

lenacapavir (Sunlenca[®])

Policy # 00844

Original Effective Date: 08/14/2023

Current Effective Date: 08/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider lenacapavir (Sunlenca[®])[‡] for the treatment of human immunodeficiency virus type 1 (HIV-1) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for lenacapavir (Sunlenca) will be considered when the following criteria are met:

- Patient has a diagnosis of HIV-1 infection; AND
- Patient is 18 years of age or older; AND
- Patient has heavily treatment-experienced multidrug resistant HIV-1, which is defined as trying and failing at least 4 of the following 6 antiretroviral classes: Nucleoside Reverse Transcriptase Inhibitors (NRTIs); Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs); Integrase Strand Transfer Inhibitors (INSTIs); Protease Inhibitors (PIs); C-C motif chemokine receptor (CCR5) antagonists; and Entry Inhibitors; AND
- Patient is failing their current antiretroviral drug regimen due to resistance, intolerance, or safety considerations; AND
- Patient will continue taking an antiretroviral drug regimen along with the requested medication; AND
- Patient has a viral load greater than or equal to 400 copies/mL.
*(Note: This specific patient selection criterion is an additional Company requirement, based on clinical trials, for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of lenacapavir (Sunlenca) when the patient does not have a viral load greater than or equal to 400 copies/mL to be **not medically necessary.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use lenacapavir (Sunlenca) for any non-FDA approved indication to be **investigational**.*

Based on review of available data, the Company considers the use lenacapavir (Sunlenca) when the patient selection criteria are NOT met (with the exception of those denoted above as **not medically necessary****) to be **investigational**.*

Background/Overview

Sunlenca, is an HIV-1 capsid inhibitor that is indicated, in combination with other antiretrovirals, 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. It is available in a tablet and subcutaneous injection formulation. Sunlenca can be initiated by one of two regimens found in the package insert, both involving the use of the tablets and injection. Sunlenca's maintenance dosing regimen consists of two 1.5 ml subcutaneous injections every six months that must be administered by a healthcare provider.

Antiviral medications are the mainstay of therapy for HIV. Treatment for HIV often involves the use of multiple drugs (either multiple tablets or a combination drug). Many classes of antiviral medications exist, including:

- Nucleoside Reverse Transcriptase Inhibitors (NRTIs): abacavir, Videx®‡, Emtriva®‡, Epivir®‡, Zerit®‡, Viread®‡, zidovudine, abacavir-lamivudine, abacavir-lamivudine-zidovudine, Truvada®‡, emtricitabine-tenofovir disoproxil fumarate, Descovy®‡, lamivudine-zidovudine, Cimduo™‡, Temixys™‡
- Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs): Rescriptor®‡, Pifeltro™‡, efavirenz, Intelence®‡, nevirapine/XR, Edurant®‡, Delstrigo™‡, Complera®‡, Odefsey®‡, Atripla®‡, efavirenz-emtricitabine-tenofovir disoproxil fumarate, Symfi®‡, Symfi Lo®‡
- Integrase Strand Transfer Inhibitors (INSTIs): Isentress®‡, Tivicay®‡, Stribild®‡, Biktarvy®‡, Triumeq®‡, Genvoya®‡, Juluca®‡, Dovato®‡
- Protease Inhibitors (PIs): Reyataz®‡, Prezista®‡, Lexiva®‡, Crixivan®‡, Viracept®‡, Norvir®‡, ritonavir, Invirase®‡, Aptivus®‡, Kaletra®‡, Prezcobix®‡, Evotaz®‡, Symtuza™‡
- C-C motif chemokine receptor (CCR5) antagonists: Selzentry®‡
- Entry Inhibitors: Fuzeon®‡

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Heavily treatment experienced adults with HIV-1 infection account for a small amount of patients who have exhausted most, if not all, treatment options. These patients are at an increased risk of AIDS progression and death, and treatment for this specific patient population is often very individualized. Sunlenca provides an additional treatment option for these patients. Trugarzo and Rukobia are two other treatment options that are also approved in adults with multidrug resistant HIV-1 infection. These drugs have not been compared directly to each other.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Sunlenca, in combination with other antiretrovirals, 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. Sunlenca was approved in December of 2022.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy and safety of Sunlenca in HIV-1 infected, heavily treatment-experienced subjects with multidrug resistance is based on 52-week data from CAPELLA, a randomized, placebo-controlled, double-blind, multicenter trial.

Eligible patients were 12 years of age or older and had received stable, failing drug therapy (as indicated by HIV-1 RNA ≥ 400 copies/mL) for 8 or more weeks. Additionally, patients had documented resistance to two or more agents from three of four main antiretroviral (ARV) 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 ARVs from the four main classes that could be effectively combined.

The trial was composed of two cohorts. Subjects were enrolled into the randomized cohort (cohort 1, N=36) if they had a $< 0.5 \log_{10}$ HIV-1 RNA decline compared to the screening visit. Subjects were enrolled into the non-randomized cohort (cohort 2, N=36) if they had a $\geq 0.5 \log_{10}$ HIV-1 RNA decline compared to the screening visit or after cohort 1 reached its planned sample size.

In the 14-day functional monotherapy period, subjects in cohort 1 were randomized in a 2:1 ratio in a blinded fashion to receive either Sunlenca or placebo, while continuing their failing regimen. This period was to establish the virologic activity of Sunlenca. After the functional monotherapy period,

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subjects who had received Sunlenca continued on Sunlenca along with an optimized background regimen (OBR); subjects who had received placebo during this period initiated Sunlenca along with an OBR. Subjects in cohort 2 initiated Sunlenca and an OBR on Day 1.

The prespecified efficacy endpoints were evaluated in cohort 1. The primary efficacy endpoint was the percentage of patients who had a reduction from baseline of $\geq 0.5 \log_{10}$ copies/mL in plasma HIV-RNA by Day 15 (end of functional monotherapy). Secondary endpoints were the percentage of patients with viral load of < 50 copies/mL and the percentage of patients with a viral load of < 200 copies/mL at Week 26 after initiation of subcutaneous (SC) Sunlenca. The efficacy of Sunlenca in cohort 2 was not included in the prespecified endpoints. Cohort 2 was primarily designed to provide access to Sunlenca for patients who had met the same eligibility criteria as those in cohort 1 but were not eligible for randomization.

In cohort 1, the primary endpoint (decline in HIV-1 RNA $\geq 0.5 \log_{10}$ copies/mL at Day 15) was met by 88% of patients in the Sunlenca group (n = 21/24) and 17% of patients in the placebo group (n = 2/12) [95% confidence interval {CI}: 35%, 90%; P < 0.0001]. The least squares (LS) mean change in viral load was $-2.10 \log_{10}$ copies/mL in the Sunlenca group and $+0.07 \log_{10}$ copies/mL in the placebo group (LS mean difference -2.17 ; 95% CI: $-2.74, -1.59$). At Week 26, in patients treated with Sunlenca SC + OBR, 81% of patients (n = 29/36) had HIV-1 RNA < 50 copies/mL; 89% of patients (n = 32/36) had HIV-1 RNA < 200 copies/mL. Mean CD4+ cell count increased from baseline by $+75$ cells/mm³. At Week 52, in patients treated with Sunlenca SC + OBT, 83% of patients (n = 30/36) had HIV-1 RNA < 50 copies/mL and 86% of patients (n = 31/36) had HIV-1 RNA < 200 copies/mL. The mean change in CD4+ cell count was $+83$ cells/mm³.

Results for cohort 2 mirror those for cohort 1, though cohort 2 was non-randomized. At Week 26 and 52, 81% (29/36) and 72% (26/36) of patients achieved HIV-1 RNA < 50 copies/mL, respectively, and the mean change from baseline in CD4+ cell count was 97 cells/mm³ and 113 cells/mm³, respectively.

References

1. Sunlenca [package insert]. Gilead Sciences. Foster City, California. Updated December 2022.
2. Sunlenca Drug Evaluation. Express Scripts. Updated January 2023.

Policy History

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07/06/2023 Medical Policy Committee review

07/12/2023 Medical Policy Implementation Committee approval. New policy.

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07/02/2024 Medical Policy Committee review

07/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/03/2025 Medical Policy Committee review

07/09/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No code
HCPCS	J1961
ICD-10 Diagnosis	All Related Diagnoses

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.