Drug Coverage Policy

Effective Date.....07/01/2024
Coverage Policy Number.....IP0394
Policy Title.....Livtencity

Infectious Disease – Livtencity

- Livtencity™ (maribavir tablets - Takeda)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

Overview
Livtencity, a protein kinase inhibitor, is indicated for the treatment of **post-transplant cytomegalovirus (CMV) infection/disease** that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet in patients ≥ 12 years of age (weighing ≥ 35 kg).[1] Co-administration 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.

Medical Necessity Criteria

Livtencity is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Cytomegalovirus Infection – Treatment.** Approve for 2 months if the patient meets the following (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 (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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Livtencity™ tablets [prescribing information]. Lexington, MA: Takeda; April 2023.
2. Maertens J, Cordonnier C, Jaksch P, et al. Maribavir for preemptive treatment of cytomegalovirus reactivation. *N Engl J Med*. 2019;381:1136-1147.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Cytomegalovirus Infection – Treatment.**	07/01/2024

	• This policy now applies to Individual and family plans. **Added** a weight restriction (≥ 35 kg) aligned to the FDA labeled indication. **Updated** the ganciclovir resistance statement to intolerance to ganciclovir or valganciclovir. **Added** a restriction prohibiting concurrent use of Livtencity with ganciclovir or valganciclovir.	

The policy effective date is in force until updated or retired.