MetroPlus Health

Policy and Procedure

Title: Apretude (Cabotegravir)	**Division: Medical Management** **Department: Utilization Management**
Approval Date: 1/31/2023	**LOB: Medicaid, HIV SNP, HARP, CHP, Medicare, UltraCare, MetroPlus Gold, Goldcare I&II, Essential Plan, QHP**
Effective Date: 1/31/2023	**Policy Number: UM-MP344**
Review Date: 1/31/2023	**Cross Reference Number:**
Retired Date:	**Page 1 of 4**

1. **POLICY DESCRIPTION:**
   Infectious Disease – Anti-Infective, Anti-Retroviral Agent, Apretude (Cabotegravir)

2. **RESPONSIBLE PARTIES:**
   Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. **DEFINITIONS:**
   Apretude (cabotegravir extended-release injectable suspension) is an HIV integrase inhibitor. Apretude inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration that is essential for the HIV replication cycle.

   Apretude is indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection.

4. **POLICY:**
   Apretude will be considered medically necessary once the following coverage criteria is met:

   INITIAL REQUEST:
   A. Apretude is being prescribed for pre-exposure prophylaxis (PrEP) **AND**
   B. Member is 12 years of age or older who weights at least 35 kg **AND**
   C. Member has a documented negative HIV test result, ideally an HIV RNA test (qualitative or quantitative), within 2 weeks prior to initiating Apretude **AND**
   D. Member does not have any signs/symptoms of acute HIV infection **AND**
   E. Member meets **ONE** of the following criteria**:**
      a. Pre-existing renal disease with a creatinine clearance (CrCl) < 60 mL/min
      b. Documented clinical diagnosis of osteoporosis defined as:
         i. Presence of a fragility fracture, particularly at the spine, hip, wrist, humerus, rib, and pelvis or a T-score ≤-2.5 standard deviations (SDs) at any site based upon bone mineral density (BMD) measurement by dual-energy x-ray absorptiometry (DXA)]
      c. History of intolerance or contraindication to generic Truvada in the last 12 months
      d. History of non-compliance to previous oral PrEP regimens **AND**
   F. Member has a substantial risk of acquiring HIV infection defined as having anal or vaginal sex in past 6 months **AND** any of the following:

i. HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)
ii. Bacterial STI in past 6 months
iii. History of inconsistent or no condom use with sexual partner(s) **AND**

G. Prescriber has processes in place to ensure member will be adherent to Apretude, specifically for in-office visit administration **AND**
H. The prescriber is knowledgeable in the prescribing and administration practices of Apretude

Initial Duration of Approval: *6 months*

RENEWAL REQUEST:
Pre-exposure prophylaxis of HIV-1 Infection.
A. Initial conditions of coverage have been met **AND**
B. Member has been responding positively to therapy **AND**
C. Member has shown appropriate amount of adherence based on prescribers judgement

Renewal Duration of Approval: *12 months*

5. LIMITATIONS/ EXCLUSIONS:

A. Apretude will only be covered as a PrEP regimen to prevent HIV-1 infection and will not be covered for other indications not listed in this policy.

6. APPLICABLE PROCEDURE CODES:

CPT	Description
J0739	Injection, cabotegravir, 1 mg

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description
Z72.51	High risk heterosexual behavior
Z72.52	High risk homosexual behavior
Z72.53	High risk bisexual behavior

8. REFERENCES:

1. Apretude [package insert]. Research Triangle Park, NC: ViiV Healthcare. December 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 April 7th, 2021.
3. Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.

REVISION LOG:

REVISIONS	DATE
Creation date	1/2023
Effective	1/31/2023

Approved: Glendon Henry Digitally signed by Glendon Henry Date: 2023.02.02 11:11:51 -05'00' **Date:**	**Approved:** Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2023.02.03 12:06:05 -05'00' **Date:**
Glendon Henry, MD **Senior Medical Director**	**Sanjiv Shah, MD** **Chief Medical Officer**

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 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.