

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.

Key References:

1. 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. December 2021. Available at: <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed: September 4, 2025.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 4, 2025.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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