MetroPlus Health

Policy and Procedure

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: 9/26/2023	**Cross Reference Number:**
Retired Date:	**Page 1 of 5**

I. POLICY DESCRIPTION:

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

II. RESPONSIBLE PARTIES:

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

III. 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.

IV. POLICY:

Cabenuva will be considered medically necessary when the following conditions of coverage have been met:

INITIAL REQUEST:

1. **Human Immunodeficiency Virus (HIV) Infection**
   - **A.** Member is 12 years or older & weighs at least 35 kg;

     AND
   - **B.** Member is currently receiving a stable antiretroviral regimen for $\geq$ 6 months;

     AND
   - **C.** Member is virologically suppressed on the current antiretroviral regimen with HIV-1 RNA less than 50 copies per mL;

     AND
   - **D.** Member has no history of treatment failure to other antiretrovirals;

     AND
   - **E.** Member has no known or suspected resistance to either cabotegravir or rilpivirine;

     AND
   - **F.** Documentation of an agreement by the patient to adhere to a monthly or every 2-month dosing schedule dosing schedule;

AND

G. Authorization is for no more than 12 months

Renewal Request:

1. Human Immunodeficiency Virus (HIV) Infection

A. Member 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

B. Member has no known or suspected resistance to either cabotegravir or rilpivirine;

AND

C. Authorization is for no more than 12 months

V. LIMITATIONS/ EXCLUSIONS:

1. Concominant 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. Concominant administration with more than 1 dose of dexamethasone
3. Concominant administration with macrolides (azithromycin, clarithromycin, erythromycin) are expected to increase concentrations of rilpivirine and are associated with a risk of Torsade de Pointes

VI. APPLICABLE PROCEDURE CODES:

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

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

VIII. REFERENCES:

1. Cabenuva [package insert]. Research Triangle Park, NC: ViiV Healthcare; February 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://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.
5. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV Developed by the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents -A Working Group of the Office of AIDS Research Advisory Council (OARAC) How to Cite the Adult and Adolescent Guidelines: Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/archive/AdultandAdolescentGL_2021_08_16.pdf. Accessed September 13, 2023.

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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
Annual review	9/26/2023

Approved: Glendon Henry Digitally signed by Glendon Henry Date: 2023.09.27 08:55:37 -04'00' **Date:**	**Approved:** Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2023.09.27 13:50:02 -04'00' **Date:**
Glendon Henry, MD **Senior Medical Director**	**Sanjiv Shah, MD** **Chief Medical Officer**

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Medical Guideline Disclaimer:

 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 andor 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.