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

Background

Livtencity™ is a cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
maribavir (Livtencity™)	Post-transplant cytomegalovirus (CMV)	Adults and Pediatric patients (12 years of age and older and weighing at least 35 kg): 400 mg (two 200 mg tablets) orally twice daily with or without food.	800 mg/day orally

Dosage Forms

- Tablets: 200 mg of maribavir.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of Post-transplant cytomegalovirus;
2. Age ≥ 12 years and weighs over 35 kg
3. History of hematopoietic stem cell transplant or (HSCT) or solid organ transplant (SOT);
4. Prescribed by or in consultation with an Infectious disease experts; transplant surgeon, oncologist;
5. Diagnosis of post-transplant CMV infection/disease with CMV DNA of ≥2730 IU/mL in whole blood or ≥910 IU/mL in plasma;
6. CMV disease refractory to previous treatment with intravenous (IV) ganciclovir, valganciclovir, foscarnet, or cidofovir;

7. Patient should not be on any other CMV antivirals;

Approval Duration
Commercial: 8 weeks
Medicaid: 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.

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CMV: cytomegalovirus
HSCT: hematopoietic stem cell transplant
SOT: solid organ transplant

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Monitor CMV DNA levels and check for resistance if patient does not respond to treatment. Some maribavir pUL97 resistance-associated substitutions confer cross-resistance to ganciclovir and valganciclovir.
- Refractory was defined in clinical trials as a documented failure to achieve greater than (>) 1 log10 decrease in CMV DNA level in whole blood or plasma after a 14 day or longer treatment period with ganciclovir, valganciclovir, foscarnet, or cidofovir.

References

1. Livtencity™. Prescribing Information. Lexington, MA. Takeda Pharmaceuticals America, Inc. November 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215596lbl.pdf. Accessed December 2, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: https://www.clinicalkey.com/pharmacology/monograph/5369?sec=monindi&n=LIVTENCITY. Accessed December 2, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/02/2021	01/17/2022