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:

- Prescribed by immune deficiency clinic (IDC) provider
  -AND-
- Prescribed for HIV pre-exposure prophylaxis (PrEP)
  -AND-
- Patient has a recent negative HIV antibody test and undetectable HIV-1 RNA viral load (VL)

-AND one of the following-

- Patient has allergy or intolerance* to emtricitabine/tenofovir disoproxil fumarate (TDF-FTC) and tenofovir-alafenamide / emtricitabine (TAF-FTC)
  -OR-
- Patient has a significant contraindication to both tenofovir alafenamide and tenofovir disoproxil fumarate defined as one of the following:
  - 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
  - Sustained proteinuria; sustained glucosuria not attributable to another cause

  -OR-
- Members experiencing structural or individual level barriers to oral PrEP use based on the prescribing clinician's judgment
  -OR-
- Patient has chronic hepatitis B infection without indication for hepatitis B treatment
  -OR-
- Patient has needed more than 2 NPEP (non-occupational post-exposure) courses over 12 months due to poor adherence to oral PrEP
  -OR-
- Patient has suboptimal adherence to daily oral PrEP with ongoing risk for HIV exposure (2 or more missed doses of oral PrEP/week)
  -OR-

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- Members who have evidence of malabsorption from GI condition (e.g., sleeve gastrectomy, gastric bypass, terminal ileitis, celiac disease, severe chronic diarrhea)
  -OR-
- Patient is a new member to Kaiser Permanente, is already stable on the drug