Clinical Oversight Review Board (CORB) Criteria for Prescribing

Cabotegravir (Apretude)

Notes:

- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Non-Formulary **cabotegravir (Apretude)** requires a clinical review. Appropriateness of therapy will be determined based on the following criteria:

Initiation (new start) criteria: Non-formulary **cabotegravir (Apretude)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescribed by immune deficiency clinic (IDC) provider
- Prescribed for HIV pre-exposure prophylaxis (PrEP)
- Patient has a recent negative HIV antibody test and undetectable HIV-1 RNA viral load (VL)
- Any one of the following clinical conditions:
    1. Patient has allergy or intolerance* to emtricitabine/tenofovir disoproxil fumarate (TDF-FTC) and tenofovir-alafenamide / emtricitabine (TAF-FTC):
        - Kidney impairment defined by creatinine clearance (CrCl) less than 30 ml/min
        - Persistently increased serum creatinine from baseline while using TDF-FTC or TAF-FTC, defined as 2 or more lab results with an increase of 0.4 mg/dL
    2. Members experiencing structural or individual level barriers to oral PrEP use based on the prescribing clinicians judgment
    3. Patient has needed more than 2 NPEP (non-occupational post-exposure) courses over 12 months due to poor adherence to oral PrEP
    4. Members who have had gastric bypass procedures
    5. Patient is a new member to Kaiser Permanente, is already stable on the drug, and has had an adequate trial of TDF-FTC and TAF-FTC in the past.