BlueCross BlueShield
Federal Employee Program

SUNLENCA
(lenacapavir)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Sunlenca (lenacapavir) is a human immunodeficiency virus type 1 (HIV-1) antiretroviral agent. It is a multistage, selective inhibitor of HIV-1 capsid function that directly binds to the interface between capsid protein (p24) subunits in hexamers. Sunlenca inhibits HIV-1 replication by interfering with multiple essential steps of the viral lifecycle, including capsid-mediated nuclear uptake of HIV-1 proviral DNA, virus assembly and release, and capsid core formation (1).

Regulatory Status

FDA-approved indication: Sunlenca, a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations (1).

Immune reconstitution inflammatory syndrome has been reported in patients treated with combination antiretroviral therapy. During the initial phase of combination antiretroviral treatment, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment (1).

Concomitant administration of Sunlenca with strong CYP3A inducers is contraindicated due to decreased lenacapavir plasma concentrations, which may result in the loss of therapeutic effect and development of resistance to Sunlenca (1).

The safety and effectiveness of Sunlenca in pediatric patients less than 18 years of age have not been established (1).

Summary

Sunlenca is a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor that is approved in combination with other antiretroviral(s) for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection. Immune reconstitution inflammatory syndrome has been reported in patients treated with combination antiretroviral therapy. The use of Sunlenca with strong CYP3A inducers is contraindicated (1).

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

References

1. Sunlenca [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2022.