Generic Name: N/A

Applicable Drugs: Apretude® (cabotegravir extended-release injectable suspension), Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate), Biktarvy® bictegravir/ emtricitabine/tenofovir alafenamide), Cabenuva™ (cabotegravir extended-release injectable suspension/ rilpivirine extended-release injectable suspension), Cimduo® (lamuvidine/tenofovir disoproxil fumarate), Descovy® (emtricitabine/tenofovir alafenamide), Emtriva® (emtricitabine), Juluca® (dolutegravir/rilpivirine), Stribilid® (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate), Sunlenca® (lenacapavir), Symfi®, Symfi Lo® (efavirenz/lamivudine/ tenofovir disoproxil fumarate), Symtuza® (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), Truvada® (emtricitabine/ tenofovir disoproxil, Vocabria™ (cabotegravir)

Preferred: abacavir, abacavir sulfate-lamivudine, Aptivus® (tipranavir), atazanavir sulfate, Crixivan® (indinavir), efavirenz, efavirenz-emtricitabine-tenofovir disoproxil fumarate, efavirenz-lamivudine-tenofovir disoproxil fumarate, emtricitabine, emtricitabine-tenofovir disoproxil fumarate, etravirine, Evotaz® (atazanivir/cobicistat), Invirase® (saquinavir mesylate), lamivudine, lopinavir-ritonavir, nevirapine, Norvir® solution, ritonavir, tenofovir disoproxil fumarate, Viracept® (nelfinavir mesylate), zidovudine

Non-preferred: Apretude® (cabotegravir extended-release injectable suspension), Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate), Biktarvy® bictegravir/ emtricitabine/tenofovir alafenamide), Cabenuva™ (cabotegravir extended-release injectable suspension/rilpivirine extended-release injectable suspension), Cimduo® (lamuvidine/tenofovir disoproxil fumarate), Descovy® (emtricitabine/tenofovir alafenamide), Emtriva® (emtricitabine), Juluca® (dolutegravir/rilpivirine), Stribilid® (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate), Sunlenca® (lenacapavir), Symfi®, Symfi Lo® (efavirenz/lamivudine/ tenofovir disoproxil fumarate), Symtuza® (darunavir/cobicistat/ emtricitabine/tenofovir alafenamide), Truvada® (emtricitabine/ tenofovir disoproxil, Vocabria™ (cabotegravir).

Date of Origin: 10/27/2022

Date Last Reviewed / Revised: 12/5/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of A, B, or C **AND** provision of documentation of **ALL** criteria listed under applicable diagnosis:

   A. HIV and documentation of **ALL** the following laboratory test results (i or ii):

i. Treatment naïve rapid start

1. Positive HIV-1/2 antigen/antibody (Ag/Ab) test.

ii. Treatment naïve non-rapid start or treatment experienced:

1. Positive HIV-1/2 antigen/antibody (Ag/Ab) test.
2. CD4 T lymphocyte (CD4) cell count.
3. Plasma HIV-RNA level.
4. Genotypic resistance testing.

B. Pre-exposure prophylaxis (PrEP) to reduce the risk of HIV acquisition and documentation satisfying criteria i through iv:

i. The patient is at high risk for HIV infection, defined as 1 or 2 below:

1. Sexually active adults or adolescents with **ANY** of the following:
   a. HIV-positive sexual partner(s) (especially when viral load is unknown or detectable).
   b. Partner(s) of unknown HIV status with no or inconsistent condom use.
   c. Bacterial sexually transmitted infection within the past 6 months.
2. Persons who inject drugs with **ANY** of the following:
   a. HIV-positive injection partner.
   b. Shares needles, syringes, or other equipment to inject drugs.

ii. Negative HIV-1/2 Ag/Ab test within a week prior to initiation.

iii. Absence of clinical symptoms consistent with acute viral infection.

iv. Counseling on safe sex practices and HIV risk reduction.

C. HIV non-occupational postexposure prophylaxis (nPEP) to reduce the risk of HIV acquisition.

i. Documentation of a known or suspected exposure to HIV in past ≤ 72 hours.

II. Documentation of baseline Hepatitis B and C testing.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines. This medication policy does not include all non-preferred HIV antiretroviral (ARV) medications. Refer to Table 1 for select medication-specific criteria. Other non-preferred agents will be reviewed case-by-case based on FDA labeling and clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the request is for a brand medication for which a generic is available, there must be a documented treatment failure or contraindication to the generic medication.

EXCLUSION CRITERIA

- Coadministration with drugs or conditions not recommended per the FDA package labeling or current clinical practice guidelines.
- Coadministration of Biktarvy®, Cabenuva™, Juluca®, Stribilid®, Symfi®, Symfi Lo®, and Symtuza® with other ARVs.

OTHER CRITERIA

Table 1. Indications, drug-specific criteria, exclusions, and quantity limits for select HIV antiretrovirals.

Drug	Indication(s), Drug-specific criteria, Exclusion(s)	Quantity limits

Apretude® (CAB-ER INJ)	• Indication:
	  ○ Reduction of the risk of acquired HIV (with or without an oral lead-in with Vocabria™) in at-risk adults and adolescents weighing ≥ 35 kg for PrEP.
	• Criteria:
	  ○ Documented clinically significant treatment failure, adverse event, or contraindication with generic emtricitabine-tenofovir disoproxil.
		Two 600 mg/3 mL vials for the first 60 days, then one 600 mg/3 mL vial every 60 days.

Atripla® (EFV/FTC/TDF)	• Indication:
	  ○ Treatment of HIV in adults or pediatrics weighing at least 40 kg.
	• Exclusions:
	  ○ History of hypersensitivity reaction (e.g., Stevens-Johnson syndrome, erythema multiforme, or toxic skin eruptions) to efavirenz.
	  ○ Moderate or severe renal impairment: eCrCl < 50 mL/min.
	  ○ Moderate or severe hepatic impairment: Child-Pugh B or C.
		30 tablets per 30 days.

Biktarvy® (BIC/FTC/TAF)	• Indications:
	  ○ Treatment of HIV in adults or pediatrics weighing ≥ 14 kg who are:
	  ▪ ARV naïve **OR**
	  ▪ To replace a stable ARV regimen **AND** all the following:
	  ○ Virologically suppressed (HIV RNA < 50 copies/mL) for at least 3 months.
	  ○ No history of treatment failure.
		30 tablets per 30 days.

	○ Resistance testing within past 3 months demonstrating virologic susceptibility to BIC, FTC, and TAF. • Exclusions: ○ Renal impairment: eCrCl 15 to < 30 mL/min, < 15 mL/min not on chronic HD, or < 15 mL/min on chronic HD if ARV naïve. ○ Severe hepatic impairment: Child-Pugh Class C.	
Cabenuva™ (CAB-ER INJ/ RPV-ER INJ)	• Indication: ○ Treatment of HIV (with or without oral lead-in with Edurant® and Vocabria™) to replace a stable ARV regimen in adults or adolescents ≥ 12 years old weighing ≥ 35 kg AND all the following: ▪ Virologically suppressed (HIV RNA < 50 copies/mL) for at least 6 months. ▪ No history of treatment failure. ▪ Resistance testing within past 3 months demonstrating virologic susceptibility to CAB and RPV.	Monthly schedule: One 600 mg CAB/900 RPV vial for the first 30 days, then one 400 mg CAB/600 mg RPV every 30 days. Two-month schedule: Two 600 mg CAB/900 RPV vial for the first 60 days, then one 600 mg CAB/900 RPV vial every 60 days.
Cimduo® (3TC/TDF)	• Indication: ○ Treatment of HIV in combination with other ARVs in adults or pediatrics weighing ≥ 35 kg. • Criteria: ○ Documented clinically significant treatment failure, adverse event, or contraindication with generic emtricitabine-tenofovir disoproxil. • Exclusion: ○ Renal impairment: eCrCl < 50 mL/min or ESRD on HD.	30 tablets per 30 days.
Descovy® (FTC/TAF)	• Indications: ○ Treatment of HIV and **ONE** of the following: ▪ in combination with other ARVs in adult or pediatrics weighing ≥ 35 kg. ▪ in combination with other ARVs (other than PIs) that require a CYP3A inhibitor in pediatric patients weighing ≥14 kg and ≤ 35 kg. ○ Reduction of the risk of acquired HIV in at-risk adults and adolescents weighing ≥ 35 kg for PrEP. • Criteria:	30 tablets per 30 days.

	○ Documented clinically significant treatment failure, adverse event, or contraindication with generic emtricitabine-tenofovir disoproxil. • Exclusions: ○ Renal impairment: eCrCl 15 to < 30 mL/min, or < 15 mL/min not on chronic HD. ○ PrEP due to risk for HIV acquisition from receptive vaginal sex.	
Emtriva® (FTC)	• Indication: ○ Treatment of HIV in combination with other ARVs in adult or pediatrics (≥ 0 months old). ○ Reduction of the risk of acquired HIV for nPEP in pediatrics 4 weeks to 12 years old as a component of a guideline recommended 3 ARV regimen within 72 hours of the exposure.	30 capsules per 30 days. Four 170 mL bottles oral solution per 30 days.
Edurant® (RPV)	• Indication: ○ Treatment of HIV in combination with other ARVs in treatment-naïve adults or pediatrics ≥ 12 years old weighing ≥ 35 kg with an HIV-RNA ≤ 100,000 copies/mL. ○ Short-term treatment of HIV in combination with Vocabria™ as an oral lead-in to assess the tolerability of Cabenuva™ or those who will miss a planned Cabenuva™ INJ in adults with **ALL** the following: ▪ Virologically suppressed (HIV RNA < 50 copies/mL) on a stable regimen. ▪ No history of treatment failure. ▪ Resistance testing (obtained within past 3 months) demonstrating virologic susceptibility to CAB and RPV.	30 tablets per 30 days.
Juluca® (DTG/RPV)	• Indication: ○ Treatment of HIV adults or adolescents ≥ 18 years old weighing ≥ 35 kg to replace a stable ARV regimen **AND** all the following: ▪ Virologically suppressed (HIV RNA < 50 copies/mL) for ≥ 6 months. ▪ No history of treatment failure. ▪ Resistance testing (obtained within past 3 months) demonstrating virologic susceptibility to DTG and RPV.	30 tablets per 30 days.
Stribilid® (EVG/COBI/FTC /TDF)	• Indication: ○ Treatment of HIV in adults or adolescents ≥ 12 years old weighing ≥ 35 kg who are:	30 tablets per 30 days.

	▪ ARV naïve **OR** ▪ To replace a stable ARV regimen **AND** all the following: • Virologically suppressed (HIV RNA < 50 copies/mL) for ≥ 6 months. • No history of treatment failure. • Resistance testing (obtained within past 3 months) demonstrating virologic susceptibility to ALL the individual components of Stribilid®. • Exclusions: o Renal impairment: ▪ Initiation with CrCl < 70 mL/min. ▪ Maintenance with CrCl < 50 ml/min. o Severe hepatic impairment: Child-Pugh Class C.	
Sunlenca® (LEN)	• Indication: o Treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 failing their current antiretroviral regimen with **ALL** of the following: ▪ Documented HIV-1 RNA level of ≥400 copies per mL despite adherence to current regimen. ▪ Documented resistance to at least two antiretroviral medications from each of ≥3 of the 4 main classes of antiretroviral medications (NRTI, NNRTI, PI, INSTI). ▪ Documentation Sunlenca will be used in combination with an optimized background regimen of other ARV(s). • Exclusions: o Concomitant administration with strong CYP3A inducers.	Initiation: 927 mg by injection (2 x 1.5mL injections) plus four 300mg tablets in 2 days, OR 927 mg injection plus five 300mg tablets in 8 days. Maintenance: 927 mg by injection (2 x 1.5mL injections) per 6 months.
Symfi® (EFV/3TC/TDF)	• Indication: o Treatment of HIV in adults or pediatrics weighing at least 40 kg. • Exclusions: o Renal impairment: CrCl < 50 mL/min or ESRD requiring HD). o Moderate or severe hepatic impairment: Child-Pugh Class B or C.	30 tablets per 30 days.
Symfi Lo® (EFV/3TC/TDF)	• Indication: o Treatment of HIV in adult or pediatrics weighing at least 35 kg. • Exclusions: o Renal impairment: CrCl < 50 mL/min or ESRD requiring HD).	30 tablets per 30 days.

	○ Moderate or severe hepatic impairment: Child-Pugh Class B or C.	
Symtuza® (DRV/COBI/FTC/TAF)	• Indications: ○ Treatment of HIV in adult or pediatrics weighing ≥ 40 kg who are: ▪ ARV naïve **OR** ▪ To replace a stable ARV regimen **AND** all the following: • Virologically suppressed (HIV RNA < 50 copies/mL) for ≥ 6 months. • Resistance testing (obtained within past 3 months) demonstrating virologic susceptibility to DRV, FTC, and TAF. • Exclusions: ○ Severe renal impairment: CrCl < 30 mL/min. ○ Severe hepatic impairment: Child-Pugh Class C.	30 tablets per 30 days.
Truvada® (FTC/TDF)	• Indications: ○ Treatment of HIV in combination with other ARVs in adult or pediatrics weighing ≥ 17 kg. ○ Reduction of the risk of acquired HIV in at-risk adults and adolescents weighing ≥ 35 kg for PrEP. ○ Reduction of the risk of acquired HIV for nPEP in adults or pediatrics ≥ 13 years old as a component of a guideline recommended 3 ARV regimen within 72 hours of the exposure. • Exclusions: ○ Renal impairment ▪ HIV treatment: CrCl < 30 mL/min or HD ▪ PrEP and nPEP: CrCl < 60 mL/min	HIV treatment and PrEP: 30 tablets per 30 days, nPEP: 28 tablets per 28 days.
Vocabria™ (CAB)	• Indication: ○ Short-term treatment of HIV in combination with Edurant® as an oral lead-in to assess the tolerability of Cabenuva™ or those who will miss a planned Cabenuva™ INJ in adults with **ALL** the following: ▪ Virologically suppressed (HIV RNA < 50 copies/mL) on a stable regimen. ▪ No history of treatment failure. ▪ Resistance testing (obtained within past 3 months) demonstrating virologic susceptibility to CAB or RPV. • As an oral lead to assess the tolerability of Apretude® to reduce the risk of sexually acquired HIV in at-risk adults and adolescents weighing ≥ 35 kg for PrEP.	30 tablets per 30 days.

Abbreviations: 3-TC, lamivudine; ARV, antiretroviral; BIC, bictegravir; CAB, cabotegravir; COBI, cobicistat; DRV, darunavir; DTG, dolutegravir; eCrCl, estimated creatinine clearance; EFV, efavirenz; EVG, elvitegravir; ESRD, end-stage renal disease; FTC, emtricitabine; HD, hemodialysis; HIV, human immunodeficiency virus; LEN, lenacapavir; nPEP, non-occupational postexposure prophylaxis; PIs, protease inhibitors; PrEP, pre-exposure prophylaxis; RAL, raltegravir; rilpivirine; RTV, ritonavir; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

Quantity / Days Supply Restrictions

- See table 1.

Approval Length

- **Authorization:**
  - Treatment of HIV: 1 year
  - Short-term Edurant® or Vocabria™ treatment (e.g., oral lead in for Apretude® or Cabenuva®, planned missed Cabenuva® injection): 1 month
  - PrEP: 6 months
  - nPEP: 28 days
- **Re-Authorization:**
  - Treatment of HIV infection: An updated progress notes and laboratory testing (e.g., CD4 cell count, plasma HIV-RNA level) showing current medical necessity criteria are met and the medication is effective.
  - PrEP: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the patient has a documented negative HIV-1/2 Ag/Ab test and HIV RNA assay at recommended intervals below.
    - Descovy® or Truvada®: every 3 months.
    - Apretude™: 1 month after first injection and every 2 months beginning with the third injection.
  - nPEP: N/A.

Appendix

N/A

References

1. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Updated March 23, 2023. Accessed December 5, 2023. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf
2. 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. Accessed December 5, 2023. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
3. Dominguez KL, Smith DK, Vasavi T, et al. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016. April 18, 2016. Updated May 23, 2018. Accessed December 5, 2023. https://stacks.cdc.gov/view/cdc/38856
4. Apretude. Prescribing information.ViiV Healthcare; 2023. Accessed December 5, 2023. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Apretude/pdf/APRETUDE-PI-PIL-IFU.PDF
5. Atripla. Prescribing information. Gilead Sciences, LLC; 2019. Accessed December 5, 2023. https://www.gilead.com/-/media/files/pdfs/medicines/hiv/atripla/atripla_pi.pdf
6. Biktarvy. Prescribing information. Gilead Sciences, Inc; 2022. Accessed December 5, 2023. https://www.gilead.com/~/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.pdf
7. Cabenuva. Prescribing information. ViiV Healthcare; 2023. Accessed December 5, 2023. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Cabenuva/pdf/CABENUVA-PI-PIL-IFU2-IFU3.PDF
8. Cimduo. Prescribing information. Mylan Specialty, LP; 2021. Accessed December 5, 2023. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a300f04d-118f-4136-aaf3-ddfd00197f86&type=display
9. Descovy. Prescribing information. Gilead Sciences, Inc; 2022. Accessed December 5, 2023. https://www.gilead.com/~/media/files/pdfs/medicines/hiv/descovy/descovy_pi.pdf?la=en
10. Emtriva. Prescribing information. Gilead Sciences, Inc; 2018. Accessed December 5, 2023. https://www.gilead.com/-/media/files/pdfs/medicines/hiv/emtriva/emtriva_pi.pdf
11. Edurant. Prescribing information. Janssen Products, LP; 2022. Accessed December 5, 2023. https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/EDURANT-pi.pdf
12. Juluca. Prescribing information. ViiV Healthcare; 2021. Accessed December 5, 2023. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Juluca/pdf/JULUCA-PI-PIL.PDF#page=1
13. Stribild. Prescribing information. Gilead Sciences, Inc; 2021. Accessed December 5, 2023. https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/stribild/stribild_pi.pdf

14. Sunlenca. Prescribing information. Gilead Sciences, Inc; 2022. Accessed December 5, 2023. https://www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi.pdf
15. Symfi. Prescribing information. Mylan Specialty, LP; 2019. Accessed December 5, 2023. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=81a55dd9-78a8-49c3-88ab-8f5bffafa359&type=display
16. Symfi Lo. Prescribing information. Mylan Specialty, LP; 2019. Accessed September 11, 2022. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=86aad85d-5460-4c38-9761-a225e6bce190&type=display#section-7.4
17. Symtuza. Prescribing information. Janssen Therapeutics; 2023. Accessed December 5, 2023. https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SYMTUZA-pi.pdf
18. Truvada. Prescribing information. Gilead Sciences, Inc; 2023. Accessed December 5, 2023. https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_pi.pdf
19. Vocabria. Prescribing information. ViiV Healthcare; 2021. Accessed December 5, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212887s000lbl.pdf