

Applicable Drugs: Apretude* (cabotegravir), Biktarvy (bictegravir-emtricitabine-tenofovir af), Cabenuva (cabotegravir-rilpivirine), Complera (emtricitabine-rilpivirine-tenofovir df), Delstrigo (doravirine-lamivudine-tenofovir df), Descovy (emtricitabine-tenofovir af), Dovato (dolutegravir sodium-lamivudine), emtricitabine-tenofovir df, fosamprenavir, Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir af), Idvynso (doravirine-islatravir), Isentress (raltegravir), Juluca (dolutegravir sodium-rilpivirine), Kaletra (lopinavir-ritonavir), maraviroc, Odefsey (emtricitabine-rilpivirine-tenofovir af), Pifeltro (doravirine), Prezcoibx (darunavir-cobicistat), Prezista (darunavir),

Reyataz (atazanavir), Rukobia (fostemsavir), Selzentry (maraviroc), Stribild (elvitegravir-cobicistat-emtricitabine-tenofovir df), Sunlenca* (lenacapavir), Symtuza (darunavir-cobicistat-emtricitabine-tenofovir af), Tivicay (dolutegravir), Triumeq (abacavir-dolutegravir-lamivudine), Trogarzo* (ibalizumab-uiyk), Truvada (emtricitabine-tenofovir df), Vocabria (cabotegravir), Yeztugo* (lenacapavir), Ziagen (abacavir).

Products marked with an asterisk () may not be covered under the plan's pharmacy benefit.*

Date of Origin: 10/27/2022

Date Last Reviewed / Revised: 9/30/2026

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of A, B, or C **AND** provision of documentation satisfying **ALL** criteria listed under applicable diagnosis:
 - A. HIV and documentation of **ALL** the listed laboratory test results under the applicable diagnosis (i or ii):
 - i. Treatment-naïve:
 1. Positive HIV-1/2 antigen/antibody (Ag/Ab) test.
 - ii. Treatment-experienced:
 1. CD4 T lymphocyte (CD4) cell count.
 2. Plasma HIV-RNA level.
 3. Genotypic resistance testing, if therapy is being initiated or modified.
 - 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).
 - b. Partner(s) of unknown HIV status with no or inconsistent condom use.

- c. History of a bacterial sexually transmitted infection within the past 6 months.
 - 2. Persons who inject drugs with any of the following:
 - a. HIV-positive injection partner(s).
 - b. Shares needles, syringes, or other equipment to inject drugs.
 - ii. Negative HIV-1/2 Ag/Ab test within one week prior to treatment 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. 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 medication-specific criteria for all 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.
- III. 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 any complete HIV regimen in combination with additional HIV antiretrovirals.
 - Examples of complete regimen products: Atripla, Biktarvy, Cabenuva, Complera, Delstrigo, Dovato, Genvoya, Juluca, Odefsey, Stribild, Symfi, Symfi Lo, Symtuza, Triumeq

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* (cabotegravir)	- Indication(s): - PrEP in adults and adolescents ≥ 12 years old weighing ≥ 35 kg. - Other Criteria: - Covered at zero cost-sharing (copay is zero) when prior authorization criteria is met for PrEP for ACA-eligible plans and the plan covers Apretude under the pharmacy benefit.	Two 600 mg/3 mL vials for the first 60 days, then one 600 mg/3 mL vial every 60 days thereafter.
Biktarvy (bictegravir-emtricitabine-tenofovir alafenamide)	- This is a complete regimen. Use of this medication with other antiretroviral (ARV) therapy is not recommended per the FDA label. Concurrent use with other ARV(s) requires additional documentation of medical necessity, including resistance testing. - Indication(s): - Treatment of HIV in adults and pediatrics weighing ≥ 14 kg who are: - ARV-naïve OR - To replace a stable ARV regimen and all the following criteria are met: - Virologically suppressed (HIV RNA < 50 copies/mL) for at least 3 months. - No history of treatment failure. - Resistance testing within past 3 months demonstrating virologic susceptibility. - Other covered condition(s): - PEP/nPEP in adults and pediatrics weighing at least 14 kg. - Exclusions: - Renal impairment: not recommended with eCrCl 15 to below 30 mL/min, below 15 mL/min not on chronic HD, or below 15 mL/min if ARV-naïve. - Severe hepatic impairment (Child-Pugh Class C)	30 tablets per 30 days.

Drug	Indication(s), Drug-specific Criteria, Exclusion(s)	Quantity Limits
Cabenuva (cabotegravir- rilpivirine)	- This is a complete regimen. Use of this medication with other antiretroviral (ARV) therapy is not recommended per the FDA label. Concurrent use with other ARV(s) requires additional documentation of medical necessity, including resistance testing. - Indication(s): - Treatment of HIV to replace a stable ARV regimen in adults and adolescents ≥12 years old weighing ≥35 kg and all the following criteria are met: - Virologically suppressed (HIV RNA < 50 copies/mL) for at least 3 months. - No history of treatment failure. - Resistance testing within past 3 months demonstrating virologic susceptibility. - Other Criteria: - Requests for monthly dosing must include clinical justification explaining why every-2-months dosing is not appropriate.	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. Monthly schedule: One 600 mg CAB/900 RPV vial for the first 30 days, then one 400 mg CAB/600 mg RPV vial every 30 days.
Descovy (emtricitabine- tenofovir alafenamide)	- Indication(s): - Treatment of HIV and ONE of the following: - Will be used in combination with other ARVs in adults and pediatrics weighing ≥ 35 kg OR - Will be used in combination with other ARVs (other than PIs) that require a CYP3A inhibitor in pediatric patients weighing ≥14 kg and < 35 kg. - PrEP in adults and adolescents ≥ 12 years old weighing ≥ 35 kg, excluding individuals at risk from receptive vaginal sex. - Other Criteria: - Treatment of HIV infection: Documented clinically significant treatment failure, intolerance, or contraindication to emtricitabine-tenofovir disoproxil. - PrEP: Covered at zero cost-sharing (copay is zero) when prior authorization criteria is met for PrEP for ACA-eligible plans. - Exclusions: - Renal impairment: not recommended with eCrCl 15 to below 30 mL/min, or below 15 mL/min not on chronic HD.	30 tablets per 30 days.

Drug	Indication(s), Drug-specific Criteria, Exclusion(s)	Quantity Limits
Dovato (dolutegravir-lamivudine)	- This is a complete regimen. Use of this medication with other antiretroviral (ARV) therapy is not recommended per the FDA label. Concurrent use with other ARV(s) requires additional documentation of medical necessity, including resistance testing. - Indication(s): - Treatment of HIV in adults and adolescents ≥12 years old weighing ≥25 kg who are: - ARV-naïve OR - To replace a stable ARV regimen and all the following criteria are met: - Virologically suppressed (HIV RNA < 50 copies/mL) for at least 3 months. - No history of treatment failure. - Resistance testing within past 3 months demonstrating virologic susceptibility.	30 tablets per 30 days.
Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir alafenamide)	- This is a complete regimen. Use of this medication with other antiretroviral (ARV) therapy is not recommended per the FDA label. Concurrent use with other ARV(s) requires additional documentation of medical necessity, including resistance testing. - Indication(s): - Treatment of HIV in adults and pediatrics weighing at least 25 kg who are: - ARV-naïve OR - To replace a stable ARV regimen and all the following criteria are met: - 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. - Exclusions: - Renal impairment: not recommended with eCrCl 15 to below 30 mL/min, or below 15 mL/min not on chronic HD. - Severe hepatic impairment (Child-Pugh Class C)	30 tablets per 30 days.

Drug	Indication(s), Drug-specific Criteria, Exclusion(s)	Quantity Limits
Idvynso (doravirine/islatravir)	- This is a complete regimen. Use of this medication with other antiretroviral (ARV) therapy is not recommended per the FDA label. Concurrent use with other ARV(s) requires additional documentation of medical necessity, including resistance testing. - Indication(s): - Treatment of HIV in adults ≥ 18 years of age to replace a stable ARV regimen and all the following criteria are met: - Virologically suppressed (HIV RNA < 50 copies/mL) for at least 3 months. - No history of treatment failure. - No known substitutions associated with resistance to doravirine - Documentation of intolerance or failure of INSTI based regimen when a 2 drug regimen is indicated	Tablets: 30 tablets per 30 days.
Isentress (raltegravir)	- Indication(s): - Treatment of HIV in combination with other ARVs in adults and pediatrics weighing ≥ 40 kg who are: - ARV-naïve OR - To replace a stable ARV regimen and all the following criteria are met: - Virologically suppressed (HIV RNA < 50 copies/mL) for at least 3 months. - No history of treatment failure. - Resistance testing within past 3 months demonstrating virologic susceptibility. - Treatment of HIV in combination with other ARVs in pediatrics and neonates weighing at least 2 kg (regardless of ARV treatment history).	Tablets: 60 tablets per 30 days. <i>If coadministered with rifampin: 120 tablets per 30 days.</i> Chewable tablets and oral suspension: quantity limits are set according to weight-based dosing schedule.
Juluca (dolutegravir/rilpivirine)	- This is a complete regimen. Use of this medication with other antiretroviral (ARV) therapy is not recommended per the FDA label. Concurrent use with other ARV(s) requires additional documentation of medical necessity, including resistance testing. - Indication(s): - Treatment of HIV to replace a stable ARV regimen in adults and all the following criteria are met: - 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.	30 tablets per 30 days.

Drug	Indication(s), Drug-specific Criteria, Exclusion(s)	Quantity Limits
Odefsey (emtricitabine- rilpivirine- tenofovir alafenamide)	- This is a complete regimen. Use of this medication with other antiretroviral (ARV) therapy is not recommended per the FDA label. Concurrent use with other ARV(s) requires additional documentation of medical necessity, including resistance testing. - Indication(s): - Treatment of HIV in adults and pediatrics ≥ 3 years old weighing at least 25 kg who are: - ARV-naïve with HIV-1 RNA $\leq 100,000$ copies/mL OR - To replace a stable ARV regimen and all the following criteria are met: - 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. - Exclusions: - Renal impairment: not recommended with eCrCl 15 to below 30 mL/min, or below 15 mL/min not on chronic HD.	30 tablets per 30 days.
Prezcobix (darunavir- cobicistat)	- Indication(s): - Treatment of HIV in combination with other ARVs in adults and pediatrics ≥ 3 years old weighing ≥ 15 kg who are: - ARV-naïve OR - To replace a stable ARV regimen and all the following criteria are met: - Virologically suppressed (HIV RNA < 50 copies/mL) for at least 3 months. - No history of treatment failure. - Resistance testing within past 3 months demonstrating virologic susceptibility.	30 tablets per 30 days.

Drug	Indication(s), Drug-specific Criteria, Exclusion(s)	Quantity Limits
Prezista (darunavir)	• Indication(s): ○ Treatment of HIV in combination with ritonavir and other ARVs in adults and pediatrics ≥ 3 years old weighing ≥ 10 kg who are: ▪ ARV-naïve OR ▪ To replace a stable ARV regimen and all the following criteria are met: ○ Virologically suppressed (HIV RNA < 50 copies/mL) for at least 3 months. ○ No history of treatment failure. ○ Resistance testing within past 3 months demonstrating virologic susceptibility.	30 tablets per 30 days.
Sunlenca* (lenacapavir)	• Indication(s): ○ Treatment of HIV in combination with other ARVs in heavily treatment-experienced adults with multidrug resistant HIV-1 failing their current antiretroviral regimen and all the following criteria are met: ▪ Documented HIV-1 RNA level of ≥ 400 copies per mL despite adherence to current regimen, or documentation of intolerance or safety considerations to current ARV 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 ≥2 other ARV(s). ▪ Drug is prescribed by or in consultation with an infectious disease or HIV specialist.	<u>Initiation:</u> 927 mg by injection (2 x 1.5 mL injections) plus four 300 mg tablets in 2 days, OR 927 mg by injection plus five 300 mg tablets in 8 days. <u>Maintenance:</u> 927 mg by injection (2 x 1.5 mL injections) per 6 months.

Drug	Indication(s), Drug-specific Criteria, Exclusion(s)	Quantity Limits
Symtuza (darunavir-cobicistat-emtricitabine-tenofovir alafenamide)	- This is a complete regimen. Use of this medication with other antiretroviral (ARV) therapy is not recommended per the FDA label. Concurrent use with other ARV(s) requires additional documentation of medical necessity, including resistance testing. - Indication(s): - Treatment of HIV in adults and pediatrics ≥ 12 years old 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 at least 6 months. - No history of treatment failure. - Resistance testing within past 3 months demonstrating virologic susceptibility. - Exclusions: - Severe renal impairment (CrCl < 30 mL/min). - Severe hepatic impairment (Child-Pugh Class C). - Pregnancy	30 tablets per 30 days.
Tivicay (dolutegravir)	- Indication(s): - Treatment of HIV in combination with other ARVs in adults and pediatrics ≥ 4 weeks old weighing ≥ 3 kg who are: - ARV-naïve OR - To replace a stable ARV regimen and all the following criteria are met: - Virologically suppressed (HIV RNA < 50 copies/mL) for at least 3 months. - No history of treatment failure. - Resistance testing within past 3 months demonstrating virologic susceptibility. - Other covered condition(s): - PEP/nPEP in adults and pediatrics weighing at least 3 kg, when used in combination with other ARVs (such as emtricitabine-tenofovir disoproxil fumarate).	30 tablets per 30 days.

Drug	Indication(s), Drug-specific Criteria, Exclusion(s)	Quantity Limits
Triumeq (abacavir-dolutegravir-lamivudine)	- This is a complete regimen. Use of this medication with other antiretroviral (ARV) therapy is not recommended per the FDA label. Concurrent use with other ARV(s) requires additional documentation of medical necessity, including resistance testing. - Indication(s): - Treatment of HIV in adults and pediatrics ≥ 3 months old weighing ≥ 6 kg who are: - ARV-naïve OR - To replace a stable ARV regimen and all the following criteria are met: - Virologically suppressed (HIV RNA < 50 copies/mL) for at least 3 months. - No history of treatment failure. - Resistance testing within past 3 months demonstrating virologic susceptibility. - Exclusions: - Presence of HLA-B*5701 allele. - Severe renal impairment (CrCl < 30 mL/min). - Hepatic impairment (Child-Pugh Class B or C).	30 tablets per 30 days. For patients weighing < 25 kg, quantity limits are set according to weight-based dosing schedule.
Yeztugo* (lenacapavir)	- Indication(s): - PrEP in adults or adolescents ≥ 12 years old weighing ≥ 35 kg. - Other Criteria: - Covered at zero cost-sharing (copay is zero) when prior authorization criteria is met for PrEP for ACA-eligible plans and the plan covers Yeztugo under the pharmacy benefit. - Supplemental doses may be necessary for patients using Yeztugo concomitantly with CYP3A inducers.	<u>Initiation:</u> 927 mg by injection (2 x 1.5 mL injections) plus four 300 mg tablets in 2 days. <u>Maintenance:</u> 927 mg by injection (2 x 1.5 mL injections) per 6 months.

Abbreviations: 3-TC, lamivudine; ARV, antiretroviral; BIC, bictegravir; CAB, cabotegravir; COBI, cobicistat; DOR, doravirine; 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; ISL, islatravir; 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.

Products marked with an asterisk () may not be covered under the plan's pharmacy benefit.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- See Table 1.

APPROVAL LENGTH

- **Authorization:**
 - Treatment of HIV: 1 year
 - PrEP: 1 year
 - PEP: 30 days
 - Short-term Edurant or Vocabria treatment (e.g., oral lead in for Apretude or Cabenuva, or missed Cabenuva injection): 30 days
- **Re-Authorization:**
 - Treatment of HIV infection: 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 and Truvada: every 3 months.
 - Apretude: 1 month after first injection, and then every 2 months beginning after the third injection.
 - nPEP: N/A.

APPENDIX

N/A

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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.