HISPANIC/ LATINE

Post hoc pooled analysis

REPRESENTATION MATTERS:

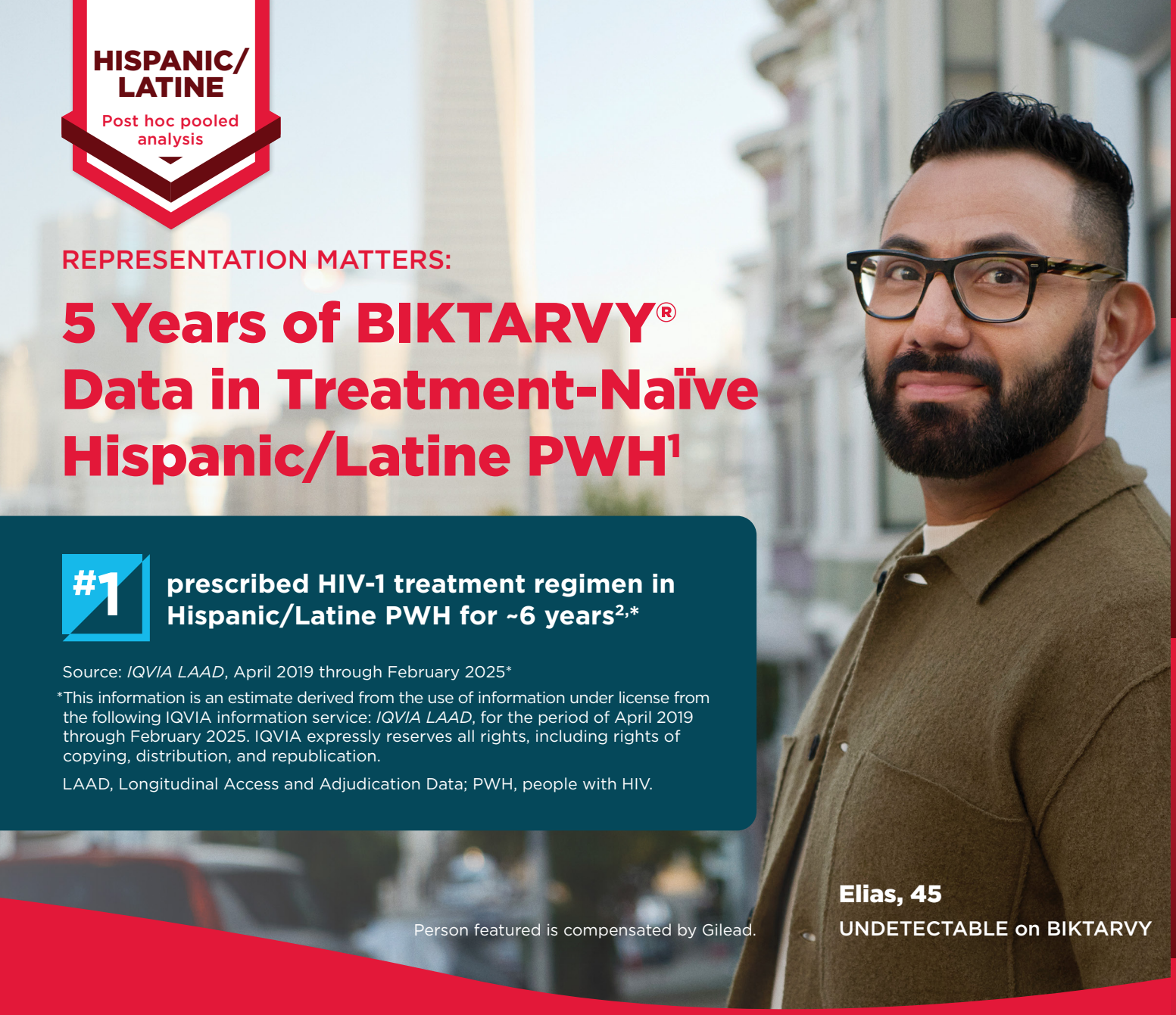
5 Years of BIKTARVY® Data in Treatment-Naïve Hispanic/Latine PWH[1]

#1 prescribed HIV-1 treatment regimen in Hispanic/Latine PWH for ~6 years[2,*]

Source: *IQVIA LAAD*, April 2019 through February 2025*

*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 April 2019 through February 2025. IQVIA expressly reserves all rights, including rights of copying, distribution, and republication.

LAAD, Longitudinal Access and Adjudication Data; PWH, people with HIV.



Elias, 45
UNDETECTABLE on BIKTARVY

Person featured is compensated by Gilead.

LATINE PWH

STUDY DESIGN

EFFICACY DATA

SAFETY DATA

RAPID INITIATION

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**.

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

Understanding the Unique Needs of Latine PWH Is Critical to Selecting an HIV Treatment

The Latine community is disproportionately impacted by HIV[3]:

LATINE INDIVIDUALS HAD A

5.2x

higher HIV diagnosis rate than White individuals

APPROXIMATELY

1 out of 3

new HIV diagnoses was among Latine individuals despite representing only **19% of the population**

Certain social determinants of health may cause gaps in HIV treatment

- Cultural stigma[4,5]
- Financial and insurance barriers[6]
- Limited Spanish-speaking HCPs[4,5]
- Housing and food access[3]

The Latine community faces the highest uninsurance rate of any racial or ethnic group.[6]

HCP, healthcare professional; PWH, people with HIV.

When Treatment Gaps Occur, Irreversible Drug Resistance Can Develop[7,8]

Based on a retrospective study evaluating ART adherence and treatment gaps in TN and TE PWH who initiated or switched their regimen (N=48,627)[9,*]:

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.[9]

*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.[8,†]

Continue to counsel patients to take their medication as prescribed.

Other considerations include side effects, out-of-pocket costs, convenience, and patient preferences.[8]

†Please see DHHS guidelines for specific recommended antiretrovirals.

ART, antiretroviral therapy; DHHS, US Department of Health and Human Services; INSTI, integrase strand transfer inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; TE, treatment-experienced; TN, treatment-naïve.

5 Years of Long-Term Data With BIKTARVY® in TN PWH, Including Hispanic/Latine Adults[1]

Phase 3 Randomized, Double-Blind, Active-Controlled Noninferiority Studies[10-12]

Study 1489[10]
Participants started on BIKTARVY (n=314) or ABC/DTG/3TC (n=315)

Study 1490[10]
Participants started on BIKTARVY (n=320) or FTC/TAF+DTG (n=325)

Primary endpoint[13,14]: Proportion of adults with HIV-1 RNA <50 copies/mL at Week 48 using the FDA snapshot algorithm, -12% noninferiority margin

Secondary endpoint[11]: Efficacy, safety, and tolerability were assessed through Weeks 96 and 144

Open-label extension[15]: Outcomes were assessed in TN adults who continued on BIKTARVY (n=506) or switched to BIKTARVY from ABC/DTG/3TC (n=254) or FTC/TAF+DTG (n=265) at Week 144 through Week 240

Select eligibility criteria[13]: Study participants with preexisting resistance substitutions causing reduced susceptibility to FTC, TAF, ABC, and 3TC were excluded at screening

Treatment-naïve post hoc pooled analysis[1]
Efficacy and safety outcomes of Hispanic/Latine vs non-Hispanic/Latine participants who received BIKTARVY in Studies 1489 and 1490, studied through 5 years (240 weeks)

Study limitations[1]

- This analysis was not prespecified and no adjustment for multiplicity was made for outcomes. Data should be considered descriptive only
- The BIKTARVY subgroups in Studies 1489 and 1490 were not randomized or matched, and there was a smaller number of Hispanic/Latine vs non-Hispanic/Latine participants
- Outcomes evaluated included data from both the randomized and the OLE phases of the studies, and the open-label design of the OLE phase of BIKTARVY may have introduced bias into the findings

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.

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

3TC, lamivudine; ABC, abacavir; DTG, dolutegravir; FDA, US Food and Drug Administration; FTC, emtricitabine; OLE, open-label extension; PWH, people with HIV; RNA, ribonucleic acid; TAF, tenofovir alafenamide; TN, treatment-naïve.

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

5 Years of Long-Term Data With BIKTARVY® in TN PWH, Including Hispanic/Latine Adults[1] (cont'd)

Select Baseline Characteristics in PWH Who Received BIKTARVY®

	Pivotal studies[11,12,15]		Post hoc pooled analysis[1,2]	
	Study 1489 (n=314)	**Study 1490** (n=320)	**Hispanic/Latine*** (n=155)	**Non-Hispanic/Latine†** (n=477)
Age, median (range), years	**31** (18–71)	**33** (18–71)	**30** (19–65)	**33** (18–71)
Male sex at birth	**91%**	**88%**	**89%**	**89%**
HIV-1 RNA >100,000 copies/mL	**17%**	**21%**	**12%**	**21%**
Weight, median, kg	**77**	**76**	**73**	**79**
eGFRCG, median, mL/min	**126**	**120**	**120**	**124**

*Hispanic/Latine participants self-identified as Hispanic or Latino ethnicity in the electronic data capture.
†Non-Hispanic/Latine participants self-identified as non-Hispanic or non-Latino ethnicity in the electronic data capture.

THE ONLY DHHS-RECOMMENDED INITIAL REGIMEN FOR MOST PWH WITH 5 YEARS

of efficacy, resistance, and safety data from phase 3, treatment-naïve clinical studies[8,15]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

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.

DHHS, US Department of Health and Human Services; eGFRCG, estimated glomerular filtration rate (Cockcroft-Gault).

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Durable Viral Suppression With BIKTARVY® at 5 Years in Pivotal Studies[10-14,16]

Virologic Response in Treatment-Naïve Adults

	Study 1489[10-13]				Study 1490[10,11,14,17]			
	Week 48		Week 144		Week 48		Week 144	
	BIKTARVY (n=314)	ABC/DTG/3TC (n=315)	BIKTARVY (n=314)	ABC/DTG/3TC (n=315)	BIKTARVY (n=320)	FTC/TAF +DTG (n=325)	BIKTARVY (n=320)	FTC/TAF +DTG (n=325)
HIV-1 RNA <50 copies/mL	**92%**	93%	**82%**	84%	**89%**	93%	**82%**	84%
HIV-1 RNA ≥50 copies/mL	**1%**	3%	**1%**	3%	**4%**	1%	**5%**	3%

BIKTARVY was noninferior to ABC/DTG/3TC and FTC/TAF+DTG at Week 144 in both studies.[10]

Study 1489[11,13]: No virologic data available for BIKTARVY and ABC/DTG/3TC at Week 48 (7%, 4%) and at Week 144 (18%, 13%).

Study 1490[11,14]: No virologic data available for BIKTARVY and FTC/TAF+DTG at Week 48 (6%, 6%) and at Week 144 (13%, 13%).

In a 96-week open-label extension from Week 144 through Week 240, virologic suppression at each study visit through Week 240 was assessed for adults who were initially randomized to BIKTARVY at Week 0[15,*]:

- In Study 1489, using an M=E analysis, 97.7% (n=213) maintained virologic suppression at Week 240. Using an M=F analysis, 66.2% (n=314) maintained virologic suppression at Week 240
- In Study 1490, using an M=E analysis, 99.5% (n=219) maintained virologic suppression at Week 240. Using an M=F analysis, 68.1% (n=320) maintained virologic suppression at Week 240

Virologic suppression was also assessed in participants who switched from either ABC/DTG/3TC or FTC/TAF+DTG to BIKTARVY at Week 144[15,*]:

- In Study 1489, using an M=E analysis, 99.5% (n=218) maintained virologic suppression at Week 240. Using an M=F analysis, 85.4% (n=254) maintained virologic suppression at Week 240
- In Study 1490, using an M=E analysis, 99.1% (n=234) maintained virologic suppression at Week 240. Using an M=F analysis, 87.5% (n=265) maintained virologic suppression at Week 240

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.

*HIV-1 RNA <50 copies/mL.

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tenofovir alafenamide 25mg tablets

Post hoc pooled analysis

Viral Suppression Rates at 5 Years in Hispanic/Latine PWH

Virologic Suppression in Treatment-Naïve Adults

	BIKTARVY® post hoc pooled analysis[1,2,18]					
	Week 48		Week 144		Week 240	
	Hispanic/ Latine PWH	Non-Hispanic/ Latine PWH	Hispanic/ Latine PWH	Non-Hispanic/ Latine PWH	Hispanic/ Latine PWH	Non-Hispanic/ Latine PWH
HIV-1 RNA <50 copies/mL using M=E analysis	**100%** n/N=146/146	**99%** n/N=437/441	**99%** n/N=133/134	**99%** n/N=393/395	**100%** n/N=118/118	**98%** n/N=308/314
HIV-1 RNA <50 copies/mL using M=F analysis	**94%** n/N=146/155	**92%** n/N=437/477	**86%** n/N=133/155	**82%** n/N=393/477	**76%** n/N=118/155	**65%** n/N=308/477

- In an **M=E analysis,** study participants with missing data are excluded when calculating the proportion of study participants with HIV-1 RNA <50 copies/mL
- In an **M=F analysis,** all missing data are treated as treatment failures with HIV-1 RNA ≥50 copies/mL

In the pooled analysis,

NUMERICALLY SIMILAR EFFICACY OUTCOMES

were observed between the Hispanic/Latine and non-Hispanic/Latine subgroups[1]

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.

3TC, lamivudine; ABC, abacavir; DTG, dolutegravir; FTC, emtricitabine; M=E, missing=excluded; M=F, missing=failure; PWH, people with HIV; RNA, ribonucleic acid; TAF, tenofovir alafenamide.

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

Pivotal studies and post hoc pooled analysis

BIKTARVY® Demonstrated a High Barrier to Resistance Through 5 Years in Treatment-Naïve PWH[12,15,19]

0 CASES

of treatment-emergent resistance to BIKTARVY through

5 YEARS*

*Based on the final resistance analysis population.[12,19]

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.

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

PWH, people with HIV.

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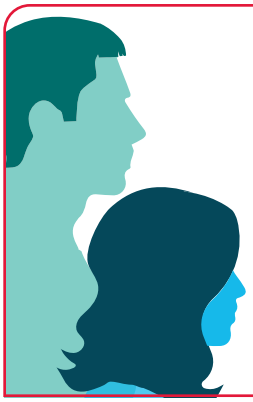
bictegravir 50mg/emtricitabine 200mg/
tenofovir alafenamide 25mg tablets

BIKTARVY® Demonstrated a High Barrier to Resistance Through 5 Years in Treatment-Naïve PWH[12,15,19] (cont'd)

Zero cases of treatment-emergent resistance to BIKTARVY® among adults who participated in Studies 1489 and 1490[10,12,15,19]:

- **634 participants** received BIKTARVY through Week 144 of the double-blind phase
- **1025 participants** received BIKTARVY through Week 96 of the extension phase
- Of the **1025 treatment-naïve adults** who participated in the OLE, **506 participants** continued on BIKTARVY, **254 participants** switched from ABC/DTG/3TC, and **265 participants** switched from FTC/TAF+DTG at Week 144

In the final resistance analysis population, no amino acid substitutions associated with BIKTARVY resistance emerged in the 11 participants who experienced treatment failure and had evaluable genotypic resistance data.[10]



In the post hoc pooled analysis in Hispanic/Latine PWH,

0 CASES OF TE RESISTANCE

were reported to the components of BIKTARVY through 5 years[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **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.

3TC, lamivudine; ABC, abacavir; DTG, dolutegravir; FTC, emtricitabine; OLE, open-label extension; TAF, tenofovir alafenamide; TE, treatment-emergent.

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

BIKTARVY® Has Established Long-Term Safety Data Through 5 Years[2,10,12]

Adverse Reactions (All Grades) Reported in ≥2% of Treatment-Naïve Adults Who Received BIKTARVY Through Week 144[10,*]

	Study 1489		Study 1490	
	BIKTARVY (n=314)	ABC/DTG/3TC (n=315)	**BIKTARVY** (n=320)	FTC/TAF+DTG (n=325)
Nausea, %	**6**	18	**3**	5
Diarrhea, %	**6**	4	**3**	3
Headache, %	**5**	5	**4**	3
Fatigue, %	**3**	4	**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 participants treated with BIKTARVY.

The majority (84%) of adverse events associated with BIKTARVY were grade 1[10]

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.

3TC, lamivudine; ABC, abacavir; DTG, dolutegravir; FTC, emtricitabine; TAF, tenofovir alafenamide.

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BIKTARVY® Has Established Long-Term Safety Data Through 5 Years[2,10,12] (cont'd)

Adverse Reactions (All Grades) Reported in ≥2% of Treatment-Naïve Adults Who Received BIKTARVY® Through Week 240[2,12]

	Study 1489		Study 1490	
	BIKTARVY (n=314)	Switched From ABC/DTG/3TC to **BIKTARVY** (n=254)	**BIKTARVY** (n=320)	Switched From FTC/TAF+DTG to **BIKTARVY** (n=265)
Headache, %	5	<1	5	<1
Diarrhea, %	6	1	3	0
Nausea, %	5	<1	3	0
Fatigue, %	3	0	3	<1
Abnormal dreams, %	3	<1	<1	0
Dizziness, %	3	0	3	0
Insomnia, %	2	0	2	0
Proteinuria, %	2	0	2	0

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.**

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.

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Post hoc pooled analysis

Long-Term Safety Data Through 5 Years in Hispanic/Latine PWH[2]

Adverse Reactions (All Grades) Reported in ≥2% of Treatment-Naïve Adults Who Received BIKTARVY® Through Week 240[2]

	Post hoc pooled analysis	
	Hispanic/Latine PWH (n=155)	Non-Hispanic/Latine PWH (n=477)
Headache, %	5	5
Nausea, %	3	5
Creatinine clearance decreased, %	3	0
Insomnia, %	3	2
Hypercholesterolemia, %	3	<1
Diarrhea, %	2	6
Dizziness, %	2	3
Fatigue, %	2	3

GRADE 3 OR 4 TEAEs WITH BIKTARVY WERE 2%
in Hispanic/Latine PWH[1]

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.

PWH, people with HIV; TEAE, treatment-emergent adverse event.

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Discontinuation Rates Due to Adverse Events in Hispanic/Latine PWH

Pivotal Trials

Treatment-naïve adults through Week 144[11]

Study 1489		Study 1490	
0.0% in BIKTARVY® (n=314)	**1.6%** in ABC/DTG/3TC (n=315)	**1.9%** in BIKTARVY (n=320)	**1.8%** in FTC/TAF+DTG (n=325)

Through Week 240 (including OLE) in study participants initially randomized to BIKTARVY[12]

Study 1489	Study 1490
1.3% in BIKTARVY (n=314)	**1.9%** in BIKTARVY (n=320)

In participants who switched to BIKTARVY at Week 144 through Week 240[15]

Study 1489	Study 1490
0.8% in ABC/DTG/3TC to BIKTARVY (n=254)	**0.0%** in FTC/TAF+DTG to BIKTARVY (n=265)

Post hoc pooled analysis

Treatment-naïve adults through Week 240 **(5 YEARS)**[1]

Hispanic/Latine PWH	Non-Hispanic/Latine PWH
1.0% in BIKTARVY (n=155)*	**1.0%** in BIKTARVY (n=477)†

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

*Due to depression (n=1).[1]
†Due to obesity (n=1); chest pain (n=1); abdominal distension (n=1); sleep disorder, dyspepsia, tension headache, depression, and insomnia (n=1).[1]

3TC, lamivudine; ABC, abacavir; DTG, dolutegravir; FTC, emtricitabine; OLE, open-label extension; TAF, tenofovir alafenamide.

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Renal and Metabolic Parameters in Treatment-Naïve PWH, Including Hispanic/Latine Adults at 5 Years

Median Change in eGFRCG (mL/min) From Baseline at Week 144 and 240

	Study 1489[2,15,18,19]		Study 1490[2,15,18,19]	
	BIKTARVY® Baseline: 126 mL/min (n=314)	ABC/DTG/3TC Baseline: 123 mL/min (n=315)	**BIKTARVY** Baseline: 120 mL/min (n=320)	FTC/TAF+DTG Baseline: 121 mL/min (n=325)
Week 144	**–9.6** (n=258)	**–11.7** (n=266)	**–9.0** (n=263)	**–11.0** (n=279)
	Entered OLE (n=252)	**Switched to BIKTARVY for OLE*** Baseline: 116 mL/min (n=254)	**Entered OLE** (n=254)	**Switched to BIKTARVY for OLE*** Baseline: 111 mL/min (n=265)
Week 240	**–8.2** (n=213)	**+2.0*** (n=217)	**–8.5** (n=217)	**+1.3*** (n=233)

*Baseline value for switch to BIKTARVY was defined as the last missing value obtained during or before the first dose of open-label BIKTARVY.[15]

	Post hoc pooled analysis[1,2]	
	BIKTARVY in Hispanic/Latine PWH Baseline: 120 mL/min (n=155)	**BIKTARVY in Non-Hispanic/Latine PWH** Baseline: 124 mL/min (n=477)
Week 144	**–5.6** (n=129)	**–5.9** (n=390)
Week 240	**–5.9** (n=117)	**–9.1** (n=313)

Median change in Total-C:HDL-C ratio from baseline through Week 144[2,19]

Study 1489: –0.1 in the BIKTARVY arm and –0.3 in the ABC/DTG/3TC arm; **Study 1490:** 0.0 in the BIKTARVY arm and –0.1 in the FTC/TAF+DTG arm; post hoc pooled analysis: +0.1 in the Hispanic/Latine arm and -0.1 in the non-Hispanic/Latine arm

Median change in Total-C:HDL-C ratio from baseline through Week 240[2]

Study 1489: 0.0 in the BIKTARVY arm and +0.1 in the ABC/DTG/3TC arm; **Study 1490:** +0.1 in the BIKTARVY arm and –0.1 in the FTC/TAF+DTG arm; post hoc pooled analysis: +0.2 in the Hispanic/Latine arm and 0.0 in the non-Hispanic/Latine arm

The long-term clinical significance of changes in eGFR is not known.

Prior to or when initiating BIKTARVY and during therapy, assess serum creatinine, estimated CrCl, urine glucose, and urine protein in all patients as clinically appropriate. In patients with chronic kidney disease, also assess serum phosphorus.[10]

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.

3TC, lamivudine; ABC, abacavir; C, cholesterol; CrCl, creatinine clearance; DTG, dolutegravir; eGFRCG, estimated glomerular filtration rate (Cockcroft-Gault); FTC, emtricitabine; HDL, high-density lipoprotein; OLE, open-label extension; PWH, people with HIV; TAF, tenofovir alafenamide.

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

Renal and Metabolic Parameters in Treatment-Naïve PWH, Including Hispanic/Latine Adults at 5 Years (cont'd)

Median Cumulative Change in Weight (kg) From Baseline at Week 144 and 240

	Study 1489[2,15,19,20]		Study 1490[2,15,19,20]	
	BIKTARVY® Baseline: 77 kg (n=314)	ABC/DTG/3TC Baseline: 78 kg (n=315)	**BIKTARVY** Baseline: 76 kg (n=320)	FTC/TAF+DTG Baseline: 76 kg (n=325)
Week 144	**+4.1** (n=260)	+3.5 (n=267)	**+4.4** (n=263)	+5.0 (n=279)
	Entered OLE (n=252)	**Switched to BIKTARVY for OLE*** Baseline: 83 kg (n=254)	**Entered OLE** (n=254)	**Switched to BIKTARVY for OLE*** Baseline: 82 kg (n=265)
Week 240	**+6.1** (n=214)	**+2.4*** (n=217)	**+6.1** (n=217)	**+1.3*** (n=234)

*Baseline value for switch to BIKTARVY was defined as the last missing value obtained during or before the first dose of open-label BIKTARVY.[15]

	Post hoc pooled analysis[1,2]	
	BIKTARVY in Hispanic/Latine PWH Baseline: 73 kg (n=155)	**BIKTARVY in Non-Hispanic/Latine PWH** Baseline: 79 kg (n=477)
Week 144	**+4.1** (n=134)	**+4.3** (n=397)
Week 240	**+6.2** (n=115)	**+6.0** (n=313)

Median cumulative change[15]:

Cumulative median weight changes at Week 240 from baseline in the blinded phase was 6.8 kg for participants who switched from ABC/DTG/3TC (Study 1489) and 5.4 kg in those who switched from FTC/TAF+DTG (Study 1490).

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.

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

BIKTARVY® Is the Only INSTI-Based STR Recommended by the DHHS Guidelines for Rapid Initiation[8,10]

BIKTARVY can be started immediately in your appropriate patients after diagnosis without waiting for testing results[8,10,*]

According to DHHS guidelines, the following tests should be performed at treatment initiation[8]:

- **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.[8]

- BIKTARVY is not indicated for patients with known or suspected substitutions associated with resistance to bictegravir or tenofovir[10]
- 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[10]

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[10]
- Prior to or when initiating BIKTARVY, test for hepatitis B virus infection[10]

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions (cont'd)

- **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 page 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 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.[8]

ART, antiretroviral therapy; CAB-LA, cabotegravir long-acting; 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

BIKTARVY® Is the Only STR to Receive an FDA-Approved Label Expansion for Use in PWH With an ART History Who Are Viremic[10]

BIKTARVY can also be restarted immediately in your appropriate patients without waiting for testing results[8,10]

Management strategies should be individualized, including assessment of viral load, resistance testing, ART history, adherence, and potential drug interactions[8]

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.[10]

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

- **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.

FDA, US Food and Drug Administration; PWH, people with HIV.

References: 1. Martorell C, Ramgopal M, Hagins D, et al. Efficacy and safety of bictegravir/emtricitabine/tenofovir alafenamide in Black and Hispanic/Latine adults with HIV-1 initiating first-line therapy: 5-year follow-up from two phase III studies. *HIV Med*. 2025;26(6):858-869. **2.** Data on file. Gilead Sciences, Inc. **3.** Emory University. Racial/Ethnic Disparities and HIV in the United States. AIDSVu. Accessed February 10, 2026. https://map.aidsvu.org/race-profile/nation/usa/overview#R0-Overview **4.** Rajabiun S, Rumptz MH, Felizzola J, et al. The impact of acculturation on Latinos' perceived barriers to HIV primary care. *Ethn Dis*. 2008;18(4):403-408. **5.** Centers for Disease Control and Prevention. Social determinants of health. Updated February 7, 2024. Accessed March 26, 2026. **6.** DHHS. Hispanic/Latino Health. Updated September 1, 2025. Accessed February 11, 2026. https://minorityhealth.hhs.gov/hispaniclatino-health **7.** 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. **8.** 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 February 10, 2026. **9.** 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. **10.** BIKTARVY. Prescribing information. Gilead Sciences, Inc.; 2025. **11.** Orkin C, DeJesus E, Sax PE, et al. Fixed-dose combination bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir-containing regimens for initial treatment of HIV-1 infection: week 144 results from two randomised, double-blind, multicentre, phase 3, non-inferiority trials. *Lancet HIV*. 2020;7(6):e389-e400. **12.** Wohl DA, Pozniak A, Workowski K, et al. B/F/TAF five-year outcomes in treatment-naïve adults. Poster presented at: Conference on Retroviruses and Opportunistic Infections; February 12-16, 2022; Virtual. Poster 494. **13.** Gallant J, Lazzarin A, Mills A, et al. Bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir, abacavir, and lamivudine for initial treatment of HIV-1 infection (GS-US-380-1489): a double-blind, multicentre, phase 3, randomised controlled non-inferiority trial. *Lancet*. 2017;390(10107):2063-2072.

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Advancing Access® Is Committed to Helping Patients Afford BIKTARVY®, Even if They Don't Have Insurance

Patient Assistance Program

If individuals lack insurance coverage and meet the program criteria, they may be eligible to receive BIKTARVY free of charge

Co-pay Support[2]

9 out of 10 commercially insured enrolled patients pay **$0 with the BIKTARVY Co-pay Savings Program***

*Eligible, commercially insured individuals enrolled in the Gilead Advancing Access Co-pay Savings Program could pay as little as $0 co-pay. Uninsured individuals can contact Gilead's Advancing Access program for information about support options. Restrictions apply. Subject to change. See full terms and conditions at www.gileadadvancingaccess.com/hcp/financial-assistance/copay-support

Multilingual help is available. Ask your Hispanic/Latine patients to call and request Spanish-language assistance

Maricela, 50
UNDETECTABLE on BIKTARVY

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References (cont'd): 14. Sax PE, Pozniak A, Montes ML, et al. Coformulated bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir with emtricitabine and tenofovir alafenamide, for initial treatment of HIV-1 infection (GS-US-380-1490): a randomised, double-blind, multicentre, phase 3, non-inferiority trial. *Lancet*. 2017;390(10107):2073-2082. **15.** Orkin C, Antinori A, Rockstroh JK, et al. Switch to bictegravir/emtricitabine/tenofovir alafenamide from dolutegravir-based therapy. *AIDS*. 2024;38(7):983-991. **16.** Wohl DA, Yazdanpanah Y, Baumgarten A, et al. Bictegravir combined with emtricitabine and tenofovir alafenamide versus dolutegravir, abacavir, and lamivudine for initial treatment of HIV-1 infection: week 96 results from a randomised, double-blind, multicentre, phase 3, non-inferiority trial. *Lancet HIV*. 2019;6(6):e355-e363. **17.** Stellbrink H-J, Arribas JR, Stephens JL, et al. Co-formulated bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir with emtricitabine and tenofovir alafenamide for initial treatment of HIV-1 infection: week 96 results from a randomised, double-blind, multicentre, phase 3, non-inferiority trial. *Lancet HIV*. 2019;6(6):e364-e372. **18.** Martorell C, Ramgopal M, Hagins D, et al. Efficacy and safety of bictegravir/emtricitabine/tenofovir alafenamide in Black and Hispanic/Latine adults with HIV-1 initiating first-line therapy: 5-year follow-up from two phase III studies. *HIV Med*. 2025;26(6)(supplemental digital content):858-869. **19.** Orkin C, Antinori A, Rockstroh J, et al. Outcomes after switching from 144 weeks of blinded DTG/ABC/3TC or DTG+F/TAF to 96 weeks of open-label B/F/TAF. Poster presented at: HIV Glasgow 2022; October 23-26, 2022; Glasgow UK. Poster P088. **20.** Orkin C, DeJesus E, Sax PE, et al. Fixed-dose combination bictegravir, emtricitabine, and tenofovir alafenamide versus dolutegravir-containing regimens for initial treatment of HIV-1 infection: week 144 results from two randomised, double-blind, multicentre, phase 3, non-inferiority trials. *Lancet HIV*. 2020;7(6)(supplementary appendix):e389-e400.

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