PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**APRETUDE**
(generic)	**(cabotegravir extended-release injectable suspension)**
Status:	

FDA-APPROVED INDICATION

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. Individuals must have a negative HIV-1 test prior to initiating Apretude (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

CRITERIA FOR APPROVAL

Is the requested drug prescribed for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired human immunodeficiency virus-1 (HIV-1) infection? [If no, then no further questions.]
----AND----
Does the patient weigh at least 35 kilograms (kg)? [If no, then no further questions.]
----AND----
Prior to initiating therapy, does the patient have a negative human immunodeficiency virus-1 (HIV-1) test?
----AND----
Trial and failure, contraindication or intolerance to BOTH of the following: • emtricitabine-tenofovir (generic Truvada) • Descovy[i] **-----OR-----** Submission of medical records (e.g., chart notes) from provider documenting BOTH of the following: • Patient would benefit from long-acting injectable therapy over standard oral regimens • Patient would be adherent to testing and dosing schedule

Approval duration: 12 months

[i] Descovy is indicated for at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex.