PHARMACY COVERAGE GUIDELINE

SUNLENCA® (lenacapavir) oral and subcutaneous injection Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Sunlenca (lenacapavir) and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Specialist in Infectious Disease

  2. Individual is 18 years of age or older

  3. Individual has a confirmed diagnosis of multidrug resistant HIV-1 infection

  4. Individual is heavily treatment-experienced with multidrug resistant HIV-1 infection who is failing current antiretroviral regimen due to resistance, intolerance, or safety considerations

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5. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
    a. Viral load ≥ 400 copies/mL
    b. Documented resistance to at least **two** antiretroviral medications from each of at least 3 of the 4 classes of antiretroviral medications (NRTI, NNRTI, PI and INSTI)
    c. Less than **two** active antiretroviral medications from the 4 classes of antiretroviral medications remaining at baseline

6. If approved will be used in combination with an optimized background regimen (OBR) with other antiretroviral(s)

7. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

8. Individual is not currently taking any other drugs which cause severe adverse reactions or significant drug interactions, such as concurrent use with:
    a. Moderate CYP3A inducers (ex., bexarotene, bosentan, dabrafenib, dexamethasone, nafcillin, others)
    b. P-gp, UGT1A1, and strong CYP3A inhibitors (ex., erythromycin, ketoconazole, itraconazole, lapatinib, pazopanib, posaconazole, voriconazole, clarithromycin, others)
    c. Atazanavir/cobicistat, atazanavir/ritonavir, efavirenz, nevirapine, or tipranavir/ritonavir
    d. Oxcarbazepine, phenobarbital, rifabutin, rifapentine
    e. Dihydroergotamine, ergotamine or methylergonovine
    f. Tadalafil when it is used for the treatment of pulmonary arterial hypertension

9. Individual does **NOT** have the FDA-label contraindication of concomitant use of strong CYP3A inducers (ex., rifampin, carbamazepine, phenytoin, and St. John's wort)

10. Individual does not have ESRD (estimated creatinine clearance less than 15 mL per minute)

11. Individual does not have severe hepatic impairment (Child-Pugh Class C)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Sunlenca (lenacapavir) and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Specialist in Infectious Disease

2. Individual's condition has responded while on therapy with response defined as **TWO** of the following:
    a. Maintained and achieves a 70%reduction in viral load
    b. Improved CD4+ cell count over baseline
    c. There is no evidence of disease progression

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3. Individual has been adherent with the medication

4. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. If approved will be used in combination with an optimized background regimen (OBR) with other antiretroviral(s)

6. Individual is not currently taking any other drugs which cause severe adverse reactions or significant drug interactions, such as concurrent use with:
    a. Moderate CYP3A inducers (ex., bexarotene, bosentan, dabrafenib, dexamethasone, nafcillin, others)
    b. P-gp, UGT1A1, and strong CYP3A inhibitors (ex., erythromycin, ketoconazole, itraconazole, lapatinib, pazopanib, posaconazole, voriconazole, clarithromycin, others)
    c. Atazanavir/cobicistat, atazanavir/ritonavir, efavirenz, nevirapine, or tipranavir/ritonavir
    d. Oxcarbazepine, phenobarbital, rifabutin, rifapentine
    e. Dihydroergotamine, ergotamine or methylergonovine
    f. Tadalafil when it is used for the treatment of pulmonary arterial hypertension

7. Individual does **NOT** have the FDA-label contraindication of concomitant use of strong CYP3A inducers (ex., rifampin, carbamazepine, phenytoin, and St. John's wort)

8. Individual does not have ESRD (estimated creatinine clearance less than 15 mL per minute)

9. Individual does not have severe hepatic impairment (Child-Pugh Class C)

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

    1. **Off-Label Use of Non-Cancer Medications**

    2. **Off-Label Use of Cancer Medications**

Description:

Sunlenca (lenacapavir), 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.

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Lenacapavir inhibits HIV-1 replication by interfering with multiple essential steps of the viral lifecycle, including capsid-mediated nuclear uptake of HIV-1 proviral DNA (by blocking nuclear import proteins binding to capsid), virus assembly and release (by interfering with Gag/Gag-Pol functioning, reducing production of capsid protein subunits), and capsid core formation (by disrupting the rate of capsid subunit association, leading to malformed capsids).

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Sunlenca (lenacapavir) product information, revised by Gilead Sciences. 12-2022. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 08, 2023.

Darr ES. Evaluation of the treatment-experienced patient failing HIV therapy. In: UpToDate, Sax PE, Mitty J (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through January 2023. Topic last updated on August 19, 2021. Accessed February 09, 2023.

Darr ES. Selecting an antiretroviral regimen for treatment-experienced patients with HIV who are failing therapy. In: UpToDate, Sax PE, Mitty J (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through January 2023. Topic last updated on October 15, 2020. Accessed February 09, 2023.

ORIGINAL EFFECTIVE DATE: 02/16/2023 | ARCHIVE DATE: | LAST REVIEW DATE: | LAST CRITERIA REVISION DATE:

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