

Cabenuva (cabotegravir and rilpivirine) Injection

Policy Number: MC/PC 005

Effective Date: September 1, 2026

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Related Policies

- n/a

Coverage Rationale

HIV

For coverage of Cabenuva (cabotegravir and rilpivirine) Injection for treatment of HIV-1 Infection, the following will be required:

- All of the following:
 - Diagnosis of HIV-1 infection **and**
 - Patient is 12 years of age or older **and**
 - Patient's weight is greater than or equal to 35 kg **and**
 - Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 3 months **and**
 - Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine **and**
 - Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens **and**
 - Prescribed by or in consultation with a clinician with HIV expertise.

OR

- For continuation of prior therapy defined as no more than a 70-day gap in therapy
 - Patient has previously received treatment with Cabenuva **and**
 - Patient has maintained virological suppression (HIV-1 RNA less than 50 copies/mL) while on Cabenuva therapy

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan

document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCP Code	Description
J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg

ICD-10 Code	Description
B20	Human immunodeficiency virus [HIV] disease
B97.35	Human immunodeficiency virus, type 2 [HIV 2] as the cause of diseases classified elsewhere
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status

Background

At present time, HIV-1 is considered a lifelong, chronic disease. As persons living with human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) live longer due to the advent of antiretroviral therapy (ART), clinicians are now challenged with treating individuals with co-morbidities. A wide spectrum of complications associated with older age have become common, some of which overlap with adverse events (AEs) from ART. Management of these complications is constantly evolving (Fauci et al 2025).

The combination/multiple drug formulations include Biktarvy (BIC/FTC/TAF), Cabenuva (CAB/RPV), Dovato (DTG/3TC), Genvoya (EVG/c/FTC/TAF), Juluca (DTG/RPV), Stribild (EVG/c/FTC/TDF), and Triumeq/Triumeq PD (DTG/ABC/3TC). All the INSTI multiple drug formulations are considered single-tablet regimens (STRs) or complete regimens. Juluca, Cabenuva, and Dovato are the 2-drug regimens considered complete regimens among all HIV therapeutic classes. Biktarvy and Dovato are the only STRs guideline-recommended as preferred in treatment-naïve adults without a history of LA CAB use for PrEP. Dovato has exceptions for use as an initial regimen (i.e., HIV RNA > 500,000 copies/mL, hepatitis B virus [HBV] coinfection, or HIV genotypic resistance testing not available). Biktarvy is the only STR approved for treatment-experienced children and adults with HIV-1 to replace the current ARV regimen in those who are not virologically suppressed. Cabenuva is a long-acting HIV-1 intramuscular (IM) formulation reserved for individuals who are living with HIV, virologically suppressed on a stable ARV regimen, and have no history of treatment failures. (Fauci et al 2025, DHHS 2026[a], Clinical Pharmacology 2026).

Adherence to ART is vital to accomplish treatment success and to mitigate any potential issues with drug resistance. Numerous studies have demonstrated increased adherence rates in individuals receiving treatment with STRs compared to those on multi-tablet regimens (MTRs). However, a number of factors, including the individual’s social situation and clinical condition, the prescribed regimen, and the person-provider relationship, can influence adherence to ART. Poor adherence is often a consequence of 1 or more behavioral, structural, and psychosocial barriers. (DHHS 2025, DHHS 2026[a-b]).

Clinical Evidence

CAB-based therapy:

Overall, the pivotal and supportive evidence demonstrates that long-acting CAB/RPV maintains virologic suppression in appropriately selected individuals with HIV-1 who are already suppressed on stable ART. Across ATLAS, FLAIR, ATLAS-2M, SOLAR, and IMPAACT 2017/MOCHA, CAB/RPV was generally noninferior to continued oral ART or alternate dosing strategies for maintenance of suppression, with injection-site reactions common but usually mild to moderate.

HIV treatment: The efficacy and safety of Cabenuva (CAB/RPV; with oral Vocabria + Edurant [RPV] lead-in) was evaluated in 1,184 adults living with HIV-1 who were virologically suppressed, on a stable oral ARV regimen via the ATLAS and FLAIR

trials after 48 weeks for treatment. The ATLAS-2M trial also evaluated CAB/RPV via every 4-week dosing regimen (currently FDA-approved) and an every 8-week dosing regimen.

ATLAS: An Open Label (OL), Non-Inferiority (NI), Randomized Control Trial (RCT) in 618 treatment-experienced, virologically suppressed adults on oral ART (NNRTI, 50%; INSTI, 33%; PI, 17%; not including Triumeq [DTG/ABC/3TC]) for ≥ 6 months, switching to long-acting CAB/RPV IM injections (CAB 600 mg and RPV 900 mg followed by subsequent injections of CAB 400 mg and RPV 600 mg administered every 4 weeks) after oral lead-in therapy (CAB 30 mg + RPV 25 mg once daily for 4 weeks; also, a bridging therapy for missed CAB/RPV injections). Individuals had no prior virological failure or archived INSTI resistance mutations.

- The proportion of adults in each arm, CAB/RPV vs oral ART, who were found to have HIV-1 RNA ≥ 50 c/mL after treatment were non-inferior to each other at week 48 (1.6 vs 1.0%, respectively; difference, 0.6%; 95% CI, -1.1 to 2.4). The proportion who were virologically suppressed (HIV-1 RNA < 50 c/mL) in both arms were also non-inferior to one another at week 48 (92.5 vs 95.5%, respectively). Virological failure occurred in 3 patients in the CAB/RPV arm vs 4 patients in the oral ART arm.
- Among patients receiving CAB/RPV, 81% reported injection-site reactions, which resolved over time. The most common treatment-related AEs reported for CAB/RPV were headache, pyrexia, and fatigue (4% for each).
- At week 48, CAB/RPV was preferred over previous oral ART in 86% of individuals. Most participants completing the Maintenance Phase transitioned to ATLAS-2M (88%, $n=502/572$).
- Overall, 52 participants were included in the Week-96 analysis of ATLAS; of these, 100% ($n=23/23$) and 97% ($n=28/29$) in the Long-acting and Switch arms had plasma HIV-1 RNA less than 50 copies/mL at Week 96, respectively. In this subgroup of ATLAS, 98% ($n=51/52$) of participants at the Extension Phase Week 96 analysis maintained virologic suppression with long-acting therapy. Safety, efficacy, and participant preference results support the therapeutic potential of long-acting CAB+RPV treatment for virologically suppressed people living with HIV-1. (Swindells et al 2020, Swindells et al 2022, Cabenuva prescribing information 2025).

ATLAS-2M: An OL, NI, RCT in 1,045 adults living with HIV-1 were randomized to CAB/RPV 600/900 mg IM every 2 months or CAB/RPV 400/600 mg IM every month ($N = 523$) (Chounta et al 2021, Overton et al 2020, Jaeger et al 2021, Cabenuva prescribing information 2025).

48-week data: Results demonstrated the 2 dosing regimens were non-inferior to one another for the proportion who were virologically suppressed. However, among the 2% ($N = 8$) of individuals with confirmed virological failure in the every 8-week dosing arm, 6 of 8 (75%) developed RPV resistance and 60% had INSTI resistance. An update at 96-weeks reported a total of 9 individuals with virologic failure in the every 8-week arm compared to 2 individuals in the every 4-week arm. The study authors did perform an archived genotype test retroactively and claimed patients had baseline resistance; however, this is not a robust process for correlating between finding resistance mutations and correlating it to drug susceptibility (Overton et al 2020, Jaeger et al 2021, Cabenuva prescribing information 2025).

- **96 week data:** At week-96, 11 (2%) of 522 participants in the every 8-week dosing group and six (1%) of 523 in the every 4-week dosing group had an HIV-1 RNA measurement of 50 copies per mL or more, with an adjusted treatment difference of 1.0 (95% CI -0.6 to 2.5), meeting the prespecified non-inferiority threshold of 4%; 475 (91%) of 522 participants in the every 8-week dosing group and 472 (90%) of 523 in the every 4-week dosing group maintained an HIV-1 RNA measurement of less than 50 copies per mL, with an adjusted treatment difference of 0.8 (95% CI -2.8 to 4.3), which met the prespecified non-inferiority threshold of -10%. One participant in the every 8-week dosing group met the confirmed virological failure criterion since the week-48 analysis at week 88, resulting in a total of nine participants in the every 8-week dosing group and two in the every 4-week dosing group having confirmed virological failure. (Jaeger et al 2021, Cabenuva prescribing information 2025). At week-152, 87% of persons in the Q8W group and 86% of persons in the Q4W group maintained virologic suppression. Overall, 12 (2.3%) persons in the Q8W arm and 2 (0.4%) persons in the Q4W group had confirmed virologic failure (Overton et al 2023).

FLAIR: An OL, NI, RCT in 566 treatment-naïve adults living with HIV-1 who were administered Triumeq (DTG/ABC/3TC; although adults were allowed DTG + 2 NRTIs if they were HLA-B*5701 positive) during an injection phase of 20 weeks until

virologically suppressed (HIV-1 RNA < 50 c/mL). Individuals were then randomized to CAB/RPV (with the same oral lead-in and dosing regimen for ATLAS) or maintained on DTG/ABC/3TC orally once daily (Orkin et al 2020[b], Orkin et al 2021[a], Cabenuva prescribing information 2025).

- **48-week data:** The proportion of adults in each arm, CAB/RPV vs oral DTG/ABC/3TC, who were found to have HIV-1 RNA $\geq$ 50 c/mL after treatment were non-inferior to each other at week-48 (2.1 vs 2.5%, respectively; difference, -0.4; 95% CI, -2.8 to 2.1). The proportion who were virologically suppressed (HIV-1 RNA < 50 c/mL) in both arms were also non-inferior to one another at week-48 (93.6 vs 93.3%, respectively). Virological failure occurred in 4 patients in the CAB/RPV arm (3 patients had NNRTI and INSTI resistance mutations) vs 3 patients in the oral DTG/ABC/3TC arm. Injection-site pain was reported in 80% of individuals who were receiving CAB/RPV. Any Grade $\geq$ 3 AEs were reported in 11% of CAB/RPV patients and 4% of oral DTG/ABC/3TC patients. After 12 months of therapy, CAB/RPV was preferred over previous oral DTG/ABC/3TC by 91% of individuals (Orkin et al 2020[b], Cabenuva prescribing information 2025).
- **96-week data:** The proportion of adults in each arm, CAB/RPV vs oral DTG/ABC/3TC, who were found to have HIV-1 RNA $\geq$ 50 c/mL after treatment continued to be non-inferior to each other at week-96 (3% in each group). The proportion who were virologically suppressed (HIV-1 RNA < 50 c/mL) in both arms were also non-inferior at week-96 (87 vs 89%, respectively). Apart from those described at week-48, no additional individuals had confirmed virological failure between week 48 and 96 with CAB/RPV. In the DTG/ABC/3TC group, 1 individual developed confirmed virologic failure at week 64, with no treatment-emergent resistance. More individuals withdrew due to AEs in the CAB/RPV group vs DTG/ABC/3TC group at week 96 (5 vs 1%). More treatment related AEs (excluding injection site reactions) occurred at week 96 in the CAB/RPV group (34 vs 12%). There were no differences in serious AEs. More treatment-related Grade $\geq$ 3 AEs occurred with CAB/RPV at week 96 (6 vs 0%). Injection site reactions were reported in 88% of CAB/RPV-treated individuals, and slightly more weight gain was seen (Orkin et al 2021[a]).
- In the FLAIR open-label extension phase from weeks 100 to 124, CAB/RPV was evaluated in 232 patients who switched from their current ART regimen to CAB/RPV with or without oral lead-in dosing. By week 124, the rates of virologic suppression were similar between patients who started the extension with an oral lead-in (93%) vs direct to injection (99%) (Orkin et al 2021[b]).

SOLAR: The SOLAR trial compared switching to long-acting CAB/RPV given every 2 months to continued BIC/FTC/TAF for the maintenance of virologic suppression (RNA levels < 50 copies/mL) in 687 adults. Patients were randomized to either long-acting CAB/RPV (n=447), of which 274 patients started with injections and 173 started with oral lead-in therapy, or continuation of BIC/FTC/TAF (n=223).

- After 11 to 12 months of the assigned maintenance therapy, CAB/RPV demonstrated noninferiority to BIC/FTC/TAF for maintenance of virologic suppression, with a loss of virologic efficacy in 1% vs <1% of patients (adjusted difference, 0.7%; 95% CI, -0.7 to 2.0). The study authors conducted a retrospective analysis of archived genotypes and claimed patients had baseline resistance; however, this is not a robust process for establishing a correlation between the identification of resistance mutations and drug susceptibility (Ramgopal et al 2023)

IMPAACT 2017/MOCHA: The IMPAACT 2017/MOCHA Phase 1/2 study evaluated the safety of switching to LA injectable CAB/RPV administered every 8 weeks in 139 virologically suppressed (HIV-1 RNA < 50 copies/mL) adolescents ($\geq$ 12 years of age and $\geq$ 35 kg) across 5 countries. The study included 2 cohorts. In cohort 1, participants remained on their background ART and received either oral CAB or RPV followed by LA CAB or RPV alone to establish appropriate dosing. In cohort 2, participants discontinued background ART and received oral CAB 30 mg and RPV 25 mg daily for 4 to 6 weeks, followed by IM CAB 600 mg and RPV 900 mg at weeks 4 and 8, and then Q8W.

- Of 144 adolescents enrolled in cohort 2, 139 were included in the evaluable analysis population. By week-24 in cohort 2, 10.8% of participants experienced grade $\geq$ 3 AEs, but none were drug-related, serious, or led to treatment discontinuation. Injection site reactions occurred in approximately 30% of participants in cohort 2, all grade 1 or 2, and 91.5% resolved within 7 days. Virologic suppression (HIV-1 RNA < 50 copies/mL) was maintained in 137 of 139 participants (98.6%) in cohort 2 (Moore et al 2025).

Clinical Guidelines

DHHS Recommendations for the Use of ARV Drugs During Pregnancy with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States (2026) (DHHS 2026[b])

This guideline recommends that if ART is not already being used during pregnancies impacted by HIV, all pregnant women with HIV should initiate ART as early in pregnancy as possible, regardless of their HIV RNA level or CD4 cell count, to maximize their health and prevent perinatal HIV transmission and secondary sexual transmission **(AI)**. In addition to benefiting personal health and preventing HIV transmission to sexual partners, the goal of ART during pregnancy is to achieve and maintain HIV viral suppression to undetectable levels to reduce the risk of perinatal transmission and maximize health during pregnancy **(AI)**. Neonates should receive ARV prophylaxis or presumptive therapy appropriate to their risk of perinatal HIV acquisition **(AI)**. When choosing an ARV drug regimen and weighing the benefits and risks of specific ARVs for use during pregnancy or when trying to conceive, providers and patients should consider multiple factors, including AEs, drug interactions, PK, convenience of the individual drugs and drug combinations in the regimen, available pregnancy safety and outcome data, virologic efficacy in nonpregnant adults (and during pregnancy if data are available), and the patient's resistance test results and comorbidities **(AIII)**. In most cases, when ART is used at the time of presentation for pregnancy care, ART regimens should be continued during pregnancy, provided that the regimen is tolerated, safe, and effective in suppressing viral replication (defined as a regimen that maintains an HIV viral load less than lower limits of detection of the assay) **(AII)**.

- CAB-LA/RPV is not recommended as initial treatment for ARV-naïve adults or adolescents (pregnant or nonpregnant) who have never received ARV drugs; there is limited efficacy, safety, and PK data on the use of CAB-LA/RPV during pregnancy.

International Antiretroviral Society (IAS)-USA Panel (2025) (Gandhi et al 2025)

- Treatment for HIV should be initiated as soon as possible after HIV diagnosis. Treatment should begin ideally within 7 days, including on the same day as diagnosis or at the first clinic visit if the patient is ready and there is no suspicion of concurrent opportunistic infection. Recommendations for therapy selection are generally consistent with the DHHS guidelines.
- Initial boosted DRV-containing regimens are recommended when INSTI resistance is suspected before the results of resistance testing are returned, particularly when there has been prior exposure to LA CAB as PrEP **(AII)**.
- INSTI-based regimens for adults
 - Recommended for most patients with HIV (with recommendation rating)
 - BIC/TAF/FTC **(AIIa)**
 - DTG plus (TAF or TDF) plus (FTC or 3TC) **(AIIa)**
 - DTG/3TC **(AIIa)** (not recommended for patients with lamivudine resistance, chronic HBV infection or HIV RNA >500,000 copies/mL [and possibly CD4 cell count <200/μL])
 - Recommended for those who received prior TAF/FTC or TDF/FTC for PrEP who are waiting for genotypic testing results
 - DTG or BIC plus (TAF or TDF) plus (FTC or 3TC) **(AIII)**
 - Recommended for those who received prior injectable CAB for PrEP who are waiting for genotypic testing results
 - Boosted DRV plus (TAF or TDF) plus (FTC or 3TC) **(AIIb)**
 - Recommended during pregnancy
 - DTG plus TAF plus (FTC or 3TC) **(AIIa)**
 - DTG plus TDF plus (FTC or 3TC) **(AIIa)**
 - If DTG is not available for either above regimen, the following may be substituted:
 - DRV/r plus (TAF or TDF) plus (FTC or 3TC) **(AIIa)**; preferred in people who have previously received LA CAB for PrEP
 - BIC/TAF/FTC **(BIIb)**; if started prior to pregnancy, maybe continued during pregnancy if tolerated **(AIIa)**
 - If pregnancy occurs in people receiving LA CAB plus RPV, switching to an oral triple-drug regimen is recommended **(AIII)**.
 - Not recommended for initiation in pregnancy **(AIII)**

- DRV-containing regimens
- LA CAB plus RPV
- DTG/3TC, DTG/RPV
- COBI-boosted regimens, due to inadequate drug levels (**AIIb**)
- Switching ART therapy
 - Individuals with virologic suppression receiving regimens that contain a boosted PI and 2 NRTIs can be switched to DTG plus (TAF or TDF) plus (FTC or 3TC) or BIC/FTC/TAF regardless of known or likely prior resistance to the NRTI pair and provided there is no history of INSTI resistance (**AIIa**).
 - Injectable LA CAB plus RPV is recommended for persons who experience stigma or other adverse consequences of taking pills daily or in response to strong patient preference (**AIIb**).
 - For people who have stopped ART, resuming the most recent DTG- or BIC-based regimen is recommended even before the results of the resistance genotype test have been returned (**AIIb**).
 - In individuals with virologic failure with extensive multiclass resistance (including to INSTIs), agents with novel mechanisms of action such as ibalizumab, fostemsavir, or lenacapavir are recommended, ideally in combination to allow for 2 fully active drugs (**AIIa**).
 - For those unable to take oral ART with advanced HIV disease, LA CAB plus RPV in conjunction with intensive case management may be considered for people with viremia who meet certain criteria as outlined in the guideline (**AIIa**).
- For PrEP, the IAS-USA recommends the following:
 - Daily oral FTC/TDF for all populations (**AIIa**), including those who are pregnant or breastfeeding (**AIIa**), although a regimen of daily FTC/TAF is preferred in those with a reduced creatinine clearance (between 30 to 60 mL/minute) or known osteopenia or osteoporosis.
 - Long-acting injectable CAB for all populations (**AIIa**), although there is not sufficient data for injectable drug users unless there is a concomitant risk of acquiring HIV from sex (**AIIII**).
 - TAF/FTC use should be limited to cisgender men and others whose exposures do not include receptive vaginal sex (including neovaginal sex) or injection drug use alone (**AIIa**).
 - On-demand (2-1-1) oral dosing of TDF/FTC is recommended for cisgender men (**AIIa**) and others (**AIIII**) having planned receptive anal (but not receptive vaginal or neovaginal) sex.
- For post-exposure prophylaxis (PEP), the IAS-USA recommends the following:
 - A 3-drug regimen of (DTG or BIC) plus (TAF or TDF) plus (FTC or 3TC) is recommended for PEP within 72 hours after an exposure and continued for 28 days (**AIIII**).

DHHS Guidelines for the Use of ARV Agents in Adults and Adolescents with HIV (2026) (DHHS 2026[a])

This guideline recommends ART for all individuals with HIV to reduce morbidity and mortality (**AI**) and to prevent the transmission of HIV to others (**AI**). Treatment should be initiated as soon as possible after HIV diagnosis (**AII**)

The goals of treatment are:

- Maximally suppress plasma HIV-1 RNA and maintain a durable response
- Restore/preserve immunologic function
- Reduce the morbidity and mortality associated with HIV
- Prevent HIV transmission
- Prolong the duration or quality of survival
- Recommendations for treatment are based on virologic efficacy, potential AEs, pill burden, dosing frequency, drug-drug interaction potential, cost, access, resistance test results, and the comorbid conditions of the person with HIV.
- Recommended initial regimens for most people with HIV who do not have a history of using LA CAB for PrEP include (all **AI**): BIC/TAF/FTC; DTG plus (TAF or TDF) plus (FTC or 3TC) (**AI**); or DTG/3TC (except for individuals with HIV RNA > 500,000 copies/mL, HBV coinfection, or in whom ART is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or HBV testing are available).
- INSTIs (specifically BIC and DTG) are recommended for initial therapy in most people because of their demonstrated efficacy, high barrier to resistance, tolerability, low potential for drug-drug interactions, convenience, and better AE profile compared with NNRTIs and boosted PIs.

- For people who have a history of LA CAB use for PrEP, INSTI genotype resistance testing should be performed before starting ART. If ART is to be started before the results of genotypic testing are available, the following regimen is recommended (**AIII**): DRV/c or DRV/r with (TAF or TDF) plus (FTC or 3TC), pending the results of the genotype test.
- Achieving viral suppression currently requires the use of combination ARV regimens that generally include 3 active drugs from 2 or more drug classes. Baseline patient characteristics and results from drug resistance testing should guide the design of the specific regimen.
- Recommended initial INSTI regimens in certain clinical situations:
 - INSTI plus 2 NRTIs
 - When concern about renal- or bone-associated AEs precludes the use of TDF or TAF: DTG/ABC/3TC (**BI**)
 - Boosted PI plus 2 NRTIs
 - To avoid INSTI-based regimen: DRV/c or DRV/r plus (TAF or TDF) plus (FTC or 3TC) (**BI**)
 - To avoid an INSTI-based regimen and when there is concern about renal- or bone-associated AEs that precludes the use of TDF or TAF: DRV/c or DRV/r plus ABC/3TC (**BII**)
 - NNRTI plus 2 NRTIs
 - To avoid an INSTI and PI-based regimen: doravirine (DOR)/TDF/3TC (**BI**) or DOR plus TAF/FTC (**BIII**)
 - To avoid an INSTI and PI-based regimen when a single-tablet regimen containing an NNRTI and TAF is desired: RPV/TAF/FTC (**BII**)
- Note: Lower concentrations of COBI and DRV have been seen during 2nd and 3rd trimesters and therefore should be avoided during pregnancy.
- In the setting of virologic suppression in treatment-experienced individuals, the following INSTI-based ART options are for consideration:
 - In patients without a history of drug resistance or virologic failure, a switch can be made to any highly-effective ART regimen recommended in treatment-naïve patients (**AI**) or to NRTI-sparing options extensively researched in switch studies, such as DTG plus RPV (**AI**) or LA CAB plus RPV (**AI**).
 - For regimen optimization in the presence of NRTI resistance, (TAF or TDF) plus (FTC or 3TC) can be combined in a regimen with either DTG (**AII**), boosted DRV (**BIII**), or BIC (**BIII**). Alternatively, as noted above, an NRTI-sparing regimen (such as DTG/RPV [**AI**] or LA CAB/RPV [**AI**]) is possible if there is no evidence of prior INSTI or RPV resistance.
 - CAB/RPV IM is recommended to replace an existing oral ART regimen in individuals with HIV with documented viral suppression for at least 3 months, no history or documented resistance to CAB or RPV, no active HBV infection (unless also receiving TAF, TDF, or entecavir), not pregnant or actively planning pregnancy, and not receiving medications with significant drug interactions with oral (during lead-in or bridging therapy) or injectable CAB or RPV (**AI**).
- For individuals who experience virologic failure to ART, a new regimen can include 2 fully active drugs if at least 1 with a high resistance barrier is included, such as a second-generation INSTI or a boosted PI; a new ARV regimen can also include a second-generation INSTI (DTG plus a boosted PI [preferably DRV]) without a NRTI if both are fully active (**AI**). ARV drugs with a high barrier to resistance are those in which emergent resistance is uncommon in people experiencing virologic failure. These include boosted DRV, DTG, and BIC.
- No longer recommended as initial ARV regimens (only those that include INSTIs are listed):
 - RAL-based regimens: low genetic barrier to resistance and higher pill burden.
 - EVG/c-based regimens: drug-drug interactions with COBI and low genetic barrier to resistance of EVG.
 - DRV/r plus RAL: higher rates of virologic failure in people with HIV RNA > 100,000 copies/mL, low genetic barrier to resistance, and high pill burden of RAL.
 - DRV/r plus 3TC: requirement for a PK enhancer with accompanying drug interactions and lacking clinical data to support its use.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

[Cabenuva](#), a 2-drug co-packaged product of cabotegravir, an HIV-1 integrase strand transfer inhibitor (INSTI), and rilpivirine, an HIV-1 non-nucleoside reverse transcriptase inhibitor (NNRTI), is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

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Policy History/Revision Information

Date	Summary of Changes
9/20/2023	Approved by OptumRx P&T Committee
3/20/2024	Annual Review. Updated references. No changes to criteria or background sections.
4/16/2025	Annual Review. Updated background section and clinical guidelines. Updated references.
07/15/2026	Annual Review. Changed coverage rationale to allow coverage for currently virologically suppressed on a stable, uninterrupted antiretroviral regimen from 6 months to 3 months to reflect updates to DHHS guidelines. Updated, background section, clinical evidence and clinical guidelines. Updated references.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Archived Policy Versions (Internal Only)

Effective Date	Policy Number	Policy Title
mm/dd/yyyy – mm/dd/yyyy	#####	Title of Policy Hyperlinked to KL or Other Internal Location

Nondiscrimination & Language Access Policy



Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن أعلى رقم الهاتف 1-800-332-6501 (رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: यान द : य द आप िहंदी बोलते ह तो आपके िलए मु त म भाषा सहायता सेवाएं उपल थ ह 1-800-332-6501 (TTY: 711) पर कॉल कर ।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).