

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

| Program Number | 2024 1405-2 |
|-------------------|-------------------------------------|
| Program | Prior Authorization/Notification |
| Medication | Sunlenca [®] (lenacapavir) |
| P&T Approval Date | 3/2023, 3/2024 |
| Effective Date | 6/1/2024 |

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.¹

Members will be required to meet the coverage criteria below.

2. Coverage Criteria^a:

A. <u>Sunlenca</u>

- 1. Sunlenca will be approved based on <u>both</u> 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 1 month.

^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.; September 2023.

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| Change Control | | |
| 3/2023 | New program. | |
| 3/2024 | Annual review with no changes to clinical criteria. Updated reference. | |