Cabenuva (cabotegravir and rilpivirine) Injection

Policy Number: MC/PC 005
Effective Date: May 1, 2025

Instructions for Use

Table of Contents **Page**

Related Policies

- n/a

Coverage Rationale

HIV

For coverage of Cabenuva (cabotegravir and rilpivirine) Injection, 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 6 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
  - 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

HCPCS 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 (*Anderson et al 2021*).

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 (DTG/ABC/3TC). All the INSTI multiple drug formulations are considered STRs or complete regimens. Juluca, Cabenuva, and Dovato are the 2-drug regimens considered complete regimens among all HIV therapeutic classes. Biktarvy, Dovato, and Triumeq are the only STRs guideline-recommended as preferred in treatment-naïve individuals. Cabenuva is the only long-acting formulation administered once monthly or once every 2 months (*Anderson et al 2021, DHHS 2023[a-c], Micromedex 2025*).

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 single-tablet regimens (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 2023[a-c]*).

Clinical Evidence

CAB-based therapy:
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, Non-Inferiority, Randomized Control Trial 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 patien in the oral ART arm. Among patients receiving CAB/RPV, 81% reported injection-site e. 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 W 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 W 96, respectively. In this subgroup of ATLAS, 98% (n = 51/52) of participants at the Extension Phase W 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 2024*).

ATLAS-2M: An OL, NI, RCT in 1,049 adults living with HIV-1 were randomized to CAB/RPV 600/900 mg IM every 8 weeks (not an FDA-approved dosing schedule, but currently filed for approval under a sNDA; N = 533) or CAB/RPV 400/600 mg IM every 4 weeks (N = 523) (*Chounta et al 2021, Overton et al 2020, Jaeger et al 2021, Cabenuva prescribing information 2024*). *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 2024*).
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 2024). 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*).
Patient reported outcomes: After 48 weeks, patient reported outcomes were evaluated for dosing regimens (IM every 4 or 8 weeks, and oral dosing). Various outcomes were measured. Overall, individuals without prior CAB/RPV exposure who received the every 8 week dosing preferred this regimen over daily oral CAB/RPV (98%, n = 300/306). Among those with prior every 4 week exposure, 94% (n = 179/191) preferred the every 8 week dosing vs the every 4 week dosing (3%, n = 6/191) or daily oral CAB/RPV (2%, n = 4/191) (*Chounta et al 2021*).

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, Orkin et al 2021 [a], Cabenuva prescribing information 2024*). *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 ≥ 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 ≥ 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, Cabenuva prescribing information 2024*). *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 ≥ 50 c/mL after treatment continued to be non-inferior to oup). The proportion who were virologically suppressed (HIV-1 RNA < 50 c/mL) in bc ek 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 ≥ 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*)

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 (2023) (*DHHS 2023[c])*
This guideline recommends that 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**). The goal of antiretroviral therapy (ART) during pregnancy is to achieve and maintain HIV viral suppression to undetectable levels (HIV RNA <50 copies/mL) to reduce the risk of perinatal transmission (**AI**). The guideline emphasizes that a suppressed viral load at the time of delivery markedly reduces this risk. The selection of which ARV drugs to use during pregnancy is best made through shared decision-making between the healthcare provider and patient after discussion of the known and potential risks and benefits to the patient and fetus, acknowledging limited data (**AIII**). However, the panel recommends use of ARV drugs in the preferred or alternative categories whenever possible (**AIII**). Neonates should receive antiretroviral prophylaxis or presumptive HIV therapy appropriate to their risk of perinatal HIV acquisition (**AI**).

- CAB/RPV is not recommended as initial treatment for ARV-naive adults or adolescents (pregnant or nonpregnant); there is limited efficacy, safety and PK data on the use of CAB/RPV during pregnancy.

International Antiretroviral Society (IAS)-USA Panel (2022) (*Gandhi et al 2023*)

- Treatment for HIV should be initiated as soon as possible after HIV diagnosis. Recommendations for therapy selection are generally consistent with the DHHS guidelines.
- INSTI-based regimens for adults
  - Recommended for most patients with HIV (with recommendation rating)

- BIC/TAF/FTC (**AIa**)
- DTG plus (TAF or TDF) plus (FTC or 3TC) (**AIa**)
- DTG/3TC (**AIa**) (not recommended for patients with chronic HBV infection or HIV RNA >500,000 copies/mL [and possibly CD4 cell count <200/µL])

▪ Recommended for those who received prior TAF/TDF with 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) (**AIII**)

▪ Recommended during pregnancy
- DTG plus TAF plus (FTC or 3TC) (**AIa**)
- DTG plus TDF plus (FTC or 3TC) (**AIa**)
- If DTG is not available for either above regimen, the followed may be substituted: RAL (**AIIa**), boosted ATV (**BIIa**), boosted DRV (**BIIa**), RPV (**BIIa**)

▪ Not recommended for initiation in pregnancy
- BIC, doravirine, CAB, DTG/3TC, DTG/RPV
- COBI-boosted regimens, due to inadequate drug levels (**AIIb**)

○ Switching ART therapy
▪ When switching from a 3-drug regimen to an oral 2-drug regimen in virologically suppressed patients, no resistance testing is required before switching unless there is a suspected or documented history of treatment failure **(BII)**.
▪ For virologically suppressed patients switching from injectable CAB/RPV to oral therapy, the switch can be made without prior resistance testing (**BIII**)

○ The following INSTI regimens are recommended for switching in cases of virologic failure:
▪ DTG plus 2 NRTIs (with 1 active drug determined by genotypic testing) is recommended after initial treatment failure with an NNRTI (**AIa**).
▪ Either boosted DRV plus (TAF or TDF) plus (FTC or 3TC) or DTG plus a boosted PI with/without additional agents are recommended if no active NRTIs are available, and a boosted PI and INSTI remain fully active (**AIa**) DTG plus (TAF or TDF) plus (FTC or 3TC) is an alternative regimen to avoid drug-interactions, although there is a risk of resistance (**AIa**).
▪ If high-level INSTI resistance is present and decreased PI susceptibility, at least 2 fully active novel agents should be used (eg, fostemsavir, lenacapavir, maraviroc ibalizumab, or enfuvirtide), along with previous NRTI therapy due to ongoing partial antiviral activity (**AIII**).

○ For PrEP, the IAS-USA recommends the following:
▪ Daily oral FTC/TDF for all populations (**AIa**), 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 (**AIa**), although there is not sufficient data for injectable drug users unless there is a concomitant risk of acquiring HIV from sex (**AIII**).

○ For post exposure prophylaxis (PEP), the IAS-USA recommend 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 (**AIII**).

DHHS Guidelines for the Use of ARV Agents in Adults and Adolescents with HIV (2023) (*DHHS 2023[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**) (see Appendix for ratings of recommendations and evidence). The goals of treatment in early HIV infection (acute or recent) are to suppress plasma HIV RNA to undetectable levels (**AI**) and prevent transmission to others (**AI**).

Initial therapy for a person with HIV generally consists of 2 NRTIs administered with a third ARV drug from 1 of 3 drug classes: an INSTI, a NNRTI, or a PI with a PK enhancer (also known as a booster). Data also support the use of the 2-drug combination regimen dolutegravir (DTG)/lamivudine (3TC).

Selection of a regimen should be guided by factors such as virologic efficacy, toxicity, pill burden, dosing frequency, drug–drug interaction potential, resistance-test results, comorbid conditions, and access.

- In the setting of virologic suppression in treatment-experienced individuals, the following INSTI-based ART are for consideration:
  - CAB/RPV IM is the only long acting INSTI, and may be prescribed in individuals with HIV currently on oral ART with documented viral suppression for at least 3 to 6 months who have good adherence and engagement in care, no baseline resistance to either medication, have no prior virologic failures, do not have active or occult HBV infection (unless also receiving an oral HBV active regimen), are not pregnant and are not planning on becoming pregnant, and are not receiving medications with significant drug interactions with oral (during lead-in or bridging therapy) or injectable CAB or RPV (**AI**). Individuals who miss doses or discontinue therapy with long-acting ARVs without bridging with an oral ARV regimen are at increased risk of virologic failure with development of drug resistance. Continuation of therapy should be re-assessed.

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.

References

1. Anderson PL, Kakuda TN, Fletcher CV. Chapter 143: Human immunodeficiency virus infection. In: DiPiro JT, Yee GC, Posey LM, Haines ST, Nolin TD, Ellingrod V, editors. *Pharmacotherapy: A Pathophysiologic Approach*, 11th edition. McGraw-Hill Medical, 2020.
2. Cabenuva [package insert]. Research Triangle Park: ViiV Healthcare; September 2024.
3. CDC. US Public Health Service Preexposure Prophylaxis for The Prevention Of HIV Infection in the United States – 2021 Update. Preexposure prophylaxis for the prevention of HIV infection in the United States -- 2021 update : a clinical practice guideline.Accessed March 24, 2025.
4. Chounta V, Overton ET, Mills A, et al. Patient-Reported Outcomes Through 1 Year of an HIV-1 Clinical Trial Evaluating Long-Acting Cabotegravir and Rilpivirine Administered Every 4 or 8 Weeks (ATLAS-2M). *Patient*. 2021 Nov;14(6):849-862.
5. DHHS panel on antiretroviral guidelines for adults and adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents living with HIV. Updated December 6, 2023[a]. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf. Accessed March 26, 2025.
6. DHHS panel on antiretroviral therapy and medical management of children living with HIV. Guidelines for the use of antiretroviral agents in pediatric HIV infection. Updated April 11, 2023[b].

https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/pedia
Accessed March 26, 2025.

7. DHHS panel on treatment of HIV during pregnancy and prevention of perinatal transmission. Recommendations for the use of antiretroviral drugs during pregnancy and interventions to reduce perinatal HIV transmission in the United States. Updated January 31, 2023[c]. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/perinatal-hiv/guidelines-perinatal.pdf. Accessed March 26, 2025.
8. Jaeger H, Overton ET, Richmond G, et al. Long-acting cabotegravir and rilpivirine dosed every 2 months in adults with HIV-1 infection (ATLAS-2M), 96-week results: a randomised, multicentre, open-label, phase 3b, non-inferiority study. *Lancet HIV* 2021 Nov;8(11):e679-e689.
9. Micromedex Healthcare Series Website. http:/www.micromedexsolutions.com/home/dispatch. Accessed March 26, 2025.
10. Orkin C, Arasteh K, Gorgolas M, et al. Long-Acting Cabotegravir and Rilpivirine after Oral Induction for HIV-1 Infection (FLAIR). *N Engl J Med* 2020[a]; 382:1124-1135.
11. Orkin C, DeJesus E, Sax P, et al. Fixed-dose combination bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir-containing regimens for initial treatment of HIV-1 infection: week 144 results from two randomised, double-blind, multicentre, phase 3, non-inferiority trials. *Lancet HIV*. 2020;7(6):e389-e400.
12. Orkin C, Oka S, Philibert P, et al. Long-acting cabotegravir plus rilpivirine for treatment in adults with HIV-1 infection: 96-week results of the randomised, open-label, phase 3 FLAIR study. *Lancet HIV*. 2021 [a] Apr;8(4):e185-e196.
13. Orkin C, Morell EB, Tan DHS, et al. Initiation of long-acting cabotegravir plus rilpivirine as direct-to-injection or with an oral lead-in in adults with HIV-1 infection: week 124 results of the open-label phase 3 FLAIR study. *Lancet HIV*. 2021 [b];8(11):e668-e678.
14. Overton ET, Richmond GJ, Rizzardini G, et al. Long-acting cabotegravir and rilpivirine dosed every 2 months in adults with HIV-1 infection (ATLAS-2M), 48-week results: a randomised, multicentre, open-label, phase 3b, non-inferiority study. *Lancet*. 2020;396(10267):1994-2005.
15. Overton ET, Richmond G, Rizzardini G, et al. Long-acting cabotegravir and rilpivirine dosed every 2 months in adults with HIV infection: 152-week results from ATLAS-2M, a randomized, open-label, Phase 3b, noninferiority study. Clin Infect Dis. 2023;76(9):1646-1654.
16. Ramgopal MN, Castagna A, Cazanave C, et al. Efficacy, safety, and tolerability of switching to long-acting cabotegravir plus rilpivirine versus continuing fixed-dose bictegravir, emtricitabine, and tenofovir alafenamide in virologically suppressed adults with HIV, 12-month results (SOLAR): a randomised, open-label, phase 3b, non-inferiority trial. *Lancet HIV*. 2023;10(9):e566-e577. doi:10.1016/S2352-3018(23)00136-4
17. Swindells S, Andrade-Villanueva JF, Richmond GJ, et al. Long-Acting Cabotegravir and Rilpivirine for Maintenance of HIV-1 Suppression (ATLAS). *N Engl J Med*. 2020;382(12):1112-1123.
18. Swindells S, Lutz T, Van Zyl L, et al. Week 96 extension results of a Phase 3 study evaluating long-acting cabotegravir with rilpivirine for HIV-1 treatment (ATLAS). *AIDS.* 2022 Feb 1;36(2):185-194.
19. Gandhi RT, Bedimo R, Hoy JF, et al. Antiretroviral drugs for treatment and prevention of HIV Infection in adults: 2022 recommendations of the International Antiviral Society-USA Panel. JAMA. 2023;329(1):63-84. doi:10.1001/jama.2022.22246
20. US Preventive Services Task Force (USPSTF). Prevention of Acquisition of HIV: Preexposure Prophylaxis: Final Recommendation Statement. August 22, 2023. https://uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis. Accessed March 26, 2025.

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.

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 اعلى رقم الهاتف1-800-332-6501(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 zurVerfügung. 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_ध 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 numer1-800-332-6501 (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 al1-800-332-6501 (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 Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).