Effective Date: 04/2024
Last Approval/Version: 04/2024
Next Review Date: 04/2025
Policy Number: C21979-A

Cabenuva - IL Medicaid Only

PRODUCTS AFFECTED

Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
HIV-1

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label along with state and federal requirements, benefits being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review.

A. HIV-1
    1. Documentation that member has a diagnosis of HIV-1 infection.
       AND
    2. Member is virologically-suppressed on current antiretroviral regimen with HIV-1 RNA less than 50 copies per mL for at least 3 months.
       AND
    3. Prescriber attestation that member has no known or suspected resistance to or treatment failure with either cabotegravir or rilpivirine.

AND

4. Prescriber attestation that Cabenuva will replace the current antiretroviral regimen, and will not be used in combination with other antiretroviral medications for the treatment of HIV.

AND

5. Prescriber attests that member has agreed to required monthly injection dosing schedule and has been counseled on the importance of adherence to scheduled dosing visits.

CONTINUATION OF THERAPY:

A. HIV-1:

1. Documentation that member has maintained viral suppression with HIV-1 RNA less than 50 copies per mL while on Cabenuva.

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
18 years of age and older

QUANTITY: See Illinois Medicaid Drug Formulary or use maximum quantity per FDA label

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the intramuscular injectable products be administered in a place of service that is a non-hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intramuscular

DRUG CLASS:
Antiretroviral

FDA-APPROVED USES:
Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension): indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension) include: previous hypersensitivity reaction to cabotegravir or rilpivirine; Coadministration with drugs where significant decreases in cabotegravir and/or rilpivirine plasma concentrations may occur, which may result in loss of virologic response.

OTHER SPECIAL CONSIDERATIONS:
Prior to initiating treatment with CABENUVA, oral lead-in dosing can be used for approximately 1 month, but is not required to assess the tolerability of cabotegravir and rilpivirine. Vocabria (cabotegravir) oral tablet is provided through ViiVConnect for oral lead-in.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg

AVAILABLE DOSAGE FORMS:

Cabenuva SUER 400 & 600MG/2ML
Cabenuva SUER 600 & 900MG/3ML

REFERENCES

1. Illinois Medicaid Preferred Drug List, Effective January 1, 2024.
2. Cabenuva (cabotegravir extended-release injectable suspension; rilpivirine extended-release injectable suspension) [prescribing information], Research Triangle Park, NC: ViiV Healthcare, April 2022
3. "Optimizing Antiretroviral Therapy in the Setting of Viral Suppression", page I-27, 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/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- Notable revisions: References	04/2024
Annual Review Completed – no updates needed	04/2023
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q4/2022