JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP066
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Cabenuva**	*Revision Date*	08/30/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: cabenuva

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I. POLICY

A. Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Cabenuva may be approved for patients who meet the following:
   1. Documentation has been submitted showing the following
      a. Patient has a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection
      b. Patient is currently receiving a stable antiretroviral regimen
      c. Patient is virologically suppressed on the current antiretroviral regimen with HIV-1 RNA less than 50 copies per mL, supported by laboratory testing
      d. Patient does not have a history of treatment failure
      e. Patient has no known or suspected resistance to either cabotegravir or rilpivirine

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient has not experienced a virologic failure while on the requested drug, 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 covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

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

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, cabotegravir, and rilpivirine, 2mg/3mg	J0741

VII. REFERENCES

1. Cabenuva [prescribing information]. Research Triangle Park, NC: ViiV Healthcare; April 2022.
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:// https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/guidelines-adult-adolescent-arv.pdf. Accessed March 21, 2022.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2022	Policy Creation
08/30/2022	Updated clinical criteria based on new FDA-approved prescribing information changes

Review Date: 04/20/2022

Revision Date: 08/30/2022