

Human Immunodeficiency Virus (HIV) Step Therapy Sunlenca (Lenacapavir) J1961 is non-preferred. The preferred products are Medicare Part D HIV Therapies: Included, but not limited to: Tenofovir, Ritonovir, etc. (no PA required for most preferred Part D alts) **Prior Authorization Step Therapy** 

Medicare Part B Request Form

Instructions: \* Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

	Standard Request– (72 Hours)			□ <b>Urgent Request</b> (standard time frame could place the member's life, health or ability in serious jeopardy)					
	Date Req	uested							
			Clinic name: _					/ Fax	
MEMBER INFORMATION									
*Name:			*	*ID#: *DOB:					
PRESCRIBER INFORMATION									
*Name:				]MD □FNP □DO □NP □PA *Phone:					
*Address:				*Fax:					
DISPENSING PROVIDER / ADMINISTRATION INFORMATION									
*Na	me:			Phone:					
*Address:				Fax:					
PROCEDURE / PRODUCT INFORMATION									
нс	PC Code	Name of Drug		Dose	e (Wt:	kg Ht:	)	Frequency	End Date if known
□ Self-administered □ Provider-administered □ Home Infusion									
Chart notes attached. Other important information:									
Diagnosis: ICD10: Description:									
□ Provider attests the diagnosis provided is an FDA-Approved indication for this drug									
CLINICAL INFORMATION									
□ New Start or Initial Request: (Clinical documentation required for all requests)									

Being used to treat human immunodeficiency virus (HIV) infection.

Being used in combination with other antiretroviral agents: List Agents:

Patient is heavily antiretroviral treatment experienced with resistance, intolerability or contraindication to antiretrovirals in at least three different classes (NRTI, NNRTI, PI or INSTI);

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

Patient has a viral load greater than or equal to 400 copies/mL.

# □ Continuation Requests: (Clinical documentation required for all requests)

□ Patient had an <u>adequate response</u> or <u>significant improvement</u> while on this medication. If not, please provide clinical rationale for continuing this medication: \_\_\_\_\_

#### ACKNOWLEDGEMENT

Request By (Signature Required):

Date:

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.



# Prior Authorization Group – HIV Step Therapy

## Drug Name(s): SUNLENCA

# LENACAPAVIR

## Criteria for approval of Non-Formulary/Preferred Drug:

- 1. Prescribed for an approved FDA diagnosis (as listed below):
- Member has tried and failed at least ONE formulary Part D Human Immunodeficiency Virus treatment regimen (See <u>www.atriohp.com</u> for all formulary Part D treatment options for HIV) OR
  - There is clinical documentation stating preferred formulary alternatives are contraindicated.
- 3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions: N/A

Coverage Duration: Approval will be for 12 months

# FDA Indications:

#### Sunlenca

 HIV infection, Heavily treatment-experienced with multidrug resistant HIV-1 infection and failing current antiretroviral regimen

# **Off-Label Uses:**

N/A

# Step Therapy Drug(s) and FDA Indications:

#### **Assorted HIV Treatment Options:**

- HIV infection, in combination with other antiretroviral agents
- HIV infection, Preexposure, in at-risk patients and excluding patients at risk from receptive vaginal sex; Prophylaxi

Age Restrictions: N/A

# Other Clinical Consideration: N/A

#### Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch? navitem=headerLogout#

For questions or assistance, please contact Customer Service at 1-877-672-8620, daily, 8am – 8pm (PST) (TTY users should call 1-800-735-2900).