



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 02/02/2023

Sunlenca[®] (lenacapavir)

HCPCS: J1961

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved age
 - b. Will be used in combination with other anti-retroviral therapy for the treatment of human immunodeficiency virus type 1 (HIV-1)
 - c. Patient is heavily treatment-experienced with multidrug resistant HIV-1 infection based on the following:
 - i. Documented resistance to at least one antiretroviral medication from three different classes of drugs.
 - d. Patient is failing their current antiretroviral regimen.
 - e. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list and/or BCBSM/BCN's prior authorization and step therapy documents.
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: One year at a time
 - c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit.

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Sunlenca (lenacapavir) is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant (MDR) HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.
- Sunlenca is an antiretroviral therapy (ART) with a novel mechanism of action as a long-acting, potent inhibitor of the HIV capsid protein. By targeting the HIV capsid protein, Sunlenca interferes with multiple early-to-late-stage processes of the viral life cycle: capsid disassembly and nuclear transport, viral production, and capsid assembly.
- Sunlenca is the third FDA-approved therapy for treatment of MDR HIV-1, following intravenous (IV) Trogarzo™ and oral Rukobia®. Maintenance treatment with Sunlenca requires less frequent subcutaneous (SC) administration by a healthcare provider once every 6 months, compared to more frequent administration with IV Trogarzo every 2 weeks and oral Rukobia, which requires twice daily oral administration with food. Therefore, Sunlenca provides a therapeutic option for MDR HIV-1 for patients who experience barriers to ART adherence.
- The efficacy of Sunlenca was evaluated in the Phase II/III, double-blinded, placebo-controlled CAPELLA (NCT04150068) trial, which randomized 36 participants (Cohort 1) with MDR HIV-1 drug resistance and a detectable viral load to receive either oral Sunlenca lead-in or placebo in a 2:1 ratio for 14 days, in addition to their failing antiretroviral regimen. Starting on Day 15, participants in Cohort 1 in the Sunlenca group (N=24) received SC Sunlenca once every 6 months, and those in the placebo group (N=12) started to receive oral Sunlenca followed by subcutaneous maintenance dosing every 6 months thereafter. An additional 36 participants (Cohort 2) were enrolled in a separate open-label treatment group. All patients continued their current optimized ART regimen in addition to Sunlenca therapy throughout the trial.
 - Of note, participants were required to have documented resistance to at least two ART medications from at least 3 ART drug classes. Overall, participants had undergone previous treatment with a median of 9 ART medications at baseline.
 - Results demonstrated that 88% of patients receiving Sunlenca (N=21/24) achieved the primary endpoint of at least a 0.5 log₁₀ reduction in HIV-1 viral load (copies per milliliter) by Day 15 compared to 17% of those receiving placebo (N=2/12). At Week 26, a viral load of <50 copies per milliliter (i.e., undetectable viral load) was reported in 81% of patients in Cohort 1 and in 83% of patients in Cohort 2. There was also a significant average increase in the CD4+ count by 75 and 104 cells per cubic millimeter, respectively, for Cohort 1 and Cohort 2 by Week 26.
- The indication reflects the patient population that was included in the clinical trial that led to its approval. Therefore, use outside of this specific patient population is not recommended as the safety and efficacy has not been established.
- More than 25 approved antiretroviral drugs in 7 classes are available to design combination antiretroviral treatment (ART) regimens. The 7 classes include: nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), fusion inhibitors (FIs), chemokine receptor type 5 (CCR5) antagonists, integrase strand-transfer inhibitors (INSTIs), a CD4 directed monoclonal antibody indicated for patients with MDR HIV-1 (Trogarzo), a gp120 attachment inhibitor indicated for patients with MDR HIV-1 (Rukobia), and a long-acting capsid inhibitor indicated for patients with MDR HIV-1 (Sunlenca). Treatment always consists of drugs from multiple categories. Viral failure can occur for many reasons including development of drug resistance, suboptimal adherence and drug intolerance/toxicity prompting a new antiretroviral regimen to be designed.

- Guidelines from the U.S. Department of Health and Human Services (2022) and International Antiviral Society–USA Panel (2020) states:
 - Virologic failure is a viral load that is persistently greater than or equal to 200 copies/mL because this level of viremia often leads to drug resistance.
 - In patients with virologic failure, it is crucial to provide continuous adherence support before and after ART regimen changes.
 - A new regimen following virologic failure should include at least two and preferably three fully active agents. A fully active agent is one that is expected to have uncompromised activity based on the patient's ART history and current and past drug-resistant test results.
 - Designing a new regimen for patients who are experiencing treatment failure should always be guided by the patient's ART history and results from current and past resistance testing.
 - For people with MDR HIV, an ART regimen that includes IV Trogarzo or oral Rukobia can be effective in achieving viral suppression, though costly. The guidelines have not been updated to include recommendations for Sunlenca. Currently, there is no data available to suggest superior efficacy of one drug over another for treatment of MDR HIV infection.

References:

1. Lenacapavir [prescribing information]. Foster City, CA: Gilead Sciences, Inc; December 2022.
2. Gilead Sciences, Inc. [manufacturer press release]. Sunlenca receives FDA approval as a first-in-class, twice-yearly treatment option for people living with multi-drug resistant HIV. Available at: <https://www.gilead.com/news-and-press/press-room/press-releases/2022/12/sunlenca-lenacapavir-receives-fda-approval-as-a-firstinclass-twiceyearly-treatment-option-for-people-living-with-multidrug-resistant-hiv>. Accessed January 2023.
3. Segal-Maurer S, DeJesus E, Stellbrink HJ, et al. Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection. *N Engl J Med*. 2022;386(19):1793-1803. doi:10.1056/NEJMoa2115542
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. Available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv>. Updated September 2022. Accessed January 2023.
5. Saag MS, Hoy, JF, Gandhi RT, et al. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults: 2020 Recommendations of the International Antiviral Society-USA Panel. *JAMA*. 2020;324(16):1651-1669.

Policy History		
#	Date	Change Description
1.0	Effective Date: 02/02/2023	New policy

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation Date patient started therapy: _____
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) Reason for Hospital Outpatient administration: _____
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: _____
- Please specify location of administration if hospital inpatient infusion: _____
- Please provide the NPI number for the place of administration: _____
- Initiation AND Continuation of therapy:**
 - What is the patient's diagnosis? _____
 - What other medication has the patient received for their condition? Please list _____
 - Please describe the response to previous therapies: _____
 - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: _____
 - Please list any labs values important for diagnosing or monitoring this patient's condition: _____
- Continuation of therapy:**
 - Has the patient progressed while on this medication? ☐ yes ☐ no
 - How has the patient's condition changed while on this medication?

☐ Improved: Please describe: _____
 ☐ Stable: please describe: _____
 ☐ Worsened; Please describe: _____
 ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021