BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
750 9th St NW
Washington, D.C. 20001
202.942.1000
Fax 202.942.1125

5.01.071

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Anti-Infective Agents	**Original Policy Date:**	December 17, 2021
Subject:	Livtencity	**Page:**	1 of 5

Last Review Date: June 13, 2024

Livtencity

Description

Livtencity (maribavir)

Background
Livtencity (maribavir) is an antiviral medication with activity against wild-type human cytomegalovirus (CMV) enzyme pUL97. Enzyme pUL97 is a protein kinase responsible for the phosphorylation of proteins. The activity of Livtencity is due to the parent drug (maribavir), which led to a reduction in CMV replication as quantified by virus yield, DNA hybridization, and plaque reduction assays (1).

Regulatory Status
FDA-approved indication: 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.

Livtencity may inhibit the antiviral activity of ganciclovir and valganciclovir due to its mechanism of action, and therefore Livtencity should not be coadministered with ganciclovir or valganciclovir. Virologic failure can occur during or after treatment with Livtencity and CMV DNA levels should be monitored to determine if patient is responding to treatment. Resistance to Livtencity could confer cross-resistance to ganciclovir and valganciclovir.

The safety and effectiveness of Livtencity in pediatric patients less than 12 years of age have not been established (1).

Related policies
Prevymis, Valcyte

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Livtencity may be considered **medically necessary** if the conditions indicated below are met.

Livtencity may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age and older

Diagnosis

Patient must have the following:

1. Cytomegalovirus (CMV) infection/disease
    a. Post-hematopoietic stem cell transplant (HSCT) **OR** post-solid organ transplant (SOT)

AND ONE of the following:
1. Refractory to treatment with **ONE** of the following:
    a. Ganciclovir
    b. Valganciclovir
    c. Cidofovir
    d. Foscarnet
2. Intolerant or contraindicated to treatment with **ONE** of the following:
    a. Ganciclovir (e.g., due to bone marrow suppression)
    b. Valganciclovir (e.g., due to bone marrow suppression)
    c. Cidofovir (e.g., due to having or being at high risk for nephrotoxicity)
    d. Foscarnet (e.g., due to having or being at high risk for nephrotoxicity)

AND ALL of the following:

1. Patient weighs at least 35 kg (77 lbs)
2. **NO** concurrent therapy with ganciclovir or valganciclovir
3. Prescriber agrees to monitor CMV DNA levels and check for resistance if patient does not respond to treatment

Prior–Approval *Renewal* Requirements

Age 12 years of age and older

Diagnosis

Patient must have the following:

1. Cytomegalovirus (CMV) infection/disease
    a. Post-hematopoietic stem cell transplant (HSCT) **OR** post-solid organ transplant (SOT)
    b. Patient has **NOT** developed resistance to Livtencity (maribavir)

AND ALL of the following:

1. Patient weighs at least 35 kg (77 lbs)
2. **NO** concurrent therapy with ganciclovir or valganciclovir
3. Prescriber agrees to monitor CMV DNA levels and check for resistance if patient does not respond to treatment

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity 672 tablets (quantity sufficient for 8 weeks)

Duration 12 weeks*

*Duration is set for 12 weeks to allow time to fill despite the quantity being for 8 weeks of therapy only

Prior–Approval *Renewal* Limits

Quantity 672 tablets (quantity sufficient for 8 weeks)

Duration 12 weeks* – **ONE** renewal **ONLY**

*Duration is set for 12 weeks to allow time to fill despite the quantity being for 8 weeks of therapy only

Rationale

Summary
Livtencity (maribavir) is an orally bioavailable antiviral medication indicated for the treatment of refractory CMV in patients that have received a solid organ transplant or hematopoietic stem cell transplant. Livtencity targets the pUL97 enzyme and its inhibition leads to reduction in viral load. The pUL97 enzyme is responsible for the antiviral activity of ganciclovir and valganciclovir, and therefore Livtencity should not be coadministered with ganciclovir and valganciclovir. Virologic failure can happen during and after treatment; CMV DNA levels and resistance should be monitored during treatment. The safety and effectiveness of Livtencity in pediatric patients less than 12 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Livtencity while maintaining optimal therapeutic outcomes.

References

1. Livtencity [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2024.

Policy History

Date	Action

December 2021	Addition to PA
March 2022	Annual review. Changed PA duration to 12 weeks from 8 weeks to allow time for patient to fill. Per SME: Added option to be intolerant or contraindicated to ganciclovir, valganciclovir, cidofovir, or foscarnet; Added quantity limit of 672 tablets for 8 weeks.
June 2023	Annual review and reference update. Changed policy number to 5.01.071
June 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.