Drug and Biologic Coverage Policy

Effective Date **5/1/2023**
Next Review Date **5/1/2024**
Coverage Policy Number **IP0394**

Maribavir

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Related Coverage Resources

Quantity Limitations – (1201)

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. 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.

Overview

This policy supports medical necessity review for maribavir (**Livtencity™**).

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

Initial Approval Criteria

Maribavir (Livtencity) is considered medically necessary for the treatment of cytomegalovirus infection when the individual meets ALL of the following criteria:

1. Age 12 years or older
2. Documented diagnois of cytomegalovirus infection is **ONE** of the following:
    a. Refractory to treatment with at least **ONE** of the following: cidofovir, foscarnet, ganciclovir or valganciclovir
    b. Resistant to ganciclovir
3. Post-transplant (for example, post hematopoietic stem cell transplant or solid organ transplant

4. 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.

Continuation of Therapy Criteria

Continuation of maribavir (Livtencity) is considered medically necessary for treatment of cytomegalovirus infection when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial and reauthorization approval duration: up to 2 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

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] 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.

References

1. Livtencity tablets [prescribing information]. Lexington, MA: Takeda; September 2022.
2. Maertens J, Cordonnier C, Jaksch P, et al. Maribavir for preemptive treatment of cytomegalovirus reactivation. *N Engl J Med*. 2019;381:1136-1147.