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PREVYMIS (letermovir)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Prevymis (letermovir) is a once-daily tablet for oral use and injection for intravenous infusion. Prevymis is an antiviral drug used for the prevention of cytomegalovirus (CMV) infection and disease. CMV is a common and potentially serious viral infection (1).

Regulatory Status

FDA-approved indications: Prevymis is a CMV DNA terminase complex inhibitor indicated for: (1)

- Prophylaxis of cytomegalovirus (CMV) infection and disease in adult and pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).
- Prophylaxis of CMV disease in adult and pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]).

Prevymis is contraindicated in patients receiving pimozide or ergot alkaloids. Prevymis is also contraindicated with pitavastatin and simvastatin when co-administered with cyclosporine (1).

Prevymis is not recommended for patients with severe (Child-Pugh Class C) hepatic impairment (1).

The safety and effectiveness of Prevymis for the prophylaxis of CMV infection and disease in CMV-seropositive recipients of an allogeneic HSCT less than 6 months of age and weighing less than 6 kg have not been established. The safety and effectiveness of Prevymis for the prophylaxis of CMV disease in a kidney transplant recipient less than 12 years of age and weighing less than 40 kg have not been established (1).

Summary

Prevymis (letermovir) is a once-daily tablet for oral use and injection for intravenous infusion. Prevymis is used for the prevention of cytomegalovirus (CMV) infection and disease. Prevymis is contraindicated in patients receiving pimozide or ergot alkaloids. Prevymis is also contraindicated with pitavastatin and simvastatin when co-administered with cyclosporine. Prevymis is not



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recommended for patients with severe (Child-Pugh Class C) hepatic impairment. The safety and effectiveness of Prevymis for the prophylaxis of CMV infection and disease in CMV-seropositive recipients of an allogeneic HSCT less than 6 months of age and weighing less than 6 kg have not been established. The safety and efficacy of Prevymis for the prophylaxis of CMV disease in a kidney transplant recipient less than 12 years of age and weighing less than 40 kg have not been established (1).

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

References

1. Prevymis [package insert]. Rahway, NJ: Merck Sharp & Dohme Corp.; August 2024.