

SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-844-668-1550.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. If information provided is not complete, correct, or legible, authorization can be delayed.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Drug Requested: **Sunlenca® (lenacapavir) (J1961) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Maintenance Dose: 927 mg by subcutaneous injection (2 x 1.5 mL injections) every 6 months (26 weeks) from the date of the last injection +/- 2 weeks

Quantity Limit: 3 mL per 184 days

Provider please note: Upon approval of Sunlenca® maintenance subcutaneous injection, a subsequent authorization will be entered under the pharmacy benefit to allow a one-time fill of Sunlenca® tablets for induction dosing.

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- Member is \geq 12 years of age and weighing \geq 35 kg, or an adult aged \geq 18 years
- Prescribed by, or in consultation with, an infectious disease specialist or specialist in HIV treatment
- Member has been identified to have multidrug resistant HIV-1 infection with documented resistance to at least **TWO (2)** antiretroviral medications from **\geq 3 of the 4 main** antiretroviral drug classes below **(must submit genotype/phenotype resistance testing results):**
 - Nucleoside Reverse Transcriptase Inhibitors/Non-nucleoside Reverse Transcriptase Inhibitors
 - Protease Inhibitors
 - Entry Inhibitors (including CCR5 antagonists)
 - Integrase Inhibitor
- Member is experiencing current virologic failure defined as having a viral load greater than 400 copies/mL before treatment initiation
- Member's current viral load has been submitted with request
 - Current Viral Load: _____ copies/mL **(must submit most recent labwork indicating viral load prior to initiating therapy, within 4-8 weeks)**
- Provider confirms requested medication will be used in conjunction with an optimized background regimen for antiretroviral therapy
- Provider confirms requested medication will be initiated using **ONE** of the following dosing regimens:

<input type="checkbox"/> Initiation Option 1	
Day 1	927 mg by subcutaneous injection (2 x 1.5 mL injections) <u>AND</u> 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
<input type="checkbox"/> Initiation Option 2	
Day 1	600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Day 8	300 mg orally (1 x 300 mg tablet)
Day 15	927 mg by subcutaneous injection (2 x 1.5 mL injections)

Medication being provided by (check applicable box(es) below):

- Physician's office
- OR**
- Specialty Pharmacy – Proprium Rx

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****
****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****