Clinical Policy Title:	maribavir
Policy Number:	RxA.720
Drug(s) Applied:	Livtencity™
Original Policy Date:	01/17/2022
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Post-transplant cytomegalovirus (CMV) (must meet all)**:**

1. Diagnosis of post-transplant cytomegalovirus infection;
2. Weight ≥ 35 kg;
3. History of hematopoietic stem cell transplant or solid organ transplant;
4. Diagnosis of post-transplant CMV infection with one of the following (a or b):
   a. CMV DNA of ≥ 2730 IU/mL in whole blood;
5. CMV DNA ≥ 910 IU/mL in plasma;CMV disease refractory to previous treatment with intravenous (IV) ganciclovir, valganciclovir, foscarnet, or cidofovir;
6. Member does not have CMV disease involving the central nervous system (including the retina);
7. Patient is not taking other CMV antivirals.

Approval Duration

All Lines of Business (except Medicare): 8 weeks

II. Continued Therapy Approval

Livtencity™ has not been studied in clinical trials for longer than 8 weeks; therefore, the safety and efficacy of the drug as well as the impact of a longer course of therapy on relapse rate when used longer than 8 weeks is unknown. Reauthorization not approved.

References

1. Shire. 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; 2021. Available at: https://clinicaltrials.gov/ct2/show/NCT02931539. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/02/2021	01/17/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.7: Updated to include new diagnostic criteria	10/26/2022	01/17/2023

Member does not have CMV disease involving the central nervous system (including the retina). 2. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated approval duration verbiage. 5. References were reviewed and updated.	8/28/2024	9/13/2024