JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS165
		Effective Date	04/19/2023
		Approval Date	04/19/2023
	Subject **Sunlenca (oral formulation)**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Sunlenca

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I. POLICY

Sunlenca oral tablets (lenacapavir) will require prior authorization to ensure it is used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Sunlenca may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing all the following:
      a. Patient has a diagnosis of HIV-1 infection
      b. Significant antiretroviral treatment experience with documented historical or baseline resistance, intolerability, and/or contraindications to at least two antiretroviral medications from each of at least 3 of the following 4 classes of antiretroviral medications:
         I. Nucleoside reverse transcriptase inhibitor (NRTI)
         II. Non-nucleoside reverse transcriptase inhibitor (NNRTI)
         III. Protease inhibitor (PI)]
         IV. Integrase strand transfer inhibitor (INSTI)
         V. *Below are examples of patient resistance experiences meeting the above criteria:
            i. 2 NRTIs, 2 NNRTIs, & 2 PIs
            ii. 2 NRTIs, 2 NNRTIs, & 2 INSTIs
            iii. 2 NRTIs, 2 PIs, & 2 INSTIs
            iv. 2 NNRTIs, 2 PIs, & 2 INSTIs
      c. Inadequate response to current antiretroviral regimens evidenced by HIV RNA viral load greater than or equal to 400 copies/mL

d. Patient has at least one responsive antiretroviral (but no more than two antiretrovirals) that can be used concurrently with Senlenca to create an effective treatment regimen

3. Prescriber is, or has consulted with, an infectious disease specialist, or a certified HIV provider

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Sunlenca oral tablets will be limited to a one-time approval of one of the following:
   1. a 4-tablet pack (as part of a 2-day initiation regimen)
   2. a 5-tablet pack (as part of a 15-day initiation regimen)

B. Limitations:
   1. Sunlenca oral tablets will not be approved as part of a maintenance regimen for HIV treatment
   2. Sunlenca subcutaneous injection is used for maintenance treatment, and eligible for Plan coverage under the medical benefit. (This formulation of Sunlenca is subject to any applicable medical benefit restrictions/limitations).
   3. This policy does not include coverage guidance for the Sunlenca subcutaneous product.

IV. EXCLUSIONS

A. Sunlenca will not be approved for the following:
   1. Pediatric patients
   2. Patients using strong cytochrome P450 3A inducers (carbamazepine, phenytoin, rifampin, enzalutamide, mitotane, St. John's wort, etc.)
   3. Patients with a history of hypersensitivity reactions to lenacapavir or any other component of Sunlenca
   4. Patients that are breast-feeding
   5. Any indications or usage that is not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. REFERENCES

1. Sunlenca [prescribing information]. Foster City, CA: Gilead Sciences Inc; December 2022.
2. Segal-Maurer S, DeJesus E, Stellbrink HJ, et al. CAPELLA Study Investigators. Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection. N Engl J Med. 2022 May 12;386(19):1793-1803. doi: 10.1056/NEJMoa2115542.

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
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