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

The BIKTARVY® Difference

Select differences in FDA-approved labeling and DHHS guideline recommendations for **BIKTARVY** and **CABENUVA**® (cabotegravir/rilpivirine)

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

DHHS, US Department of Health and Human Services; FDA, US Food and Drug Administration.

The BIKTARVY® Difference

Review select differences between
BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide) and
CABENUVA® (cabotegravir/rilpivirine).

FDA-approved indications, dosing, and select in-label information

Select DHHS guideline recommendations

BIKTARVY*
(BIC/FTC/TAF)

CABENUVA*
(IM CAB + RPV)

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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.
- **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.

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

*Products shown are not actual size.

BIC, bictegravir; CAB, cabotegravir; DHHS, US Department of Health and Human Services; FDA, US Food and Drug Administration; FTC, emtricitabine; IM, intramuscular; RPV, rilpivirine; TAF, tenofovir alafenamide.

FDA Approved for Starting, Restarting, and Switching ART

BIKTARVY®[1] (BIC/FTC/TAF)	CABENUVA®[2] (IM CAB + RPV)
YES	NOT FDA APPROVED FOR STARTING OR RESTARTING ART
BIKTARVY is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥14 kg: **START:** with no antiretroviral (ARV) treatment history, or **RESTART:** 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 **SWITCH:** 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.	CABENUVA 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: **SWITCH:** 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.

Source: Prescribing Information, section 1: *Indications and Usage*

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IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **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.

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; BIC, bictegravir; CAB, cabotegravir; DHHS, US Department of Health and Human Services; FDA, US Food and Drug Administration; FTC, emtricitabine; IM, intramuscular; RNA, ribonucleic acid; RPV, rilpivirine; TAF, tenofovir alafenamide.

Duration of In-Label Phase 3 Clinical Trial Follow-Up

BIKTARVY®[1] (BIC/FTC/TAF)	CABENUVA®[2] (IM CAB + RPV)
UP TO 240 WEEKS	**UP TO 124 WEEKS**
Trials 1489 and 1490 were phase 3 noninferiority trials in adults with no antiretroviral treatment history: 144-week, double-blind, active-controlled phase in which 634 participants received BIKTARVY, followed by an extension phase in which 1025 participants from Trials 1489 and 1490 received open-label BIKTARVY for 96 weeks. Trial 1844 was a phase 3, randomized, double-blind, active-controlled, noninferiority trial in virologically suppressed adults (HIV-1 RNA less than 50 copies per mL) switching to BIKTARVY (n=282) through 48 weeks. Trial 1878 was a phase 3, randomized, open-label, active-controlled, noninferiority trial in virologically suppressed adults (HIV-1 RNA less than 50 copies per mL) switching to BIKTARVY (n=290) through 48 weeks.	CABENUVA has been evaluated in 2 phase 3 randomized, multicenter, active-controlled, parallel-arm, open-label, non-inferiority trials: • Trial 201584 (FLAIR): antiretroviral treatment (ART)-naïve participants (n=629) received DTG-containing regimen for 20 weeks; participants who were virologically suppressed (HIV-1 RNA <50 copies/mL) (n=566) were then randomized (1:1) to receive either CAB + RPV (n=283) or remain on current regimen (n=283) for 96 weeks • In the FLAIR study extension phase (Week 100 to Week 124), CABENUVA was evaluated in patients who switched at Week 100 (n=232) from their current ART to CABENUVA • Trial 201585 (ATLAS), virologically suppressed (HIV-1 RNA <50 copies/mL) participants (n=616) were randomized to remain on their current ART (n=308) or CAB + RPV (n=308) for 48 weeks Trial 207966 (ATLAS-2M): CABENUVA dosed every 2 months has been evaluated in 1 phase 3b randomized, multicenter, parallel-arm, open-label, noninferiority trial in virologically suppressed participants (n=1045) who were randomized to receive CAB + RPV dosed monthly or every 2 months for 48 weeks.

Source: Prescribing Information, section 14: *Clinical Studies*

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IMPORTANT SAFETY INFORMATION (cont'd)

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**.

BIC, bictegravir; CAB, cabotegravir; DHHS, US Department of Health and Human Services; DTG, dolutegravir; FTC, emtricitabine; IM, intramuscular; RNA, ribonucleic acid; RPV, rilpivirine; TAF, tenofovir alafenamide.

Extensively Studied Across In-Label Clinical Trials in Virologically Suppressed PWH Aged 65 Years and Older

BIKTARVY®[1] (BIC/FTC/TAF)	CABENUVA®[2] (IM CAB + RPV)
YES Clinical trials in virologically suppressed participants (Trials 4449, 1844, and 1878) included 111 participants aged 65 years and over who received BIKTARVY.	NO Clinical trials of CABENUVA did not include sufficient numbers of participants aged 65 years and older to determine whether they respond differently from younger participants.

Source: Prescribing Information, section 8.5: *Geriatric Use*

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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.

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.

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

BIC, bictegravir; CAB, cabotegravir; DHHS, US Department of Health and Human Services; FTC, emtricitabine; IM, intramuscular; PWH, people with HIV; RPV, rilpivirine; TAF, tenofovir alafenamide.

In-Label Clinical Trial in Virologically Suppressed PWH Who Are Pregnant

BIKTARVY®[1] (BIC/FTC/TAF)	CABENUVA®[2] (IM CAB + RPV)
YES	NO
BIKTARVY was evaluated in an open-label clinical trial of 33 virologically suppressed (HIV-1 RNA <50 copies/mL) pregnant adults with HIV-1 and no known substitutions associated with resistance to BIC, FTC, or TAF.	There are insufficient human data on the use of CABENUVA during pregnancy to adequately assess a drug-associated risk of birth defects and miscarriage.

Source: Prescribing Information, section 8.1: *Pregnancy*

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IMPORTANT SAFETY INFORMATION (cont'd)

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.

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

BIC, bictegravir; CAB, cabotegravir; DHHS, US Department of Health and Human Services; FTC, emtricitabine; IM, intramuscular; PWH, people with HIV; RNA, ribonucleic acid; RPV, rilpivirine; TAF, tenofovir alafenamide.

FDA Approved for Pediatric Patients With HIV Weighing ≥14 kg

BIKTARVY®[1] (BIC/FTC/TAF)	CABENUVA®[2] (IM CAB + RPV)
YES	NO
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.	CABENUVA is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older 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.

Source: Prescribing Information, section 1: *Indications and Usage*

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IMPORTANT SAFETY INFORMATION (cont'd)

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**.

ARV, antiretroviral; BIC, bictegravir; CAB, cabotegravir; DHHS, US Department of Health and Human Services; FDA, US Food and Drug Administration; FTC, emtricitabine; IM, intramuscular; RNA, ribonucleic acid; RPV, rilpivirine; TAF, tenofovir alafenamide.

FDA-Approved Dosing and Administration Does Not Require Injections 6 Times a Year Administered by a Healthcare Provider

BIKTARVY®[1] (BIC/FTC/TAF)	CABENUVA®[2] (IM CAB + RPV)
YES	NO
The recommended dosage of BIKTARVY is one tablet taken orally once daily with or without food.	• CABENUVA must be administered by a healthcare provider by gluteal intramuscular injection • CABENUVA can be injected monthly or every 2 months

Source: Prescribing Information, section 2: *Dosage and Administration*

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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.
- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.

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

BIC, bictegravir; CAB, cabotegravir; DHHS, US Department of Health and Human Services; FDA, US Food and Drug Administration; FTC, emtricitabine; IM, intramuscular; RPV, rilpivirine; TAF, tenofovir alafenamide.

Can Be Stored at Room Temperature

BIKTARVY®[1] (BIC/FTC/TAF)	CABENUVA®[2] (IM CAB + RPV)
YES	NO
• Store bottle below 30 °C (86 °F) • Store blister pack at 25 °C (77 °F), excursions permitted to 15–30 °C (59–86 °F) (see USP Controlled Room Temperature).	• Store CABENUVA in the refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton until ready to use. Do not freeze. Do not mix with any other product or diluent • Prior to administration, vials should be brought to room temperature (not to exceed 25°C [77°F]). Vials may remain in the carton at room temperature for up to 6 hours; do not put back into the refrigerator. If not used within 6 hours, they must be discarded.

Source: Prescribing Information, section 16: *How Supplied/Storage and Handling*

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IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **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.

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

BIC, bictegravir; CAB, cabotegravir; DHHS, US Department of Health and Human Services; FTC, emtricitabine; IM, intramuscular; RPV, rilpivirine; TAF, tenofovir alafenamide.

DHHS Guidelines–Recommended for Rapid Initiation for PWH Who Do Not Have a History of Using CAB-LA as PrEP

BIKTARVY®[3] (BIC/FTC/TAF)	CABENUVA®[3] (IM CAB + RPV)
RECOMMENDED	**NOT RECOMMENDED**
BIKTARVY is recommended for use in people who have not previously used CAB-LA for PrEP and plan to start ART before resistance testing results are available (eg, with rapid initiation of ART after diagnosis).	Not recommended as initial therapy for people with HIV because of the lack of data supporting the efficacy of this combination in people who are ART-naïve.

Source: DHHS guidelines, *What to Start, Initial Combination Antiretroviral Regimens for People With HIV;* Table 7, *Antiretroviral Regimen Considerations for Initial Therapy Based on Specific Clinical Scenarios*

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Required testing at initiation of BIKTARVY:

According to DHHS guidelines, the following tests should be performed at treatment initiation: resistance, CD4 count, viral load, and HBV. However, you do not have to wait for these test results before starting your patients on BIKTARVY.[3]

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

Testing with BIKTARVY according to the Prescribing Information[1]:

- 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
- Prior to or when initiating BIKTARVY, test for hepatitis B virus infection

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]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **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.

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; BIC, bictegravir; CAB, cabotegravir; CAB-LA, long-acting cabotegravir; CD4, cluster of differentiation 4; CrCl, creatinine clearance; DHHS, US Department of Health and Human Services; FTC, emtricitabine; HBV, hepatitis B virus; IM, intramuscular; PrEP, pre-exposure prophylaxis; PWH, people with HIV; RPV, rilpivirine; TAF, tenofovir alafenamide.

DHHS Guidelines–Recommended as an Initial ART Regimen for Most PWH Who Do Not Have a History of Using CAB-LA as PrEP

BIKTARVY®[3] (BIC/FTC/TAF)	CABENUVA®[3] (IM CAB + RPV)
RECOMMENDED	**NOT RECOMMENDED**
BIKTARVY is recommended as an initial regimen for most people with HIV.	The Panel does not recommend the LA CAB/RPV as initial therapy for people with HIV because of the lack of data supporting the efficacy of this combination in people who are ART-naïve.

Source: DHHS guidelines, *What to Start; Initial Combination Antiretroviral Regimens for People With HIV* (Table 6a, *Recommended Initial Regimens for Most People With HIV*)

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According to DHHS guidelines, selection of antiretroviral therapy (ART) should be based on the regimen's virologic efficacy, potential adverse effects, pill burden, dosing frequency, drug–drug interaction potential, cost, access, resistance test results, and the comorbid condition of the person with HIV.[3]

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

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

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**.

ART, antiretroviral therapy; BIC, bictegravir; CAB, cabotegravir; CAB-LA, long-acting cabotegravir; DHHS, US Department of Health and Human Services; FTC, emtricitabine; IM, intramuscular; LA, long-acting; PrEP, pre-exposure prophylaxis; PWH, people with HIV; RPV, rilpivirine; TAF, tenofovir alafenamide.

DHHS Pediatric Guidelines–Recommended as a Preferred Initial ART Regimen for Children With HIV Aged ≥2 Years Old and Weighing ≥14 kg

BIKTARVY®[4] (BIC/FTC/TAF)	CABENUVA®[4] (IM CAB + RPV)
RECOMMENDED	**NOT RECOMMENDED**
INSTI-based regimens (INSTI plus 2 NRTIs) are preferred for initial ART.	The regimen of LAI CAB and RPV is not approved or recommended for initial ARV therapy.
Source: DHHS pediatric guidelines, *Panel Recommendations for Initial Antiretroviral Therapy Regimens in Infants and Children*	Source: DHHS pediatric guidelines, *Antiretroviral Drugs and Drug Combinations Not Recommended for Initial Therapy in Children*

This chart should not be interpreted to imply comparable indications or patient populations, and does not compare clinical efficacy or effectiveness, safety, or tolerability. This information is not comprehensive or intended to be a full re-creation of the DHHS guidelines or product labeling. Please refer to the full prescribing information for each medication, including for information on warnings and precautions, use in specific populations, and clinical data. Please refer to the full DHHS guidelines for comprehensive recommendations.

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.

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; ARV, antiretroviral; BIC, bictegravir; CAB, cabotegravir; DHHS, US Department of Health and Human Services; FTC, emtricitabine; IM, intramuscular; INSTI, integrase strand transfer inhibitor; LAI, long-acting injectable; NRTI, nucleoside reverse transcriptase inhibitor; RPV, rilpivirine; TAF, tenofovir alafenamide.

DHHS Perinatal Guidelines–Recommended as a Preferred ARV for Use During Pregnancy When Switching to a New Regimen or for Starting a Regimen When Trying to Conceive

BIKTARVY®[5] (BIC/FTC/TAF)		CABENUVA®[5] (IM CAB + RPV)
PREFERRED		INSUFFICIENT DATA
Preferred	Switching to a new ART regimen during pregnancy when current regimen is not well tolerated	Insufficient data
Preferred	Starting ART when trying to conceive*	Insufficient data

Section: DHHS perinatal guidelines, Table 7, *Situation-Specific Recommendations for Use of Antiretroviral Drugs During Pregnancy and When Trying to Conceive*

This chart should not be interpreted to imply comparable indications or patient populations, and does not compare clinical efficacy or effectiveness, safety, or tolerability. This information is not comprehensive or intended to be a full re-creation of the DHHS guidelines or product labeling. Please refer to the full prescribing information for each medication, including for information on warnings and precautions, use in specific populations, and clinical data. Please refer to the full DHHS guidelines for comprehensive recommendations.

*This guidance is intended only when actively trying to conceive in the context of starting ART for the first time or currently receiving ART. For ART recommendations where the possibility exists for unintended pregnancy, please see Adult and Adolescent Antiretroviral Guidelines.

IMPORTANT SAFETY INFORMATION (cont'd)

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; ARV, antiretroviral; BIC, bictegravir; CAB, cabotegravir; DHHS, US Department of Health and Human Services; FTC, emtricitabine; IM, intramuscular; RPV, rilpivirine; TAF, tenofovir alafenamide.

Why BIKTARVY®

prescribed regimen for people **starting, restarting,** and **switching** HIV-1 treatment[6]

Source: *IQVIA LAAD*, August 2025*

Rapid Initiation

DHHS guidelines–recommended for **rapid initiation** for PWH who do not have a history of using CAB-LA as PrEP[3]

Please see page 10 for information on testing required prior to or when initiating BIKTARVY

5-Year Treatment-Naïve Data

The only DHHS guidelines–recommended initial regimen for most PWH with **5 years of efficacy, resistance, and safety data** from phase 3 clinical trials[1,3]

*This information is an estimate derived from the use of information under license from the following IQVIA information service: *IQVIA LAAD*, for the period of August 2025. IQVIA expressly reserves all rights, including rights of copying, distribution, and republication.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

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

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

CAB-LA, long-acting cabotegravir; DHHS, US Department of Health and Human Services; LAAD, Longitudinal Access and Adjudication Data; PrEP, pre-exposure prophylaxis; PWH, people with HIV.

Why BIKTARVY®

Use During Pregnancy

DHHS perinatal guidelines-recommended as a preferred ARV **for use in PWH during pregnancy** when switching to a new regimen or for starting ART when trying to conceive[5]

The only second-generation INSTI-based STR with in-label clinical trial data exclusively in VS adults who are pregnant[1]

Pediatric Patients

FDA approved and DHHS guidelines–recommended as a preferred initial regimen **for pediatric patients with HIV** aged ≥2 years old and weighing ≥14 kg[1,4]

Adults Aged ≥65 Years

Extensively studied across in-label clinical trials in virologically suppressed PWH aged **65 years and older**[1]

Nearly 500,000 PWH take BIKTARVY® as their HIV-1 treatment[6]

Source: *IQVIA LAAD*, July 2022 through July 2025*

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IMPORTANT SAFETY INFORMATION (cont'd)

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.
- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported.

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

ART, antiretroviral therapy; ARV, antiretroviral; DHHS, US Department of Health and Human Services; FDA, US Food and Drug Administration; INSTI, integrase strand transfer inhibitor; LAAD, Longitudinal Access and Adjudication Data; PWH, people with HIV; STR, single-tablet regimen; VS, virologically suppressed.

BIKTARVY®

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

Why BIKTARVY®

Learn more at BiktarvyHCP.com

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

References: 1. BIKTARVY. Prescribing information. Gilead Sciences, Inc.; 2025. **2.** CABENUVA. Prescribing information. ViiV Healthcare; 2024. **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 September 25, 2025. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf **4.** 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 **5.** 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 29, 2025. https://clinicalinfo.hiv.gov/en/guidelines/perinatal **6.** Data on file. Gilead Sciences, Inc.; 2025.

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