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# 5.01.071

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2023
<b>Subsection:</b>	Anti-Infective Agents	<b>Original Policy Date:</b>	December 17, 2021
<b>Subject:</b>	Livtency	<b>Page:</b>	1 of 5

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**Last Review Date:** June 15, 2023

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## Livtency

### Description

#### Livtency (maribavir)

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#### Background

Livtency (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 Livtency 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: Livtency 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.

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

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

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## 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.*

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

Livtency 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)

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**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

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## 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 Livtency (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\*

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

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## 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

Livtency (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. Livtency 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 Livtency 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 Livtency 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 Livtency while maintaining optimal therapeutic outcomes.

#### References

1. Livtency [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; September 2022.

### Policy History

Date	Action
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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

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.**