UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 1405-4
Program	Prior Authorization/Notification
Medication	*Sunlenca® (lenacapavir) *This program applies to the oral tablet formulation of Sunlenca.
P&T Approval Date	3/2023, 3/2024, 3/2025, 9/2025
Effective Date	12/1/2025

1. Background:

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.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Authorization

1. **Sunlenca** oral tablets will be approved based on **both** of the following criteria:

   a. Patient has been diagnosed with multidrug-resistant HIV-1 infection

   -AND-

   b. Patient is currently taking or will be prescribed an optimized background antiretroviral regimen

Authorization will be issued for 6 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Sunlenca [Package Insert]. Foster City, CA: Gilead Sciences, Inc.; November 2024.

Program	Prior Authorization/Notification - Sunlenca® (lenacapavir)
Change Control	
3/2023	New program.
3/2024	Annual review with no changes to clinical criteria. Updated reference.
3/2025	Annual review with no changes to clinical criteria. Updated reference.
9/2025	Updated authorization period to six months due to oral bridging for planned missed injections per label.