



RX.PA.082.CCH SUNLENCA (LENACAPAVIR)

The purpose of this policy is to define the prior authorization process for Sunlenca (lenacapavir) for treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection and are failing their current antiretroviral regimen (due to resistance, intolerance, or safety considerations).

DEFINITIONS

AIDS = Acquired Immunodeficiency Syndrome

HIV = Human Immunodeficiency Virus

INSTIs = Integrase strand transfer inhibitors

NRTIs = Nucleoside and nucleotide reverse transcriptase inhibitors

NNRTIs = Non-nucleoside reverse transcriptase inhibitors

PIs = protease inhibitors

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Sunlenca (lenacapavir), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must be age 18 years or older
- Must be prescribed by, or in consultation with, a provider who specializes in the treatment of HIV/AIDS
- Must have a diagnosis of HIV-1 infection

- Must be prescribed at a dose within the manufacturer’s dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must be given in combination with other antiretroviral medications
- Must have documented treatment failure to the member’s current antiretroviral regimen (e.g., resistance, intolerance, safety considerations)
- Must have documented resistance to at least TWO antiretroviral medications from at least THREE of the following drug classes:
 - INSTIs (e.g., cabotegravir, dolutegravir, elvitegravir, raltegravir)
 - NRTIs (e.g., abacavir, emtricitabine, lamivudine, stavudine, tenofovir, zidovudine)
 - NNRTIs (e.g., doravirine, efavirenz, etravirine, nevirapirine, ripivirine)
 - PIs (e.g., atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, saquinavir, tipranavir)

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Indefinite
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J1961	Sunlenca	Injection, lenacapavir, 1 mg

References:

1. Sunlenca [package insert]. Foster City, CA; Gilead Sciences, Inc; December 2022
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv>.

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	01/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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