

# Sunlenca (lenacapavir) Effective 09/01/2025

Plan	☐ MassHealth UPPL  ☐ Commercial/Exchange		<ul><li>☑ Prior Authorization</li><li>☐ Quantity Limit</li><li>☐ Step Therapy</li></ul>
Benefit	<ul><li>☑ Pharmacy Benefit</li><li>☑ Medical Benefit</li></ul>	Program Type	
Specialty	This medication has been designated specialty and must be filled at a contracted		
Limitations	specialty pharmacy.		
	Medical and Specialty Medications		
Contact	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	Sunlenca tablet is available through the pharmacy benefit Sunlenca subcutaneous injection is available through the medical benefit only		

## Overview

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 whose current antiretroviral regimen is failing due to resistance, intolerance, or safety considerations.

Sunlenca is available in two dosage forms: tablets and subcutaneous injection. Tablets are administered at treatment initiation. Sunlenca subcutaneous injection is administered by a healthcare provider once every six months (26 weeks). Tablets may be used for oral bridging for up to six months if scheduled injections are to be missed.

## **Coverage Guidelines**

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

#### OR

Authorization may be granted for treatment when all the following criteria are met:

- 1. Member has a diagnosis HIV-1 infection
- 2. Member is 18 years of age or older
- 3. Provider attestation that the member is treatment experienced with multidrug-resistant HIV and has received at least two prior systemic therapies from different classes (e.g., nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, protease inhibitors, integrase inhibitors)

# **Continuation of Therapy**

Requests for reauthorization will be granted when all of the following criteria are met:

1. Member has no evidence of unacceptable toxicity or disease progression while on the current regimen.

# Limitations

1. Initial approvals and reauthorizations will be granted for 12 months

## References

1. Sunlenca (lenacapavir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; November 2024.

# **Review History**

04/12/2023 – Reviewed and Created for April P&T; Effective 7/1/23 08/13/2025 – Reviewed and updated for August P&T. Administrative update – updated criteria for members who are new to the plan. Effective 09/01/2025.

