Policy Title:	Apretude (cabotegravir) (intramuscular)		
		Department:	PHA
Effective Date:	11/01/2022		
Review Date:	08/04/2022, 4/27/2023, 12/14/2023, 01/04/2024		

Purpose: To support safe, effective, and appropriate use of Apretude (cabotegravir).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Apretude (cabotegravir) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Coverage of Apretude (cabotegravir) will be reviewed prospectively via the prior authorization process based on criteria below.

Summary of Evidence:

Apretude (cabotegravir)is an HIV-1 integrase strand transfer inhibitor indicated in at-risk adults and adolescents weighing 35kg or more to reduce the risk of sexually acquired HIV-1 infection. Two randomized, double-blind, clinical trials with a total of 7,782 patients evaluated the incidence of HIV-1 infection with Apretude or Truvada (emtricitabine/tenofovir). Fewer patients acquired HIV with Apretude than Truvada (12 vs. 29, $p = 0.0003$ and 3 vs. 36, $p<0.0001$, respectively), indicating Apretude had a 69% and 90% reduction in the risk of HIV-1 incident infection relative to Truvada. The most common side effects seen include headache, injection site reactions, and increased creatine phosphokinase. Use of Apretude is contraindicated with concomitant use of uridine diphosphate-glucuronosyl transferase 1A1 enzyme inducers such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampin, and rifapentine. Depressive disorders have been seen in some patients during treatment, and hepatotoxicity was also seen in some patients and as a result liver function tests should be monitored during treatment.

Criteria:

- Patient must have an adequate trial, intolerance or contraindication to treatment with emtricitabine/tenofovir disoproxil fumarate (Truvada).

Coverage durations:

- Initial coverage: 12 months

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Apretude was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Apretude according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 1 mg)
PrEP	• 600mg IM, followed by second administration of 600mg IM at 1 month, then 600mg every 2 months	Initial: 600 billable units on day 1, then 600 billable units 1 month later Maintenance: 600 billable units every 2 months

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J0739	Injection, cabotegravir, 1mg, FDA approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment for HIV)

References

1. Apretude [package insert]. Research Triangle Park, NC; ViiV; February 2023. Accessed November 2023.
2. Landovitz RJ, Donnell D, Clement ME, et al. Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women. N Engl J Med. 2021; 385(7): 595- 608. DOI: 10.1056/NEJMoa2101016.
3. CDC HIV Statistics Overview. Available at: https://www.cdc.gov/hiv/statistics/overview/index.html. Accessed January 12, 2022.
4. The state of the HIV epidemic in the U.S. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/state-of-the-hiv-epidemic-factsheet.html#recent-progress. Accessed January 12, 2022
5. Preexposure prophylaxis for the prevention of HIV infection in the United States – 2021 Update Clinical Practice Guideline. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Accessed January 12, 2022.