Livtencity (maribavir)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Post-transplant cytomegalovirus (CMV) infection/disease is a common complication following solid organ transplantation. CMV is a double-stranded DNA virus that belongs to the herpesvirus family, and it can cause severe morbidity and mortality in transplant recipients. While antiviral therapy is available for CMV infection/disease, some cases may be refractory to treatment.

Antiviral therapy is the mainstay of treatment for CMV infection/disease. The most commonly used drugs are ganciclovir, valganciclovir, and foscarnet. However, some cases of CMV infection/disease may be refractory to treatment. Refractory CMV infection/disease is defined as persistent or progressive CMV infection/disease despite appropriate antiviral therapy for at least 2 weeks.

Livtencity (maribavir) is indicated for the treatment of adults and pediatrics (12 years of age and older and weighing at least 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

Definitions

"Antiviral" is an agent that kills a virus or that suppresses its ability to replicate, multiply and reproduce.

"Cytomegalovirus (CMV)" is a common type of herpes virus.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Hematopoietic stem-cell transplantation (HSCT)" is a medical procedure that consists of infusing stem cells after a short course of chemotherapy or radiotherapy to treat various types of cancers.

"No evidence of" indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

"Refractory" refers to a condition or disease that does not respond to treatment or becomes resistant to it. In the context of medical treatment, refractory can mean that a patient's symptoms or disease are persisting, progressing, or recurring despite receiving standard therapies.

"[s]" indicates state mandates may apply.

"Solid organ transplant (SOT)" is a medical procedure where an organ is removed from one body and placed in the body of a recipient, to replace a damaged or missing organ.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Post-Transplant Cytomegalovirus Infection

The Plan considers Livtencity (maribavir) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with an infectious disease specialist, hematologist, or transplant specialist; *AND*
2. The member is 12 years of age or older; *AND*
3. The member weighs at least 35 kg; *AND*
4. The member has a history of hematopoietic stem cell transplant (HCST) or solid organ transplant (SOT); *AND*
5. The member has a diagnosis of post-transplant cytomegalovirus (CMV) infection/disease that is refractory following at least 14 days of ONE (1) of the following treatments:[s]
    a. Cidofovir*; or*
    b. Foscarnet*; or*
    c. Ganciclovir*; or*
    d. Valganciclovir*; AND*
6. Is being prescribed for use meeting ALL of the following:
    a. Livtencity (maribavir) will not be used concomitantly with other CMV antivirals; *and*
    b. Livtencity (maribavir) will not be used for prevention of CMV infection; *and*
    c. Livtencity (maribavir) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication; *and*
    d. The treatment duration with Livtencity (maribavir) will not exceed 8 weeks; *AND*
7. Supporting chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Livtencity (maribavir) will be approved for a single 8-weeks treatment course. [s]

Experimental or Investigational / Not Medically Necessary [s]

Livtencity (maribavir) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven, or not medically necessary. Non-covered indications include, but are not limited to, the following:

- As an initial treatment for CMV disease. Livtencity (maribavir) has been approved explicitly in those who have failed at least one of the following: ganciclovir, valganciclovir, cidofovir, or foscarnet.

- HIV-related CMV disease. There are no high-quality data to support the safety and efficacy of Livtencity (maribavir) for the management of HIV-related CMV.
- In combination with other CMV antiviral agents. Livtencity (maribavir) has not been adequately studied in combination with other CMV antiviral agents.
- In other non-transplant populations. There are not enough high quality studies to support the safety and efficacy of Livtencity (maribavir) in other non-transplant populations.
- Prophylaxis of CMV infection. In one study (n=307) assessing the safety of efficacy of Livtencity (maribavir) versus ganciclovir for the prevention of CMV for liver transplant recipients, Livtencity (maribavir) was found to be non-inferior. Studies comparing Livtencity (maribavir) to placebo have been conflicting, with one larger (n=681) randomized placebo-controlled showing no benefit, and another smaller (n=111) showing significant improvement in CMV prevention compared to placebo.

References

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