Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Livtencity (maribavir)

Effective: November 1, 2023

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Livtencity (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.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Livtencity (maribavir) when all the following criteria are met:

1. Documented diagnosis of post-transplant cytomegalovirus (CMV) infection/disease

AND

2. Viral load of CMV DNA is ≥2,730 IU/mL in whole blood or ≥910 IU/mL in plasma

AND

3. Patient has had treatment failure, intolerance, or confirmed virological resistance to TWO or contraindication to ALL of the following drugs: ganciclovir, valganciclovir, cidofovir, foscarnet

AND

4. Livtencity is not being used for prevention of CMV infections

Renewal Authorization for Livtency (maribavir)

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

Limitations

1. Duration of initial approval for Livtencity (maribavir) is limited to 8 weeks. Duration of reauthorization is limited to 8 weeks. Coverage of Livtencity (maribavir) is limited to no more than a total of 16 weeks.
2. The plan does not provide coverage of Livtencity (maribavir) for prevention of CMV infection.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

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4. Food and Drug Administration (FDA). Frequently asked questions: breakthrough therapies. January 4, 2018. https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy
5. Food and Drug Administration (FDA). Maribavir sponsor briefing document. Antimicrobial drug advisory committee. October 7, 2021. Accessed December 18, 2021. https://www.fda.gov/media/152715/download
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7. Livtencity. Prescribing information. Takeda Pharmaceuticals U.S.A.; April 2023. Accessed June 28, 2023.
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10. Pande A, Dubberke E. cytomegalovirus infections of the stem cell transplant recipient and hematologic malignancy patient. *Infect Dis Clin North Am.* 2019;33(2):485-500. doi: 10.1016/j.idc.2019.02.008
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Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 8, 2023: Effective November 1, 2023, updated limitations to limit coverage of Livtencity to no more than a total of 16 weeks.

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.