

LIVTENCITY (maribavir)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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).



Federal Employee Program.

LIVTENCITY (maribavir)

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.