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Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Anti-Infective Agents	**Original Policy Date:**	July 14, 2023
Subject:	Sunlenca	**Page:**	1 of 4

Last Review Date: December 8, 2023

Sunlenca

Description

Sunlenca (lenacapavir)

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).

Related policies
Cabenuva, Trogarzo

Policy

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

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

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

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

HIV-1 infection

AND ALL of the following:

1. Viral load (VL) ≥ 400 copies/mL
2. Have multidrug resistant HIV-1 infection including documented resistance to at least **TWO** medications **EACH** from **THREE** of the following classes:
    a. Protease inhibitors (PI)
    b. Nucleoside reverse transcriptase inhibitors (NRTI)
    c. Non-nucleoside reverse transcriptase inhibitors (NNRTI)
    d. Integrase strand transfer inhibitors (INSTI)

3. Physician agrees to start an optimized background regimen (OBR) of anti-retroviral therapy (ART)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

HIV-1 infection

AND ALL of the following

1. Decrease in viral load from baseline
2. Patient continues to take an optimized background regimen (OBR) of anti-retroviral therapy (ART) throughout Sunlenca therapy

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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).

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.

Policy History

Date	Action
July 2023	Addition to PA
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.