BIKTARVY® IS FDA APPROVED FOR PWH

Restarting ART[1]

People featured are compensated by Gilead.

THE FIRST AND ONLY STR

to receive an FDA-approved label expansion for use in PWH with an ART history who are not virologically suppressed[1]

INDICATION

BIKTARVY is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥14 kg with no antiretroviral (ARV) treatment history; or with an ARV treatment history and not virologically suppressed, with no known or suspected substitutions associated with resistance to the integrase strand inhibitor class, emtricitabine, or tenofovir; or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Severe acute exacerbations of hepatitis B have been reported in patients with HIV-1 and HBV who have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients with HIV-1 and HBV who discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.**

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

ART, antiretroviral therapy; FDA, US Food and Drug Administration; PWH, people with HIV; STR, single-tablet regimen.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

When Treatment Gaps Occur, Irreversible Drug Resistance Can Develop[2,3]

Based on a retrospective study evaluating ART adherence and treatment gaps in TN and TE PWH on Medicare who initiated or switched their regimen (N=48,627)[4,*]:

55%
had at least one continuous treatment gap
≥7 days

26%
had a treatment gap
≥30 days

10%
discontinued treatment
≥90 days

Adherence to anchor medications (PIs, NNRTIs, or INSTIs) was measured using prescription fill data collected from Medicare between 2014 and 2017, including fill date and days' supply reported on each prescription claim.[4]

*The fill date of the first prescription of the new anchor medication was deemed the index date. Treatment gaps were defined as periods with no supply of an anchor medication after the days' supply of the most recent ART prescription was exhausted. Discontinuation of treatment was defined as a continuous 90-day gap without any anchor medication supply.[4]

DHHS guidelines recommend choosing a **high barrier to resistance** regimen for PWH with adherence challenges.[3,†]

Continue to counsel patients to take their medication as prescribed.

†Please see DHHS guidelines for specific recommended antiretrovirals.

ART, antiretroviral therapy; DHHS, US Department of Health and Human Services; INSTIs, integrase strand transfer inhibitors; NNRTIs, non-nucleoside reverse transcriptase inhibitors; PIs, protease inhibitors; PWH, people with HIV; TE, treatment-experienced; TN, treatment-naïve.

IF DEVELOPED,

Resistance May Limit Future Treatment Options—A Risk to the Individual and the Community[2,5]

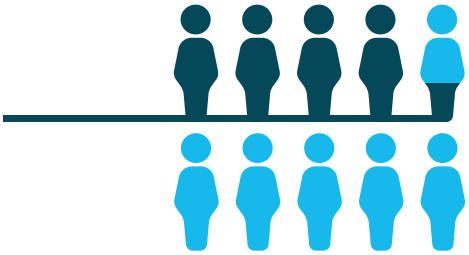
APPROXIMATELY

1 in 3 **diagnosed PWH are not virologically suppressed[6]**

According to the CDC at year end 2023.[6]

According to DHHS guidelines, virologic failure may be associated with a variety of factors, including HIV-related, ART-related, or social- and adherence-related factors.[3]

43% **of new HIV transmissions**



were a result of people who **were aware of their HIV status, but not engaged in care[7]**

Based on a 2019 CDC report on HIV transmissions in 2016.[7]

According to DHHS, **achieving and maintaining an undetectable viral load prevents sexual transmission of HIV (U=U)*** and may help delay or prevent treatment-emergent resistance.[3]

*According to the DHHS guidelines, achieving and maintaining an undetectable viral load (HIV RNA <200 copies/mL) for at least 6 months prevents sexual transmission of HIV to partners.[3]

ART, antiretroviral therapy; CDC, US Centers for Disease Control and Prevention; DHHS, US Department of Health and Human Services; PWH, people with HIV; RNA, ribonucleic acid; U=U, undetectable=untransmittable.

BIKTARVY® Is Indicated for Most People With HIV-1 When Starting, Restarting, or Switching ART[1,5,8]

Differences in indications for select HIV treatment regimens

	 **BIKTARVY[1,*]** (bictegravir/ emtricitabine/tenofovir alafenamide)	 **DOVATO®[9,*]** (dolutegravir/ lamivudine)	 **SYMTUZA®[10,*]** (darunavir/cobicistat/ emtricitabine/tenofovir alafenamide)	 **CABENUVA®[11,*]** (cabotegravir/ rilpivirine)
	Indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥14 kg	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 25 kg	Indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 40 kg	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
TREATMENT-NAÏVE No antiretroviral treatment history	✓	✓	✓	✗
TREATMENT-EXPERIENCED AND NOT VIROLOGICALLY SUPPRESSED	✓ • with no known or suspected substitutions associated with resistance to the integrase strand inhibitor class, emtricitabine, or tenofovir	✗	✗	✗
VIROLOGICALLY SUPPRESSED To replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable ARV regimen	✓ • with no known or suspected substitutions associated with resistance to bictegravir or tenofovir	✓ • with no history of treatment failure ***and*** • no known substitutions associated with resistance to the individual components of DOVATO	✓ • for at least 6 months ***and*** • have no known substitutions associated with resistance to darunavir or tenofovir	✓ • with no history of treatment failure ***and*** • with no known or suspected resistance to either cabotegravir or rilpivirine

This chart showing indications is not intended to compare clinical efficacy or effectiveness, safety, tolerability, dosing, or use considerations. Please refer to the full prescribing information for each medication, including for information on warnings and precautions, use in specific populations, and clinical data.

Restarting ART can be an opportunity to reassess an individual's regimen[3]

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- **Coadministration:** Do not use BIKTARVY with dofetilide or rifampin.

Warnings and precautions

- **Drug interactions:** See Contraindications and Drug Interactions sections. Consider the potential for drug interactions prior to and during BIKTARVY therapy and monitor for adverse reactions.

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

BIKTARVY®
bictegravir 50mg/emtricitabine 200mg/ tenofovir alafenamide 25mg tablets

*Products shown are not actual size.

ART, antiretroviral therapy; ARV, antiretroviral; RNA, ribonucleic acid.

BIKTARVY® Is DHHS Guideline–Recommended in a Broad Range of PWH[3,12,13]

- As an **initial regimen for most people** living with HIV[3]
- As a **preferred initial regimen for children** with HIV ≥2 years old weighing ≥14 kg[12]
- As a **preferred ARV for use during pregnancy** when switching to a new regimen* or for starting a regimen **when trying to conceive** per the perinatal guidelines[13]
- In virologically suppressed people with **M184V/I resistance mutation (BIII)**[3,†]
- For **those with adherence challenges**[3]
  - Other considerations include side effects, out-of-pocket costs, convenience, and patient preferences. *Counsel your patients to take BIKTARVY once daily*[1,3]

BIKTARVY is recommended in pregnant individuals who are virologically suppressed on a stable ARV regimen with no known substitutions associated with resistance to any of the individual components of BIKTARVY. Lower plasma exposures of BIKTARVY were observed during pregnancy; therefore, viral load should be monitored closely during pregnancy.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.
- **New onset or worsening renal impairment:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with tenofovir alafenamide (TAF)–containing products. Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min except in virologically suppressed adults <15 mL/min who are receiving chronic hemodialysis. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue BIKTARVY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome.
  Renal monitoring: Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, assess serum phosphorus.
- **Lactic acidosis and severe hepatomegaly with steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including FTC and TDF. Discontinue BIKTARVY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse reactions

- **Most common adverse reactions** (incidence ≥5%; all grades) in clinical studies through week 144 were diarrhea (6%), nausea (6%), and headache (5%).

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

*When current regimen is not well tolerated.
†Rating of recommendation: B=Moderate. Rating of evidence: III=Expert opinion.

ARV, antiretroviral; DHHS, US Department of Health and Human Services; PWH, people with HIV.

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BIKTARVY® Is the Only INSTI-Based STR Recommended by the DHHS Guidelines for Rapid Initiation[1,3]

BIKTARVY can be started immediately in your appropriate patients after diagnosis without waiting for testing results[1,3,*]

According to DHHS guidelines, the following tests should be performed at treatment initiation[3]:

- **Resistance**
- **HBV**
- **CD4 count**
- **Viral load**

However, you do not have to wait for these test results before starting your patients on BIKTARVY.*

People who acquired HIV after having received long-acting cabotegravir as pre-exposure prophylaxis should wait for results of an INSTI resistance test before beginning treatment with BIKTARVY.

When the results of drug-resistance tests are available, the treatment regimen can be modified if needed.[3]

- BIKTARVY is not indicated for patients with known or suspected substitutions associated with resistance to bictegravir or tenofovir[1]
- BIKTARVY is not recommended in patients with severe hepatic impairment (Child-Pugh Class C). For patients weighing ≥25 kg, BIKTARVY is not recommended in patients with severe renal impairment (estimated CrCl <30 mL/min) except in virologically suppressed patients with CrCl <15 mL/min on chronic hemodialysis. BIKTARVY is not recommended for patients weighing ≥14 kg to <25 kg with CrCl <30 mL/min[1]

Testing with BIKTARVY according to the Prescribing Information:

- Prior to or when initiating BIKTARVY, and during treatment, assess serum creatinine, estimated CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, assess serum phosphorus[1]
- Prior to or when initiating BIKTARVY, test for hepatitis B virus infection[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions

- **Prescribing information:** Consult the full prescribing information for BIKTARVY for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.
- **Enzymes/transporters:** Drugs that induce P-gp or induce both CYP3A and UGT1A1 can substantially decrease the concentration of components of BIKTARVY. Drugs that inhibit P-gp, BCRP, or inhibit both CYP3A and UGT1A1 may significantly increase the concentrations of components of BIKTARVY. BIKTARVY can increase the concentration of drugs that are substrates of OCT2 or MATE1.
- **Drugs affecting renal function:** Coadministration of BIKTARVY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of FTC and tenofovir and the risk of adverse reactions.

Please see additional Important Safety Information on the following pages, and click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

*Except for individuals with a history of long-acting cabotegravir as pre-exposure prophylaxis, where genotype testing done before the start of ART should include screening for integrase strand transfer inhibitor (INSTI)-resistance mutations. Because of the long half-life of CAB-LA, persistent drug exposure at levels suboptimal to prevent infection may select for INSTI-resistant virus.[3]

ART, antiretroviral therapy; CAB-LA, long-acting cabotegravir; CD4, cluster of differentiation 4; CrCl, creatinine clearance; DHHS, US Department of Health and Human Services; HBV, hepatitis B virus; INSTI, integrase strand transfer inhibitor; STR, single-tablet regimen.

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bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

Consider BIKTARVY® for Rapid Restart[1]

BIKTARVY can also be restarted immediately in your appropriate patients without waiting for testing results[1,3]

Management strategies should be individualized, including assessment of viral load, resistance testing, ART history, adherence, and potential drug interactions[3]

BIKTARVY is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥14 kg with no antiretroviral (ARV) treatment history; or with an ARV treatment history and not virologically suppressed, with no known or suspected substitutions associated with resistance to the integrase strand inhibitor class, emtricitabine, or tenofovir.[1]

Please see Important Safety Information below regarding use in patients with renal and hepatic impairment, and testing requirements prior to or when initiating BIKTARVY.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration

- **Dosage:** Adult and pediatric patients weighing ≥25 kg: 1 tablet containing 50 mg bictegravir (BIC), 200 mg emtricitabine (FTC), and 25 mg tenofovir alafenamide (TAF) taken once daily with or without food. Pediatric patients weighing ≥14 kg to <25 kg: 1 tablet containing 30 mg BIC, 120 mg FTC, and 15 mg TAF taken once daily with or without food. For these pediatric patients, who are unable to swallow a whole tablet, the tablet can be split and each part taken separately as long as all parts are ingested within approximately 10 minutes.
- **Renal impairment:** For patients weighing ≥25 kg, not recommended in patients with CrCl 15 to <30 mL/min, or <15 mL/min who are not receiving chronic hemodialysis, or <15 mL/min who are receiving chronic hemodialysis and have no antiretroviral treatment history. For patients weighing ≥14 kg to <25 kg, not recommended in patients with CrCl <30 mL/min.
- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.
- **Prior to or when initiating:** Test patients for HBV infection.
- **Prior to or when initiating, and during treatment:** As clinically appropriate, assess serum creatinine, CrCl, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, assess serum phosphorus.

Pregnancy and lactation

- **Pregnancy:** BIKTARVY is recommended in pregnant individuals who are virologically suppressed on a stable ARV regimen with no known substitutions associated with resistance to any of the individual components of BIKTARVY. Lower plasma exposures of BIKTARVY were observed during pregnancy; therefore, viral load should be monitored closely during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for BIC, FTC, or TAF show no difference in the rates of birth defects compared with a US reference population.
- **Lactation:** Individuals with HIV-1 should be informed of the potential risks of breastfeeding.

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ART, antiretroviral therapy.

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#1 BIKTARVY® Is the #1 Prescribed Regimen Across the HIV-1 Treatment Journey for Starting, Restarting, and Switching ART[14,*]

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INDICATION

BIKTARVY is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥14 kg with no antiretroviral (ARV) treatment history; or with an ARV treatment history and not virologically suppressed, with no known or suspected substitutions associated with resistance to the integrase strand inhibitor class, emtricitabine, or tenofovir; or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies per mL) on a stable ARV regimen with no known or suspected substitutions associated with resistance to bictegravir or tenofovir.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- **Severe acute exacerbations of hepatitis B have been reported in patients with HIV-1 and HBV who have discontinued products containing emtricitabine (FTC) and/or tenofovir disoproxil fumarate (TDF), and may occur with discontinuation of BIKTARVY. Closely monitor hepatic function with both clinical and laboratory follow-up for at least several months in patients with HIV-1 and HBV who discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.**

Please click to see full Prescribing Information for BIKTARVY, including **BOXED WARNING**.

ART, antiretroviral therapy; LAAD, Longitudinal Access and Adjudication Data.

References: 1. BIKTARVY. Prescribing information. Gilead Sciences, Inc.; 2025. **2.** Ehrenkranz P, Rosen S, Boulle A, et al. The revolving door of HIV care: Revising the service delivery cascade to achieve the UNAIDS 95-95-95 goals. *PLoS Med.* 2021;18(5):e1003651. **3.** 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 September 25, 2025. Accessed October 2, 2025. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new **4.** Li P, Prajapati G, Geng Z, et al. Antiretroviral treatment gaps and adherence among people with HIV in the U.S. Medicare Program. *AIDS Behav.* 2024;28(3):1002-1014. **5.** Kagan RM, Baxter JD, Kim T, Marlowe EM. HIV-1 drug resistance trends in the era of modern antiretrovirals: 2018-2024. Poster presented at: Conference on Retroviruses and Opportunistic Infections (CROI); March 9-12, 2025; San Francisco, CA. Poster 730. **6.** Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data—United States and 6 Territories and Freely Associated States, 2023. Centers for Disease Control and Prevention. Published April 29, 2025. Accessed November 25, 2025. https://www.cdc.gov/hiv-data/nhss/national-hiv-prevention-and-care-outcomes.html **7.** Li Z, Purcell DW, Sansom SL, Hayes D, Hall HI. Vital signs: HIV transmission along the continuum of care — United States, 2016. *MMWR Morb Mortal Wkly Rep.* 2019;68:267-272. **8.** Bajema KL, Nance RM, Delaney JAC, et al. Substantial decline in heavily treated therapy-experienced persons with HIV with limited antiretroviral treatment options. *AIDS*. 2020;34(14):2051-2059. **9.** DOVATO. Package insert. ViiV Healthcare; 2025. **10.** SYMTUZA. Package insert. Janssen Pharmaceuticals; 2023. **11.** CABENUVA. Package insert. ViiV Healthcare; 2025. **12.** Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Department of Health and Human Services. Updated September 30, 2025. Accessed October 2, 2025. https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv/whats-new **13.** Panel on HIV Treatment 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. Department of Health and Human Services. Updated June 12, 2025. Accessed October 2, 2025. https://clinicalinfo.hiv.gov/en/guidelines/perinatal **14.** Data on file. Gilead Sciences, Inc.

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