

Title: Cabenuva (Cabotegravir-Rilpivirine)	Division: Medical Management Department: Pharmacy, Utilization Management
Approval Date: 2/28/2022	LOB: Medicaid, HIV SNP, CHP, MetroPlus Gold, Goldcare I&II, Market Plus, Essential, HARP
Effective Date: 2/28/2022	Policy Number: UM-MP330
Review Date: 2/28/22, 10/3/2022	Cross Reference Number:
Retired Date:	Page 1 of 4

1. POLICY DESCRIPTION:

Human Immunodeficiency Virus (HIV) Type-1 Infection – Antiretrovirals, Integrase Strand Inhibitor and Non-Nucleoside Reverse Transcriptase Inhibitor, Cabenuva

2. RESPONSIBLE PARTIES:

Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. DEFINITIONS:

Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in virologically suppressed patients. Cabotegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral DNA integration which is essential for the HIV replication cycle. Rilpivirine is a diarylpyrimidine non-nucleoside reverse transcriptase inhibitor that non-competitively inhibits HIV-1 reverse transcriptase, thereby inhibiting the replication of HIV.

4. POLICY:

- A. Human Immunodeficiency Virus (HIV) Infection
Cabenuva will be considered medically necessary when the following conditions of coverage have been met:

Initial Approval

- 1. Patient is 12 years or older & weighs at least 35 kg **AND**
- 2. Member is currently receiving a stable antiretroviral regimen for \geq 6 months **AND**
- 3. Member is virologically suppressed on the current antiretroviral regimen with HIV-1 RNA less than 50 copies per mL **AND**
- 4. Member has no history of treatment failure to other antiretrovirals **AND**
- 5. Member has no known or suspected resistance to either cabotegravir or rilpivirine **AND**
- 6. Documentation of an agreement by the patient to adhere to a monthly or every 2-month dosing schedule dosing schedule.

Approved for 12 months

Renewal Request:

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1. 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
AND
2. Member has no known or suspected resistance to either cabotegravir or rilpivirine

Approved for 12 months

5. LIMITATIONS/ EXCLUSIONS:

1. Concomitant administration with any uridine diphosphate (UDP)-glucuronosyl transferase (UGT)1A1 and/or cytochrome P450 (CYP)3A enzyme inducing medications while on Cabenuva therapy:
 - a. Anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
 - b. Antimycobacterials: Rifabutin, rifampin, rifapentine
 - c. St. John's Wort
2. Concomitant administration with more than 1 dose of dexamethasone

6. APPLICABLE PROCEDURE CODES:

CPT	Description
J0741	Injection, cabotegravir and rilpivirine, 2 mg/3 mg

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
B20	Human immunodeficiency virus [HIV] disease
O98.711	Human immunodeficiency virus [HIV] disease complicating pregnancy, first trimester
O98.712	Human immunodeficiency virus [HIV] disease complicating pregnancy, second trimester
O98.713	Human immunodeficiency virus [HIV] disease complicating pregnancy, third trimester
O98.719	Human immunodeficiency virus [HIV] disease complicating pregnancy, unspecified trimester

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O98.72	Human immunodeficiency virus [HIV] disease complicating childbirth
O98.73	Human immunodeficiency virus [HIV] disease complicating puerperium

8. REFERENCES:

1. Cabenuva [package insert]. Research Triangle Park, NC: ViiV Healthcare; January 2021.
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/sites/default/files/inline-files/AdultandAdolescentGL.pdf>. Accessed February 15, 2021.
3. Orkin C et al. Long-acting cabotegravir and Rilpivirine after oral ... Long-Acting Cabotegravir and Rilpivirine after Oral Induction for HIV-1 Infection. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa1909512?articleTools=true>. Published March 4, 2020. Accessed December 10, 2021.
4. Efficacy, safety and tolerability study of long-acting cabotegravir plus long-acting rilpivirine (cab LA + RPV La) in human-immunodeficiency virus-1 (HIV-1) infected adults - full text view. Full Text View - ClinicalTrials.gov. <https://clinicaltrials.gov/ct2/show/NCT03299049>. Published June 2020. Accessed December 10, 2021.

REVISION LOG:

REVISIONS	DATE
Creation date	2/28/2022
Removed oral-lead in requirement, updated age/weight requirement	8/25/2022
Update	10/3/2022

Approved:	Date:	Approved:	Date:
Glendon Henry, MD Senior Medical Director		Sanjiv Shah, MD Chief Medical Officer	

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Medical Guideline Disclaimer:

Property of Metro Plus Health Plan. All rights reserved. The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member’s benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.