

Pharmacy Medical Necessity Guidelines: Livtency (maribavir)

Effective: November 1, 2023

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan			Fax Numbers: RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Livtency (maribavir) 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.

COVERAGE GUIDELINES

The plan may authorize coverage of Livtency (maribavir) for Members when the following criteria are met:

Initial:

1. Documented diagnosis of post-transplant cytomegalovirus (CMV) infection/disease
- AND**
2. Viral load of CMV DNA is $\geq 2,730$ IU/mL in whole blood or ≥ 910 IU/mL in plasma
- AND**
3. The Member has had treatment failure, intolerance, or confirmed virological resistance to TWO or contraindication to ALL of the following drugs: ganciclovir, valganciclovir, cidofovir, foscarnet

Reauthorization:

1. Documented confirmation that there is no virological resistance to Livtency (maribavir)

LIMITATIONS

1. Coverage of Livtency (maribavir) is limited to maximum quantity of 4 tablets per day
2. Duration of initial approval for Livtency (maribavir) is limited to 8 weeks. Duration of reauthorization is limited to 8 weeks. Coverage of Livtency is limited to no more than a total of 16 weeks.
3. The plan does not provide coverage of Livtency for prevention of CMV infections

CODES

None

REFERENCES

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5. Food and Drug Administration (FDA). Maribavir sponsor briefing document. Antimicrobial drug advisory committee. October 7, 2021c. Accessed December 18, 2021. <https://www.fda.gov/media/152715/download>
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8. National Institute for Health and Care Excellence (NICE). Maribavir for treating refractory or resistant cytomegalovirus infection after transplant [ID3900]. October 22, 2021b. Accessed December 10, 2021. <https://www.nice.org.uk/guidance/indevelopment/gid-ta10792>
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APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. August 8, 2023: Effective November 1, 2023, updated approval lengths to 8 weeks for initial and 8 weeks for reauthorization. Specified in limitations section that members will not be approved for more than 16 weeks of treatment.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

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