Oscar Clinical Guideline: Livtencity (maribavir) (PG113, Ver. 3)

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 pediatric patients (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.

"**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.

"**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.

"**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.

Medical Necessity Criteria for Authorization

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

1. The member is 12 years of age or older; ***AND***
2. The member weighs at least 35 kg; ***AND***
3. The member has a history of hematopoietic stem cell transplant (HCST) or solid organ transplant (SOT); ***AND***
4. The member has a diagnosis of post-transplant cytomegalovirus (CMV) infection/disease that is refractory following at least 14 days of **ONE** of the following treatments:
    - **a.** cidofovir***; or***
    - **b.** foscarnet***; or***
    - **c.** ganciclovir***; or***
    - **d.** valganciclovir***; AND***
5. Is being prescribed for use meeting **ALL** of the following:
    - a. will not be used concomitantly with other CMV antivirals; ***and***
    - b. will not be used for prevention of CMV infection; ***and***
    - c. will be dosed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature; ***and***
    - d. treatment duration with Livtencity (maribavir) will not exceed 8 weeks; ***AND***
6. 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.

Experimental or Investigational / Not Medically Necessary

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

- as an initial treatment for CMV disease
- HIV-related CMV disease
- in combination with other CMV antiviral agents
- in other non-transplant populations
- prophylaxis of CMV infection

References

1. A Phase 3, Multicenter, Randomized, Open-label, Active-controlled Study to Assess the Efficacy and Safety of Maribavir Treatment Compared to Investigator-assigned Treatment in Transplant Recipients With Cytomegalovirus (CMV) Infections That Are Refractory or Resistant to Treatment With Ganciclovir, Valganciclovir, Foscarnet, or Cidofovir. ClinicalTrials.gov Identifier: NCT02931539. Updated November 3, 2021. Accessed February 28, 2022. https://clinicaltrials.gov/ct2/show/NCT02931539
2. Avery RK, Alain S, Alexander BD et al. Maribavir for Refractory Cytomegalovirus Infections With or Without Resistance Post-Transplant: Results from a Phase 3 Randomized Clinical Trial. Clin Infect Dis Off Publ Infect Dis Soc Am.
3. Kotton CN, Kumar D, Caliendo AM et al. The Transplantation Society International CMV Consensus Group. The Third International Consensus Guidelines on the Management of Cytomegalovirus in Solid-organ Transplantation. Transplantation. 2018 Jun;102(6):900-931.
4. Lalezari, J. P., Aberg, J. A., Wang, L. H., Wire, M. B., Miner, R., Snowden, W., ... & Drew, W. L. (2002). Phase I dose escalation trial evaluating the pharmacokinetics, anti-human cytomegalovirus (HCMV) activity, and safety of 1263W94 in human immunodeficiency virus-infected men with asymptomatic HCMV shedding. Antimicrobial agents and chemotherapy, 46(9), 2969-2976.
5. Livtencity (maribavir) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc; April 2023.
6. Maertens J, Cordonnier C, Jaksch P et al. Maribavir for Preemptive Treatment of Cytomegalovirus Reactivation. N Engl J Med. 2019; 381:1136-47.

Clinical Guideline Revision / History Information

Original Date: 03/17/2022 Reviewed/Revised: 3/23/2023, 3/21/2024