MEDICAL MUTUAL®

Drug Policy

Policy:	Sunlenca (lenacapavir)	Annual Review Date:
SD		02/20/2024
		Last Revised Date:
		02/20/2024

OVERVIEW

Sunlenca, a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor, is indicated in combination with other antiretroviral(s) 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.

POLICY STATEMENT

This policy involves the use of Sunlenca. Prior authorization is recommended for pharmacy benefit coverage of Sunlenca. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Sunlenca be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Human Immunodeficiency Virus (HIV)-1 Infection, Treatment, Initial Therapy**
   Criteria. *Patient must meet the following criteria*
   - A. Patient is ≥ 18 years of age; AND
   - B. According to the prescriber, the patient is failing a current antiretroviral regimen for HIV; AND
   - C. According to the prescriber, the patient has resistance to two or more agents from at least THREE of the following antiviral classes:
     - 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 delaviridine, 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
[NOTE: examples of integrase strand inhibitors include raltegravir, dolutegravir, elvitegravir]

D. The medication will be taken in combination with an optimized antiviral background regimen, including one or more other antiretroviral agents; AND

E. The medication is prescribed by or in consultation with a physician who specializes in the treatment of HIV infection.

2. Human Immunodeficiency Virus (HIV)-1 Infection, Treatment, Continuation of Therapy
Criteria. *Patient must meet the following criteria*

A. The medication will continue to be taken in combination with an optimized antiviral background regimen including one or more other antiretroviral agents; AND

B. 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.]

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sunlenca has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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).

2. **Human Immunodeficiency Virus (HIV), Treatment in Treatment-Naïve Patients.** Sunlenca is under investigation; however it is under investigation in one Phase II, unpublished, and ongoing clinical trial in treatment-naïve adults with HIV-1 (CALIBRATE).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Sunlenca® tablets and subcutaneous injection [prescribing information]. Foster City, CA: Gilead; December 2022.
2. Segal-Maurer S, DeJesus E, Stelbrinka HJ; for the CAPELLA Study Investigators. Capsid inhibition with lenacapavir in multidrug-resistant HIV-1 infection. *N Engl J Med*. 2022; 1793-1803.
3. Gupta SK, Sims J, Brinson C, et al. Lenacapavir as part of a combination regimen in treatment-naïve people with HIV: Week 54 results [poster]. Presented at: CROI 2022; Virtual Event; February 12-16, 2022.
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: September 21, 2022. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Accessed December 26, 2022.
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*. [Epub ahead of Print Dec 1, 2022].
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].
7. Gilead Sciences. Pre-exposure prophylaxis study of lenacapavir and emtricitabine/tenofovir alafenamide in adolescent girls and young women at risk of HIV infection (PURPOSE 1). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2023 Dec 19]. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT04994509. NLM Identifier: NCT049945091.
8. Gilead Sciences. Study of lenacapavir for HIV pre-exposure prophylaxis in people who are at risk for HIV infection (PURPOSE 2). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2023 Dec 19]. Available at: https://www.clinicaltrials.gov/study/NCT04925752. NLM Identifier: NCT04925752.