PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Livtencity (maribavir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Livtencity is a cytomegalovirus pUL97 kinsae inhibitor initially approved by the FDA in November 2021. It is the first medication for the treatment of refractory post-transplant CMV with or without genotypic resistance. Livtencity was evaluated in the SOLSTICE Phase 3 clinical trial, where 56% [95% CI 22·80–42·74]; p<0·001)] achieved CMV viremia clearance by the end of week 8. Livtencity is not FDA-approved in patients with human immunodeficiency virus (HIV) or other nontransplant populations, nor is it approved for prophylaxis of CMV infection.

Livtencity (maribar) will be considered for coverage when the following criteria are met:

Post-Transplant CMV Infection

For **initial** authorization:

1. Member is at least 12 years of age and weigh at least 35 kg; AND
2. Medication must be prescribed by or in consultation with an infectious disease specialist, hematologist, or transplant specialist; AND
3. Member has documentation of previous hematopoietic stem cell transplant (HSCT) or solid organ transplant (SOT); AND
4. Member has documentation of CMV infection, as evidenced by CMV DNA of ≥2730 IU/mL in whole blood or ≥910 IU/mL in plasma;
5. Member has a previous 14 day trial and inadequate response to at least one of the following: ganciclovir, valganciclovir, cidofovir or foscarnet; AND
6. Member will not be using with ganciclovir or valganciclovir.
7. **Dosage allowed/Quantity limit:** 400mg twice daily (112 tablets per 28 days).

If all the above requirements are met, the medication will be approved for 8 weeks.

For **reauthorization**:

1. Medication will not be reauthorized.

CareSource considers Livtencity (maribavir) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/07/2022	New policy for Livtencity created.

References:

1. Livtencity (maribavir) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc; 11/2021.
2. Del Pozo Martín Y. 47th Annual Meeting of the EBMT. Lancet Haematol. 2021 May;8(5):e317-e318.
3. Razonable RR, et al. Cytomegalovirus in solid organ transplant recipients—Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9):e13512
4. Robin K et al, Maribavir for Refractory Cytomegalovirus Infections With or Without Resistance Post-Transplant: Results from a Phase 3 Randomized Clinical Trial. *Clinical Infectious Diseases*, 2021;ciab988, https://doi.org/10.1093/cid/ciab988

Effective date: 07/01/2022
Revised date: 01/07/2022