

Arizona ADAP - Prior Authorization Policy Lenacapavir (Sunlenca) Tablets and Injection Solution

Indications:

Lenacapavir, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (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.

Prior Authorization Criteria

Adherence to an optimized background regimen is crucial for successful treatment. The DHHS guidelines recommend 2 fully active agents in a complete HIV-1 treatment regimen, as long as at least one has a high resistance barrier. Otherwise, 3 fully active agents are recommended.

- 1) Patients must have HIV-1 infection and be failing their current regimen despite provider confirmed adherence.
- 2) Laboratory confirmation/clinical evidence of multidrug/multiclass resistance, intolerance, or contraindication.
 - a. Patients will have resistance, intolerance, or documented failure of at least three ART classes (NRTI, NNRTI, PI, CCR5 antagonist, INSTI, gp120-directed attachment inhibitor, CD4-directed post-attachment HIV-1 inhibitor)
- 3) Proposed new ART regimen including 2-3 fully active medications.
- 4) Approval will be for:
 - a. Initiation
 - i. Oral lead-in (4 tablets) and one 927 mg SQ administration (total of two 1.5ml injections) with subsequent approvals based on demonstrated adherence and successful virologic suppression (provider determined).

b. Maintenance

- i. One year of therapy; two 927 mg SQ administrations (total of four 1.5ml injections)

- 5) Approvals for maintenance therapy will require demonstrated successful virologic suppression (provider determined).
- 6) Unless indicated differently by the program, Lenacapavir approval will be limited to 10 patients statewide that remain in an active status for ADAP.
- 7) Patient's who fall outside these guidelines, but whose provider feels lenacapavir is necessary for optimal patient care, may contact ADAP to discuss the clinical situation/patient need at **602.364.3610**.

Provider Request for Lenacapavir

___ Request for Initial Authorization:

- ___ Current CD4 and VL.
- ___ Current (failing) ART regimen.
- ___ Documentation of multiclass resistance and or intolerance (resistance assay(s) or provider narrative summary). (attach)
- ___ Proposed new ART regimen with brief rationale. (attach)
- ___ Provider certification of failure of current ART in adherent patient due to multiclass ART resistance and that they feel lenacapavir is necessary to construct an optimal ART regimen.

Provider Signature _____

___ Request for Maintenance Therapy Authorization:

- ___ Current CD4 and VL.
- ___ Current ART regimen.
- ___ Provider certification that, in their opinion, the current lenacapavir containing regimen is the best available regimen for patient.

Provider Signature _____

Please submit this form and supporting documents to the ADAP office by fax at 602.364.3263. Questions, please call 602.364.3610.