets the following criteria (A, B, C, D, E, and 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 meets one of the following criteria (i or ii):
     - **i.** Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir; OR
     - **ii.** Patient has significant intolerance to 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Livtencity is not recommended in the following situations:

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

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/01/2021
Selected Revision	**Cytomegalovirus Infection – Treatment:** The criterion "Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir" was revised to include exception for patients with significant intolerance to ganciclovir or valganciclovir. The new criterion is that the patient must meet one of the following: 1) Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of cidofovir, foscarnet, ganciclovir, or valganciclovir OR 2) Patient has significant intolerance to ganciclovir or valganciclovir.	01/19/2022