PRIOR AUTHORIZATION POLICY

POLICY: Human Immunodeficiency Virus – Sunlenca Prior Authorization Policy
- Sunlenca® (lenacapavir tablets and subcutaneous injection – Gilead)

REVIEW DATE: 01/03/2024; selected revision 07/17/2024

OVERVIEW

Sunlenca, a human immunodeficiency virus-1 (HIV-1) capsid inhibitor, is indicated in combination with other antiretroviral(s) for the treatment of **multidrug resistant HIV-1 infection** in heavily treatment-experienced adults failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.[1] Of note, Sunlenca is also available as tablets which are not addressed in this policy.

Clinical Efficacy

The efficacy of Sunlenca was evaluated in one Phase II/III, randomized, double-blind, placebo-controlled, multicenter, pivotal study in patients with multidrug resistant HIV-1.[2] Eligible patients had documented resistance to two or more agents from three of four main antiretroviral classes (nucleoside reverse transcriptase inhibitor [NRTI], non-nucleoside reverse transcriptase inhibitor [NNRTI], protease inhibitor, and integrase strand-transfer inhibitor [INSTI]) and two or fewer active antiretrovirals from the four main classes that could be effectively combined for optimized background therapy.

Guidelines

According to the Department of Health and Human Services Guidelines (February 27, 2024) for the use of antiviral agents in adults and adolescents with HIV infection, treatment-experienced patients with ongoing detectable viremia who lack sufficient treatment options to construct a fully suppressive regimen may be candidates for Trogarzo® (ibalizumab-uiyk intravenous infusion), Rukobia™ (fostemsavir extended-release tablets), or Sunlenca.[4] Patients who continue to have detectable viremia and who lack sufficient treatment options to construct a fully suppressive regimen may also be candidates for research studies or expanded access programs, or they may qualify for single-patient access to an investigational new drug as specified in FDA regulations. The goal of therapy is viral resuppression, if possible; otherwise, to keep the viral load as low as possible and CD4 T-cell count as high as possible. The CD4 T-cell count is used to assess a patient's immunologic response to treatment. CD4 T-cell count is recommended to be monitored at entry into care, when switching or modifying ARVs, and then every 3, 6, or 12 months depending on CD4 T-cell count and the duration of viral suppression. The CD4 T-cell count response to ARV therapy varies widely, but a poor CD4 T-cell response in a patient with viral suppression is rarely an indication for modifying a treatment regimen. For people with multidrug-resistant HIV-2, Trogarzo and Sunlenca may be considered based on *in vitro* data. Optimal treatment strategies for individuals with HIV-2 are not defined.

The International Antiviral Society-USA (December 2022) provides some guidance on patients with viral failure; Sunlenca is mentioned in patients with INSTI resistance as a product under FDA review.[5] Management of INSTI resistance can be difficult and guidance from an expert in HIV drug resistance is recommended for selection of the optimal regimen. If INSTI resistance is relatively limited, and a new regimen is to include an INSTI, dolutegravir should be administered twice daily. The regimen should also include at least one, and preferably two other fully active drugs, optimally from drug classes not previously used. Therapies may include Rukobia, Sunlenca, Selzentry® (maraviroc tablets, generic and oral solution), Trogarzo, or Fuzeon® (enfuvirtide SC injection).

POLICY STATEMENT

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Prior Authorization is recommended for prescription benefit coverage of Sunlenca. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Sunlenca as well as the monitoring required for adverse events and long-term efficacy, approval requires Sunlenca to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sunlenca is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Human Immunodeficiency Virus (HIV)-1 Infection, Treatment.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** According to the prescriber, the patient is failing a current antiretroviral regimen for HIV; AND
     - **iii.** According to the prescriber, the patient has resistance to two or more agents from at least THREE of the following antiviral classes (a, b, c, d):
       - **a)** Nucleoside reverse transcriptase inhibitor;
         Note: Examples of nucleoside reverse transcriptase inhibitors include abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil fumarate, tenofovir alafenamide, zidovudine.
       - **b)** Non-nucleoside reverse transcriptase inhibitor;
         Note: Examples of non-nucleoside reverse transcriptase inhibitors include delavirdine, efavirenz, etravirine, nevirapine, nevirapine XR, rilpivirine.
       - **c)** Protease inhibitor;
         Note: Examples of protease inhibitors include atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir.
       - **d)** Integrase strand transfer inhibitor; AND
         Note: Examples of integrase strand transfer inhibitors include raltegravir, dolutegravir, elvitegravir.
     - **iv.** The medication will be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND
     - **v.** The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.
   - **B)** Patient is Currently Receiving Sunlenca. Approve for 1 year if the patient meets BOTH of the following (i and ii):
     - **i.** The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND
     - **ii.** Patient has responded to a Sunlenca-containing regimen, as determined by the prescriber.
       Note: Examples of a response are HIV RNA < 50 cells/mm^3, HIV-1 RNA ≥ 0.5 $\log_{10}$ reduction from baseline in viral load, improvement or stabilization of CD4 T-cell count.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Sunlenca is not recommended in the following situations:

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1. **Pre-Exposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV).** Sunlenca is not approved for this indication; however, it is under investigation in two Phase III, unpublished, and ongoing clinical trials for PrEP (PURPOSE 1 and PURPOSE 2).[7,8]

2. **Human Immunodeficiency Virus (HIV), Treatment in Treatment-Naïve Patients.** Sunlenca is not approved for this indication; however, it is under investigation in one Phase II ongoing clinical trial in treatment-naïve adults with HIV-1 (CALIBRATE).[3]

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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4. 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. Last Updated: February 24, 2024. Available at: clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Accessed on: July 09, 2024.
5. Gandhi RT, Bedimo R, Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults 2022 recommendations of the International Antiviral Society–USA Panel. *JAMA.* 2023;329(1):63-84.
6. Smith RA, Raugi DN, Nixon RS, et al; on behalf of the University of Washington-Senegal HIV-2 Study Group. Antiviral activity of lenacapavir against HIV-2 isolates and drug resistant HIV-2 mutants. *J Infect Dis.* 2023 Dec 7. [Epub ahead of print].
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