Apretude (cabotegravir extended-release injectable suspension) Quantity Limit

Override(s)	Approval Duration
Quantity Limit	1 year

Medications	Quantity Limit
Apretude (cabotegravir extended-release injectable suspension) 600 mg/3 mL vial	1 vial per 2 months

APPROVAL CRITERIA FOR QUANTITY OVERRIDE:

Initiation of therapy: May approve one additional vial in the first two months of initiating therapy OR re-initiating therapy after missed doses.

NOTE:
Apretude has a black box warning for risk of drug resistance when used in individuals with undiagnosed HIV infection. Individuals must be tested for HIV infection prior to initiating Apretude and with each subsequent injection of Apretude. Drug-resistant HIV variants have been identified with use of Apretude in individuals with undiagnosed HIV infection. Individuals who become infected with HIV while receiving Apretude for PrEP must transition to a complete HIV treatment regimen.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: December 27, 2021.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.