

MEDICAL REVIEW GUIDELINE

Cabotegravir Diagnosis Specific Policy



Apretude® (cabotegravir)

Effective Date: 5/1/2024

Medical Care Management Committee Approval: 2/15/2024

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Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following Apretude® (cabotegravir) product:

| HCPCS Code | Description | Maximum Dosage per Administration |
|------------|------------------------------|-----------------------------------|
| J0739 | Injection, cabotegravir 1 mg | 600 mg IM |

Diagnosis-Specific Criteria

Apretude® (cabotegravir) will be considered medically necessary for members meeting ALL of the following criteria:

1. Member weight is $\geq 35\text{kg}$; AND
2. Used for HIV-1 pre-exposure prophylaxis (PrEP); AND
3. Provider attests that member has a negative HIV-1 test result ≤ 1 week prior to the dose of Apretude; AND
4. Provider confirms that the member will be tested for HIV-1 infection with each subsequent injection; AND
5. Provider attests that member demonstrates treatment readiness by both of the following:
 - a. Member understands the risks of missed doses of Apretude.
 - b. Member has the ability to adhere to the required every 2 months injection and testing appointments; AND
6. Dosing is in accordance with the United States Food and Drug Administration approved labeling; AND
7. Initial authorization is for no more than 12 months

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

| HCPSC Code | Description |
|------------|------------------------------|
| J0739 | Injection, cabotegravir 1 mg |

| Diagnosis Code | Description |
|----------------|------------------------------|
| Z29.81 | HIV pre-exposure prophylaxis |

Policy Revision History

| Status | Effective Date | Description |
|----------|----------------|--|
| Baseline | 5/1/24 | Initial version of Apretude (cabotegravir) Diagnosis Specific Policy |
| Update | 12/8/26 | Formally removed oral therapy step requirement |