JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS177
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	Subject **Cabenuva**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Cabenuva

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I. POLICY

A. Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended release injectable suspension) 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 JHHP Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Cabenuva** may be approved for patients who meet the following:
   1. Patient is 12 years of age and older and weighs at least 35 kg
   2. Documentation has been submitted showing the following:
      1. Diagnosis of human immunodeficiency virus type 1 (HIV-1) infection
      2. Patient is currently receiving a stable antiretroviral regimen
      3. Patient is virologically suppressed on the current antiretroviral therapy with laboratory results showing a HIV-1 RNA level less than 50 copies per mL
      4. Patient does not have a history of treatment failure
      5. Patient does not have known or suspected resistance to either cabotegravir or rilpivirine

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be granted for 12 months of therapy.

B. Approval for continuation of therapy can be extended in 12-month intervals with clinical documentation and laboratory findings showing the patient has not experienced a virologic failure* while on Cabenuva therapy (*Virologic failure is defined as two consecutive plasma HIV-1 RNA levels greater than or equal to 200 copies per mL)

IV. EXCLUSIONS

A. Cabenuva will not be approved for the following:
   1. Any indications or uses that are 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

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

VI. REFERENCES

1. Cabenuva [prescribing information]. Research Triangle Park, NC: ViiV Healthcare; December 2023.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. Accessed May 2024.

VII. APPROVALS

Signature on file at JHHP

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy Creation

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