

#1 PRESCRIBED REGIMEN FOR HIV-1 TREATMENT

Source: Ipsos Healthcare US HIV Therapy Monitor & Scope Study Oct-Dec 2019.



BIKTARVY®

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

Indication

BIKTARVY® is indicated as a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients weighing ≥ 25 kg who have no antiretroviral (ARV) treatment history 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 history of treatment failure and no known resistance to any component of BIKTARVY.

Important Safety Information

BOXED WARNING: POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

- Severe acute exacerbations of hepatitis B have been reported in patients who are coinfecting with HIV-1 and HBV and 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 who are coinfecting with HIV-1 and HBV and discontinue BIKTARVY. If appropriate, anti-hepatitis B therapy may be warranted.

RNA = ribonucleic acid.

Please click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY](#)®.





BIKTARVY[®]

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

**IMPORTANT SAFETY
INFORMATION**

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

Important Safety Information (cont.)

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:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. In clinical trials of BIKTARVY, there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min. 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 \geq 5%; all grades) in clinical studies through week 144 were diarrhea (6%), nausea (6%), and headache (5%).

Please click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVI](#)[®].



BIKTARVY[®]

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

**IMPORTANT SAFETY
INFORMATION**

**TREATMENT GOALS
& CONSIDERATIONS**

**DHHS RECOMMENDATIONS
& TREATMENT PATTERNS**

COMPONENTS & MOA

EFFICACY

**RESISTANCE
& SAFETY PROFILE**

SUMMARY

Important Safety Information (cont.)

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:** Patients weighing ≥ 25 kg: 1 tablet taken once daily with or without food.
- **Renal impairment:** 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:** There is insufficient human data on the use of BIKTARVY during pregnancy. Dolutegravir, another integrase inhibitor, has been associated with neural tube defects. Discuss the benefit-risk of using BIKTARVY during pregnancy and conception. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for FTC shows no difference in the rates of birth defects compared with a US reference population.
- **Lactation:** Women infected with HIV-1 should be instructed not to breastfeed, due to the potential for HIV-1 transmission.

Please click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVI](#)[®].



IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

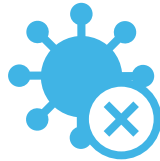
EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

HIV Transmission in the US Continues to Be a Challenge

~40,000 new infections per year in the US¹



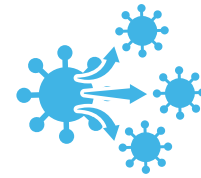
Approximately half of the
1.1 million PLWH

in the US are in care and
virologically suppressed^{2,*}



~8 in 10 new
HIV infections

come from PLWH who are
unaware of their infection
or are not in care^{3,*}



~1 in 5 infections
were transmitted

from PLWH who were in
care but not virologically
suppressed^{3,*}

*2016 CDC data.

CDC = Centers for Disease Control and Prevention; PLWH = people living with HIV.

REFERENCES: **1.** Centers for Disease Control and Prevention. HIV surveillance report, 2018 (updated); vol. 31. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2020. Accessed May 10, 2020. **2.** HIV.gov. HIV care continuum, 2016. <https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum>. Accessed May 15, 2020. **3.** Li Z, et al. *MMWR Morb Mortal Wkly Rep.* 2019;68(11):267-272.



IMPORTANT SAFETY
INFORMATION

**TREATMENT GOALS
& CONSIDERATIONS**

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

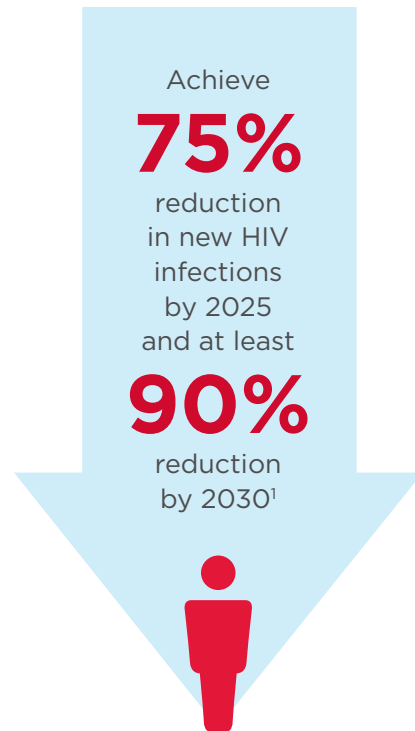
EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

Ending the Epidemic Requires a Holistic Approach

The US Department of Health and Human Services has launched “Ending the HIV Epidemic: A Plan for America”



Strategies are being implemented to¹:

Diagnose

all people with HIV as early as possible after infection.

Treat

the HIV infection rapidly and effectively to achieve sustained viral suppression.

Prevent

new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

Respond

quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

REFERENCE: 1. HIV.gov. Ending the HIV Epidemic: A Plan for America. <https://files.hiv.gov/s3fs-public/ending-the-hiv-epidemic-flyer.pdf>. Accessed May 10, 2020.



IMPORTANT SAFETY
INFORMATION

**TREATMENT GOALS
& CONSIDERATIONS**

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

Early and Effective HIV Treatment Is Crucial



According to DHHS, rapid ART (initiating therapy as soon as possible, even as early as the same day of HIV diagnosis) is a strategy that may¹:

- Increase ART uptake and engagement in care
- Accelerate the time to ART-mediated viral suppression



Undetectable = Untransmittable

- People living with HIV who take their treatment as prescribed and achieve and maintain an undetectable viral load cannot transmit HIV to sexual partners

ART = antiretroviral therapy.

REFERENCE: 1. 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. <http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Updated December 18, 2019. Accessed April 16, 2020.



IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

Drug Resistance Can Render an Antiretroviral (ARV) Class Ineffective^{1,2}



HIV is one of the fastest-mutating pathogens and can mutate millions of times per day³⁻⁶



Mutations can affect ARV target proteins, resulting in potential drug resistance⁷

- Drug-resistant mutations may develop when drug levels are suboptimal¹
- Drug-resistant HIV strains may be associated with suboptimal response to ART¹
- The most commonly transmitted resistant HIV strains were NNRTI- or NRTI-resistant, based on studies ranging from 2010 to 2016¹

Choosing a treatment with a high barrier to resistance is key¹

NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor.

REFERENCES: **1.** 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. <http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Updated December 18, 2019. Accessed April 16, 2020. **2.** Saag MS, et al. *JAMA*. 2018;320(4):379-396. **3.** Sanjuán R, Domingo-Calap P. *Cell Mol Life Sci*. 2016;73(23):4433-4448. **4.** Clavel F, et al. *N Engl J Med*. 2004;350(10):1023-1035. **5.** Perelson AS, et al. *Science*. 1996;271(5255):1582-1586. **6.** Perelson AS. *Nat Rev Immunol*. 2002;2(1):28-36. **7.** Wensing AM, et al. *Top Antivir Med*. 2016;24(4):132-133.



IMPORTANT SAFETY
INFORMATION

**TREATMENT GOALS
& CONSIDERATIONS**

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

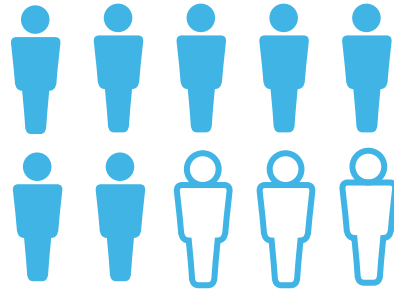
COMPONENTS & MOA

EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

Prescribing Considerations as the HIV Population Ages



According to research,

**>70% of Americans living with HIV
will be aged ≥ 50 years in 2020¹**

- According to DHHS, for older PLWH, ART is especially important because they potentially have a blunted immunologic response to ART²
- For aging PLWH experiencing declining immune systems, long-term virologic suppression is a critical treatment goal²



**Polypharmacy should be considered
when selecting a treatment for**

**aging PLWH with multiple
chronic conditions²**

- More than half of HIV and non-HIV medications had the potential for drug-drug interactions in a review of medications commonly prescribed to older patients²

DHHS = Department of Health and Human Services.

REFERENCES: 1. American Psychological Association. National HIV/AIDS and aging awareness day. <https://www.apa.org/pi/aids/resources/aging-awareness>. Accessed April 16, 2020. 2. 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. <http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Updated December 18, 2019. Accessed April 16, 2020.



BIKTARVY®

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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

**DHHS RECOMMENDATIONS
& TREATMENT PATTERNS**

COMPONENTS & MOA

EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

Key DHHS Recommendations



BIKTARVY® is recommended:

As an initial regimen for most people with HIV¹

- Recommended regimens are those with demonstrated durable virologic efficacy, favorable tolerability and toxicity profiles, and ease of use
- Only integrase inhibitor-based regimens are currently recommended as initial regimens for most people with HIV



BIKTARVY is recommended:

For rapid ART initiation¹

- ART should be initiated as soon as possible after HIV diagnosis
 - Resistance, CD4, and viral-load testing should be performed at treatment initiation; however, it is not necessary to wait for the results before starting BIKTARVY
 - Once test results are received, evaluate the appropriateness of continuing treatment
 - BIKTARVY is not indicated for patients with resistance to any component of BIKTARVY
- Only select triple therapies are currently recommended for rapid ART initiation

ART = antiretroviral therapy; DHHS = Department of Health and Human Services.

Important Safety Information

Contraindications

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

Please click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY®](#).

REFERENCE: 1. 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. <http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Updated December 18, 2019. Accessed April 16, 2020.



BIKTARVY[®]

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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

**DHHS RECOMMENDATIONS
& TREATMENT PATTERNS**

COMPONENTS & MOA

EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

#1

REGIMEN FOR HIV-1 TREATMENT fueled by THE POWER OF BICTEGRAVIR, THE #1 INSTI

PRESCRIBED Source: Ipsos Healthcare US HIV Therapy Monitor & Scope Study Oct-Dec 2019.



DHHS RECOMMENDED

As an initial regimen for most people with HIV-1 and an option for rapid ART initiation¹



EXTENSIVE CLINICAL TRIALS

With over 1500 people, including various age groups and ethnicities^{2,3}



LONG-TERM DATA

Demonstrated efficacy and safety profile in treatment-naïve adults through Week 144^{2,4-7}

INSTI = integrase strand transfer inhibitor.

Important Safety Information

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 click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY](#)[®].

REFERENCES: 1. 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. <http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Updated December 18, 2019. Accessed April 16, 2020. 2. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019. 3. Kityo C, et al. Poster presented at: Conference on Retroviruses and Opportunistic Infections; March 4-7, 2018; Boston, MA. Poster 500. 4. Orkin C, et al. Poster presented at: 17th European AIDS Conference; November 6-9, 2019; Basel, Switzerland. Poster PE3/14. 5. Molina JM, et al. *Lancet HIV*. 2018;5(7):e357-e365. 6. Daar ES, et al. *Lancet HIV*. 2018;5(7):e347-e356. 7. Data on file. Gilead Sciences, Inc.



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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

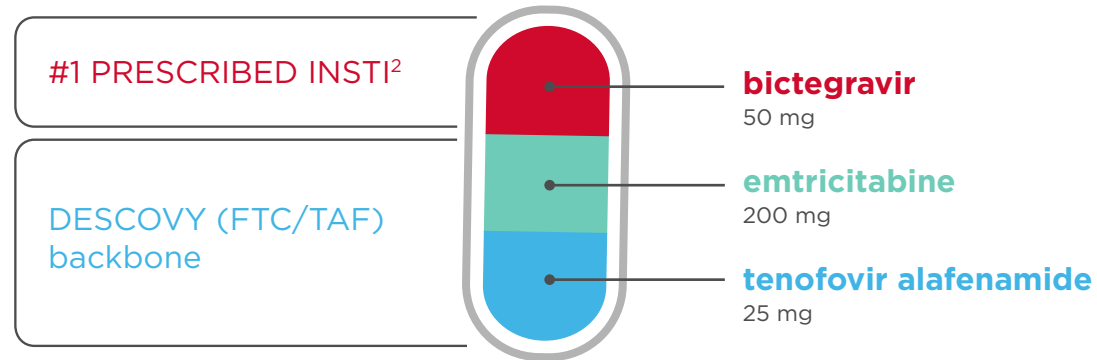
COMPONENTS & MOA

EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

Components Matter: A Triple Therapy STR That Pairs the Power of Bictegravir With the **DESCOVY**[®] (FTC/TAF) Backbone¹



FTC/TAF = emtricitabine/tenofovir alafenamide; INSTI = integrase strand transfer inhibitor.

Important Safety Information

Warnings and precautions (cont.)

- **New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. In clinical trials of BIKTARVY[®], there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min. 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.

Please click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY](#)[®].

REFERENCES: 1. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019. 2. Ipsos Healthcare. US HIV Therapy Monitor & Scope Study. October-December 2019.



BIKTARVY[®]

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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

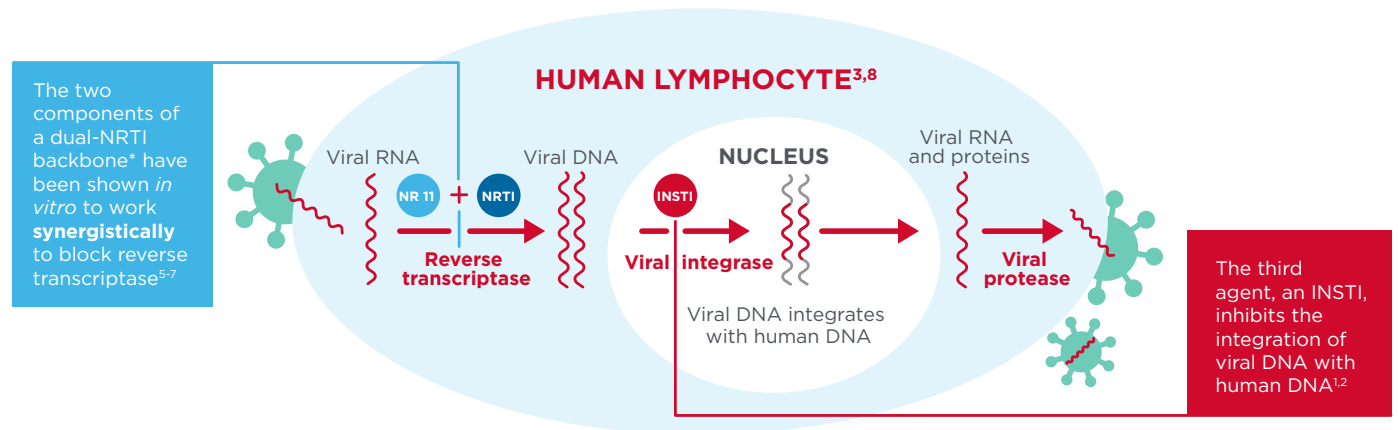
EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

A Dual-NRTI Backbone Is an Essential Part of a Complete Regimen¹⁻⁸

Triple therapy that combines a dual-NRTI backbone with an INSTI that inhibits viral replication and can reduce the risk of ARV resistance^{1,3,4}



*Dual-NRTI backbones included FTC/TAF, FTC/TDF, and ABC/3TC.

3TC = lamivudine; ABC = abacavir; FTC = emtricitabine; NRTI = nucleoside reverse transcriptase inhibitor; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate.

Important Safety Information

Adverse reactions

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

Please click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY](#)[®].

REFERENCES: 1. 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. <http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Updated December 18, 2019. Accessed April 16, 2020. 2. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019. 3. Department of Health and Human Services. The HIV life cycle. AIDSinfo website. <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/19/73/the-hiv-life-cycle>. Last reviewed July 1, 2019. Accessed April 16, 2020. 4. Department of Health and Human Services. FDA-approved HIV medicines. AIDSinfo website. <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/58/fda-approved-hiv-medicines>. Last reviewed January 30, 2020. Accessed April 16, 2020. 5. Callebaut C, et al. *Antimicrob Agents Chemother*. 2015;59(10):5909-5916. 6. Feng JY, et al. *Retrovirology*. 2009;6:44. 7. Ray AS, et al. *Antivir Ther*. 2005;10(3):451-457. 8. Laskey SB, Siliciano RF. *Nat Rev Microbiol*. 2014;12(11):772-780.



BIKTARVY®

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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

EFFICACY

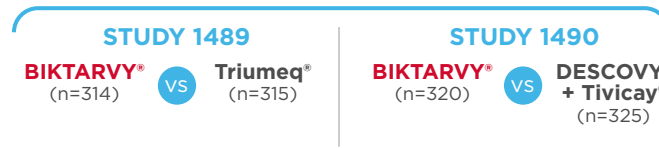
RESISTANCE
& SAFETY PROFILE

SUMMARY

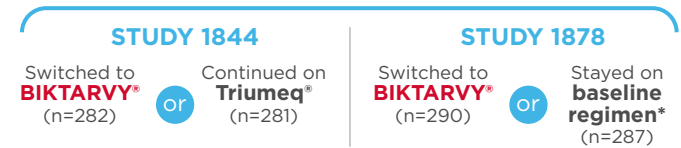
Backed by Robust Clinical Trial Experience^{1,2}

Extensive clinical trials with over 1500 people including various age groups and ethnicities.

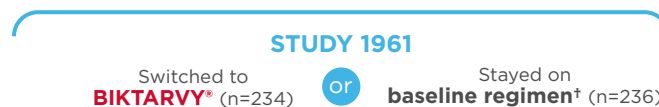
TREATMENT-NAÏVE ADULTS



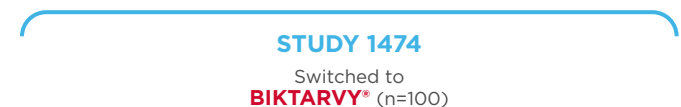
VIROLOGICALLY SUPPRESSED ADULTS



VIROLOGICALLY SUPPRESSED ADULT WOMEN



VIROLOGICALLY SUPPRESSED PEDIATRIC PATIENTS



DESCOVY (emtricitabine/tenofovir alafenamide); Tivicay (dolutegravir); Triumeq (abacavir/dolutegravir/lamivudine).

*Reyataz® (atazanavir) or Prezista® (darunavir) boosted with either Norvir® (ritonavir) or TYBOST® (cobicistat) including Evotaz® (atazanavir/cobicistat) or Prezcofix® (darunavir/cobicistat) + either TRUVADA® (emtricitabine/tenofovir disoproxil fumarate) or Epzicom® (abacavir/lamivudine).

†GENVOYA® (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide) or STRIBILD® (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate) or TRUVADA + Reyataz boosted with Norvir.

‡Open-label, single-arm trial included virologically suppressed adolescents, ages 12 to less than 18 years weighing at least 35 kg (n=50), and virologically suppressed children, ages 6 to less than 12 years weighing at least 25 kg (n=50).

Important Safety Information

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 click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY](#).

REFERENCES: 1. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019. 2. Kityo C, et al. Poster presented at: Conference on Retroviruses and Opportunistic Infections; March 4-7, 2018; Boston, MA. Poster 500.

STUDY DESIGN & BASELINE CHARACTERISTICS



BIKTARVY[®]

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

Durable Power: Long-Term Efficacy in Treatment-Naïve Adults at Week 144

IMPORTANT SAFETY INFORMATION

TREATMENT GOALS & CONSIDERATIONS

DHHS RECOMMENDATIONS & TREATMENT PATTERNS

COMPONENTS & MOA

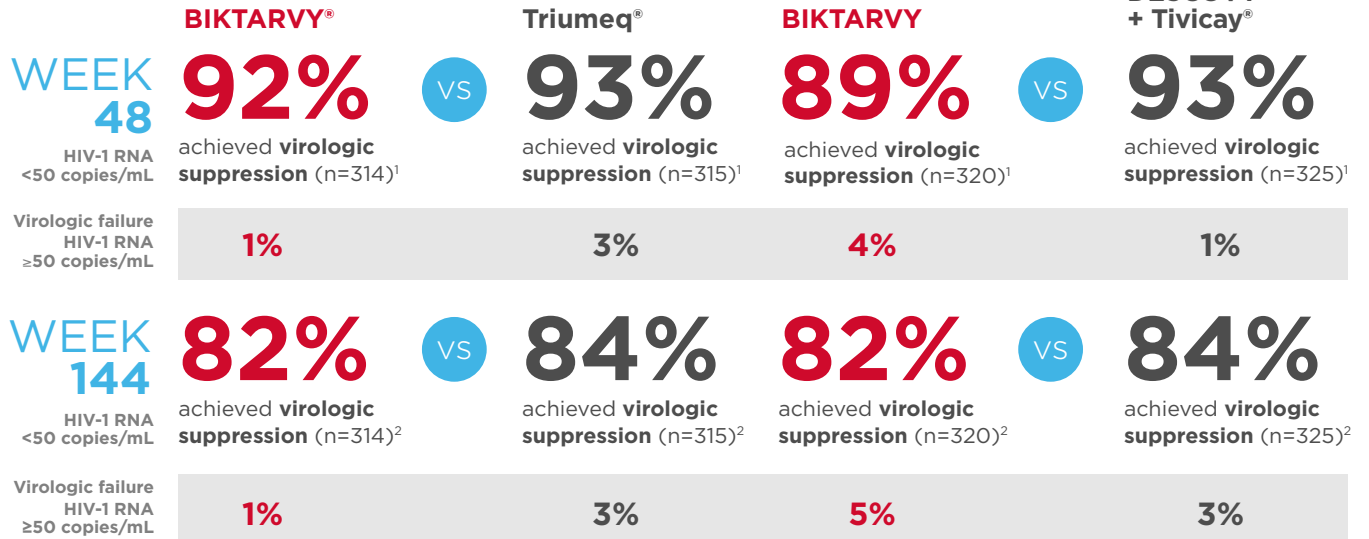
EFFICACY

RESISTANCE & SAFETY PROFILE

SUMMARY

STUDY 1489

STUDY 1490



Treatment outcomes were similar across subgroups, regardless of age, sex, race, baseline viral load, and baseline CD4 cell count.¹

Important Safety Information

Dosage and administration

- **Dosage:** Patients weighing ≥25 kg; 1 tablet taken once daily with or without food.
- **Renal impairment:** Not recommended in patients with CrCl <30 mL/min.
- **Hepatic impairment:** Not recommended in patients with severe hepatic impairment.

Please click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY](#).

REFERENCES: 1. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019. 2. Orkin C, et al. Poster presented at: 17th European AIDS Conference; November 6-9, 2019; Basel, Switzerland. Poster PE3/14.





BIKTARVY®

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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

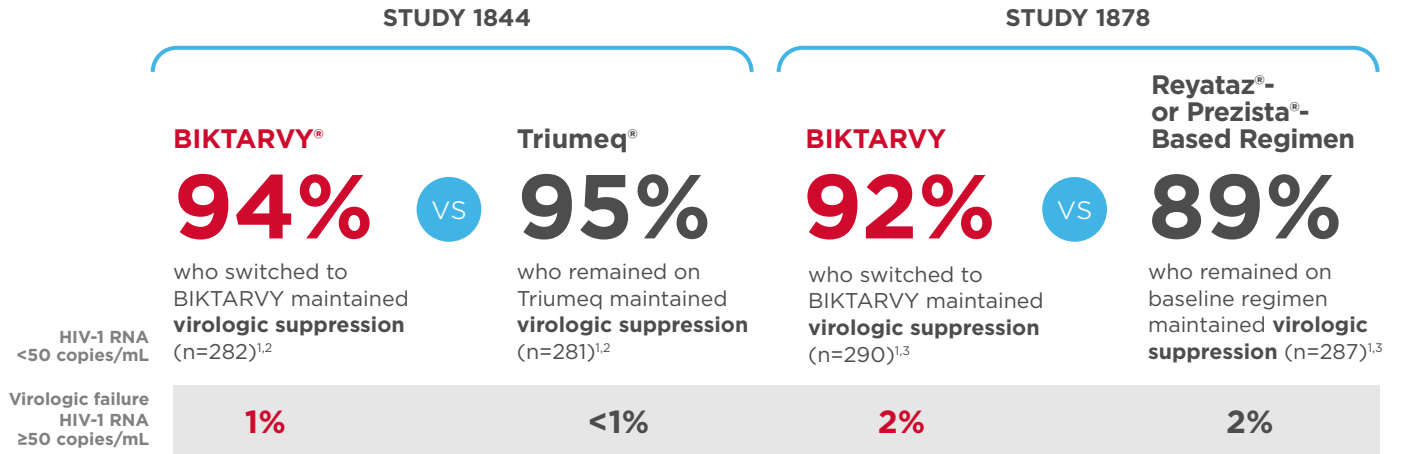
COMPONENTS & MOA

EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

Powerful Efficacy in Virologically Suppressed Adults at Week 48



In both studies, treatment outcomes were similar across subgroups by age, sex, race, and region.¹

Important Safety Information

Dosage and administration (cont.)

- **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 click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY®](#).

REFERENCES: 1. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019. 2. Molina JM, et al. *Lancet HIV*. 2018;5(7):e357-e365. 3. Daar ES, et al. *Lancet HIV*. 2018;5(7):e347-e356.





BIKTARVY®

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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

EFFICACY

**RESISTANCE &
SAFETY PROFILE**

SUMMARY

No Treatment-Emergent Resistance

In four large phase 3 clinical trials in treatment-naïve adults and virologically suppressed adults:

0 **CASES**
OF RESISTANCE
WITH BIKTARVY®

AND

- Among 634 treatment-naïve adults in Studies 1489 and 1490, 8 treatment-failure subjects were tested and no amino acid substitutions emerged that were associated with BIKTARVY resistance through Week 144¹⁻⁴
- Among 572 virologically suppressed adults in Studies 1844 and 1878, 2 virologic rebound subjects had genotypic and phenotypic data (1 for RT, 1 for IN and RT) and no virologically suppressed subjects had treatment-emergent genotypic or phenotypic resistance to BIKTARVY through Week 48^{1,5-7}

IN = integrase; RT = reverse transcriptase.

Important Safety Information

Pregnancy and lactation

- **Pregnancy:** There is insufficient human data on the use of BIKTARVY during pregnancy. Dolutegravir, another integrase inhibitor, has been associated with neural tube defects. Discuss the benefit-risk of using BIKTARVY during pregnancy and conception. An Antiretroviral Pregnancy Registry (APR) has been established. Available data from the APR for FTC shows no difference in the rates of birth defects compared with a US reference population.
- **Lactation:** Women infected with HIV-1 should be instructed not to breastfeed, due to the potential for HIV-1 transmission.

Please click to see full Prescribing Information, including **BOXED WARNINGS**, for **BIKTARVY** and **DESCOVIY®**.

REFERENCES: **1.** BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019. **2.** Orkin C, et al. Poster presented at: 17th European AIDS Conference; November 6-9, 2019; Basel, Switzerland. Poster PE3/14. **3.** Stellbrink H-J, et al. *Lancet HIV*. 2019;6(6):e364-e372. **4.** Wohl DA, et al. *Lancet HIV*. 2019;6(6):e355-e363. **5.** Daar ES, et al. *Lancet HIV*. 2018;5(7):e347-e356. **6.** Andreatta K, et al. Poster presented at: Conference on Retroviruses and Opportunistic Infections; March 4-7, 2018; Boston, MA. Poster 506. **7.** Molina JM, et al. *Lancet HIV*. 2018;5(7):e357-e365.

**STUDY DESIGN &
BASELINE CHARACTERISTICS**



BIKTARVY®

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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

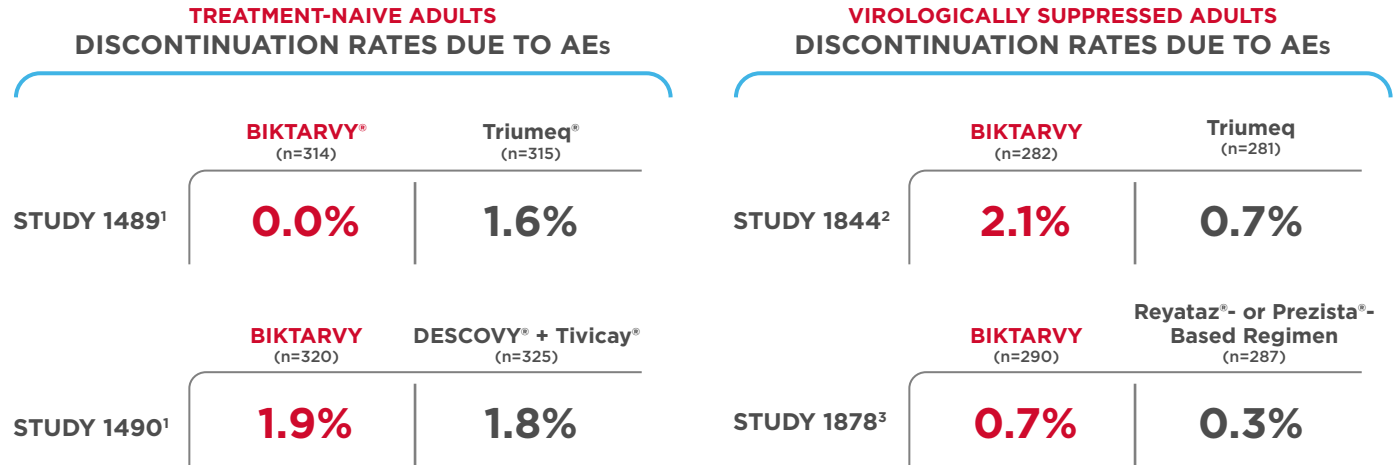
COMPONENTS & MOA

EFFICACY

**RESISTANCE &
SAFETY PROFILE**

SUMMARY

Overall, 1% of Adults Discontinued Due to AEs



No adults discontinued BIKTARVY due to renal-, hepatic-, or bone-related adverse events.¹⁻³

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.⁴

DESCOVY (emtricitabine/tenofovir alafenamide); Prezista (darunavir); Reyataz (atazanavir); Tivicay (dolutegravir); Triumeq (abacavir/dolutegravir/lamivudine).

AE = adverse event; CrCl = creatinine clearance.

Important Safety Information

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 click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY](#).

REFERENCES: 1. Data on file. Gilead Sciences, Inc. 2. Molina JM, et al. *Lancet HIV*. 2018;5(7):e357-e365. 3. Daar ES, et al. *Lancet HIV*. 2018;5(7):e347-e356. 4. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019.

STUDY DESIGN & BASELINE CHARACTERISTICS



BIKTARVY[®]

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

A Demonstrated Long-Term Safety and Tolerability Profile in Treatment-Naïve Adults Through Week 144

IMPORTANT SAFETY INFORMATION

TREATMENT GOALS & CONSIDERATIONS

DHHS RECOMMENDATIONS & TREATMENT PATTERNS

COMPONENTS & MOA

EFFICACY

RESISTANCE & SAFETY PROFILE

SUMMARY

STUDY 1489

STUDY 1490

Adverse Reactions (All Grades) Reported in ≥2% of Adults Who Received BIKTARVY¹

BIKTARVY[®]
(n=314)

Triumeq[®]
(n=315)

BIKTARVY
(n=320)

DESCOVY[®]
+Tivicay[®]
(n=325)

	BIKTARVY [®] (n=314)	Triumeq [®] (n=315)	BIKTARVY (n=320)	DESCOVY [®] +Tivicay [®] (n=325)
Nausea, %	6	18	3	5
Diarrhea, %	6	4	3	3
Headache, %	5	5	4	3
Fatigue, %	3	3	2	2
Abnormal dreams, %	3	3	<1	<1
Dizziness, %	2	3	2	1
Insomnia, %	2	3	2	<1
Abdominal distension, %	2	2	1	2

- Frequencies of adverse reactions are based on all adverse events attributed to trial drugs by the investigator. No adverse reactions of Grade 2 or higher occurred in >1% of subjects treated with BIKTARVY²
- The majority (84%) of AEs associated with BIKTARVY were Grade 1¹
- In Study 1489, an AE of weight increase was reported for BIKTARVY (2.9%), Triumeq (4.1%), and AE of weight decrease for BIKTARVY (1.9%), Triumeq (1.6%)¹
- In Study 1490, an AE of weight increase was reported for BIKTARVY (2.5%), DESCOVY + Tivicay (3.1%), and AE of weight decrease for BIKTARVY (0.9%), DESCOVY + Tivicay (0.9%)¹

Important Safety Information

Contraindications

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

Please click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY](#).

REFERENCES: 1. Data on file. Gilead Sciences, Inc. 2. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019.



BIKTARVY[®]

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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

EFFICACY

**RESISTANCE &
SAFETY PROFILE**

SUMMARY

A Demonstrated Safety and Tolerability Profile in Virologically Suppressed Adults Through Week 48

Adverse Reactions (ARs) (All Grades) Reported in $\geq 2\%$ of Adults Who Switched to BIKTARVY ^{1,2,*}	STUDY 1844		STUDY 1878	
	BIKTARVY [®] (n=282)	Triumeq [®] (n=281)	BIKTARVY (n=290)	Reyataz [®] - or Prezista [®] - Based Regimen (n=287)
Headache, %	2	3	5	0
Flatulence, %	0	2	2	0
Nausea, %	0	2	2	0
Diarrhea, %	1	1	2	0

- The majority of adverse events associated with BIKTARVY were Grade 1 in Study 1878 (76%) and in Study 1844 (58%)³
- The most common ARs (incidence $\geq 5\%$; all grades) in clinical trials of treatment-naïve adults who received BIKTARVY were diarrhea, nausea, and headache³
- Overall, the safety profile of BIKTARVY in virologically suppressed adults was similar to that of treatment-naïve adults⁴

*Frequencies of ARs are based on all adverse events attributed to trial drugs by the investigator. No ARs of Grade 2 or higher occurred in $\geq 1\%$ of subjects treated with BIKTARVY.

Important Safety Information

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 click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY](#)[®].

REFERENCES: 1. Molina JM, et al. *Lancet HIV*. 2018;5(7):e357-e365. 2. Daar ES, et al. *Lancet HIV*. 2018;5(7):e347-e356. 3. Data on file. Gilead Sciences, Inc. 4. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019.



BIKTARVY[®]

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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

EFFICACY

**RESISTANCE &
SAFETY PROFILE**

SUMMARY

Few Contraindications and Drug-Drug Interactions

BIKTARVY[®] is contraindicated with two medications: dofetilide and rifampin.

ESTABLISHED AND POTENTIALLY SIGNIFICANT* DRUG INTERACTIONS: ALTERATION IN REGIMEN MAY BE RECOMMENDED¹

Concomitant Drug Class: Drug Name	Clinical Comment
Antiarrhythmics <ul style="list-style-type: none"> Dofetilide 	Coadministration is contraindicated due to the potential for serious and/or life-threatening events associated with dofetilide therapy.
Anticonvulsants <ul style="list-style-type: none"> Carbamazepine[†] Oxcarbazepine Phenobarbital Phenytoin 	Coadministration with alternative anticonvulsants should be considered.
Antimycobacterials <ul style="list-style-type: none"> Rifabutin[†] Rifampin^{††} Rifapentine 	Coadministration with rifampin is contraindicated due to its effect on bictegravir. Coadministration with rifabutin or rifapentine is not recommended.
Herbal products <ul style="list-style-type: none"> St. John's wort[§] 	Coadministration with St. John's wort is not recommended.
Medications or oral supplements containing polyvalent cations (eg, Mg, Al, Ca, Fe): <ul style="list-style-type: none"> Calcium or iron supplements[†] Cation-containing antacids or laxatives[†] Sucralfate Buffered medications 	Antacids containing Al/Mg: BIKTARVY can be taken at least 2 hours before or 6 hours after taking antacids containing Al/Mg. Routine administration of BIKTARVY together with, or 2 hours after, antacids containing Al/MG is not recommended. Supplements or antacids containing calcium or iron: BIKTARVY and supplements or antacids containing calcium or iron can be taken together with food. Routine administration of BIKTARVY under fasting conditions together with, or 2 hours after, supplements or antacids containing calcium or iron is not recommended.
Metformin	Refer to the prescribing information of metformin for assessing the benefit and risk of concomitant use of BIKTARVY and metformin.

*Table is not all inclusive.

[†] Drug-drug interaction study was conducted with either BIKTARVY or its components as individual agents.

^{††} Strong inducer of CYP3A and P-gp, and inducer of UGT1A1.

[§] The induction potency of St. John's wort may vary widely based on preparation.

Please click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVY](#)[®].

REFERENCE: 1. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019.



BIKTARVY[®]

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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

EFFICACY

**RESISTANCE &
SAFETY PROFILE**

SUMMARY

No Known Dose Adjustments When Coadministered With These Medications

DRUGS WITH NO CLINICALLY SIGNIFICANT INTERACTIONS WITH BIKTARVY^{®1}

Drug Class	Drug Within Class
Oral contraceptive	Ethinyl estradiol, norgestimate
HCV antiviral	Sofosbuvir, sofosbuvir/velpatasvir, ledipasvir/sofosbuvir, and sofosbuvir/velpatasvir/voxilaprevir
Benzodiazepine	Midazolam
Selective serotonin reuptake inhibitor	Sertraline

HCV = hepatitis C virus.

Important Safety Information

Warnings and precautions (cont.)

- **New onset or worsening renal impairment:** Cases of acute renal failure and Fanconi syndrome have been reported with the use of tenofovir prodrugs. In clinical trials of BIKTARVY, there have been no cases of Fanconi syndrome or proximal renal tubulopathy (PRT). Do not initiate BIKTARVY in patients with estimated creatinine clearance (CrCl) <30 mL/min. 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.

Please click to see full Prescribing Information, including **BOXED WARNINGS**, for [BIKTARVY](#) and [DESCOVIY](#)[®].

REFERENCE: 1. BIKTARVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; 2019.



BIKTARVY®

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

IMPORTANT SAFETY
INFORMATION

TREATMENT GOALS
& CONSIDERATIONS

DHHS RECOMMENDATIONS
& TREATMENT PATTERNS

COMPONENTS & MOA

EFFICACY

RESISTANCE
& SAFETY PROFILE

SUMMARY

#1

REGIMEN FOR HIV-1 TREATMENT fueled by
THE POWER OF BICTEGRAVIR, THE #1 INSTI

PRESCRIBED Source: Ipsos Healthcare US HIV Therapy Monitor & Scope Study Oct-Dec 2019.