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| Clinical Policy Title: | maribavir |
| Policy Number: | RxA.720 |
| Drug(s) Applied: | Livtency™ |
| 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 \geq 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 \geq 2730 IU/mL in whole blood;
5. CMV DNA \geq 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

Livtency™ 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 |

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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| <p>Member does not have CMV disease involving the central nervous system (including the retina).</p> <p>2. References were reviewed and updated.</p> | | |
| <p>Policy was reviewed.</p> | <p>10/19/2023</p> | <p>10/19/2023</p> |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated approval duration verbiage. 5. References were reviewed and updated. | <p>8/28/2024</p> | <p>9/13/2024</p> |