

# Biktarvy<sup>®</sup> (BIC/FTC/TAF)

## Switching Treatment-Experienced Patients With Viremia

This document is in response to your request for information regarding switching people with HIV-1 (PWH) who are not virologically suppressed (VS) on their current antiretroviral (ARV) regimen to Biktarvy<sup>®</sup> (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]).

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**The full indication, important safety information, and boxed warnings are available at: [www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi).**

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## Summary

### Product Labeling<sup>1</sup>

BIC/FTC/TAF is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg who have no ARV treatment history, or with an ARV treatment history and not virologically suppressed, with no known or suspected substitutions associated with resistance to the INSTI class, FTC, or TFV, or to replace the current ARV regimen in those who are VS (HIV-1 RNA <50 c/mL) on a stable ARV regimen with no known or suspected substitutions associated with resistance to BIC or TFV.

Use of BIC/FTC/TAF in those with an ARV treatment history and not virologically suppressed is supported by a scientific rationale that this population is expected to have similar virologic response rates to those with no history of ARV treatment provided that the virus is susceptible to the individual components of the regimen. Because limited clinical trial data are available supporting the efficacy of BIC/FTC/TAF in patients with baseline INSTI resistance substitutions, this indication states use in individuals with an ARV treatment history and who are not virologically suppressed with no evidence of known or suspected substitutions associated with resistance to the INSTI class, rather than only to BIC. Additionally, this indication states the individuals should have no known or suspected substitutions associated with resistance to FTC, or TFV.

### Clinical Data on Switching TE Patients With Viremia

In the BASE study, a phase 4 prospective trial that evaluated the efficacy and safety of BIC/FTC/TAF use in PWH with SUD, 74.4% and 48.8% achieved virologic suppression at Week 24 and Week 48, respectively.<sup>2</sup>

### Real-World Data on Switching TE Patients With Viremia

In the BICSTaR study of 88 participants with viremia at baseline, 100% of participants with any preexisting PRMs (9/9) and 85% of participants without preexisting PRMs (44/52) achieved virologic suppression at Month 12.<sup>3</sup>

In a subanalysis of the BICTARG study that assessed virologic suppression rates in 185 PWH with a history of VF, virologic suppression was achieved by 96% and 94% at Week 24 and Week 48, respectively. No cases of VF occurred with BIC/FTC/TAF treatment, and no new RAMs emerged during follow-up.<sup>4</sup>

In a single-center, retrospective study that was conducted to compare the clinical outcomes between PWH who were VS and those who were not VS when they were switched to BIC/FTC/TAF, 36.8% of patients who were not VS at the time of switch achieved virological suppression, 19.7% experienced low-level viremia, and 43.4% experienced VF.<sup>5</sup>

In a retrospective study that compared the efficacy of switching to BIC/FTC/TAF or DTG + 2 NRTIs after a virologic rebound, 82.5% of patients who received BIC/FTC/TAF and 76.9% of patients who received a DTG-based regimen achieved virologic resuppression within 48 weeks; after 48 weeks, 95% and 84.6% re-achieved and maintained virologic suppression for the entire observation period.<sup>6</sup>

## Clinical Data on Switching TE Patients With Viremia

### BASE Study in Participants With SUD<sup>2</sup>

#### Study design and demographics

The BASE study was a single-center, phase 4, open-label, single-arm, prospective trial that evaluated the efficacy and safety of BIC/FTC/TAF use in PWH with SUD (N=43). Participants ≥19 years of age with HIV-1 RNA ≥1000 c/mL and any documented SUD in the past 6 months were eligible. Exclusion criteria included resistance mutations that reduce susceptibility to components of BIC/FTC/TAF (ie, baseline INSTI or TFV-related RAMs); however, participants with TAMs and M184V/I mutations were permitted. The primary endpoint was the proportion of VS (HIV-1 RNA <50 c/mL) participants at Week 24 by FDA Snapshot analysis in the ITT population. Genotypic resistance testing for RT, PIs, and INSTIs were performed on all participants with CVF (HIV-1 RNA >400 c/mL on two consecutive assessments at Week 24 or beyond).

**Table 1. BASE Study: Baseline Demographics and Disease Characteristics<sup>2</sup>**

Key Demographics and Characteristics		BIC/FTC/TAF (N=43)
Age, median (range), years		38 (21–62)
Male sex, n (%)		34 (79.1)
Race or ethnicity, n (%)		White/Black/Native American/Hispanic
Overall HIV-1 RNA, median (range), c/mL		35 (81.4)/6 (14)/2 (4.6)/7 (16.3)
CD4 count, median (range), cells/mcL		55,800 (1212–2,280,000)
TE participants, n (%)		460 (40–1653)
HIV-1 RNA, median (range), c/mL		31 (72.1)
Previous ART regimen, n (%)	INSTI + 2 NRTIs	43,700 (1212–2,280,000)
	PI + 2 NRTIs	22 (71)
Genotypic drug resistance, n (%)	Any	9 (29)
	NNRTI-based	19 (44.2)
	M184V/I	12 (28)
	PI-based	5 (11.6)
	Any TAMs	1 (2.3)

## Results

Through Week 48, the mean adherence was 82.2% by subjective reporting and 78.4% by percentage of days covered. Of the 31/43 participants (72.1%) who completed 48 weeks of treatment, 21/43 participants (48.8%) achieved virologic suppression at Week 48. In the PP analyses, 86.1% at Week 24 and 67.7% at Week 48 were VS. In a subgroup analysis at Week 48, significantly more ARV-naïve participants than TE participants achieved virologic suppression (ARV naïve, n/N=9/9 [100%]; TE, n/N=12/22 [54.5%];  $P=0.029$ ); no other significant differences in rates of virologic suppression were observed across assessed subgroups. CVF was reported in 7 participants (16.3%) through Week 48; 1 of the 3 participants who returned for repeat testing and had a sufficient sample for genotyping developed treatment-emergent resistance (M184V).

Twenty-seven Grade  $\geq 3$  AEs were reported in 15 participants (34.9%), with suicidal ideation being the most frequently reported event (5/43 participants; 11.6%); however, all cases were in the setting of methamphetamine intoxication, and no cases of suicidal ideation were attributed to BIC/FTC/TAF. No BIC/FTC/TAF discontinuations due to severe AEs occurred.

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## Real-World Data on Switching TE Patients With Viremia

### BICSTaR Study<sup>3</sup>

#### Study design and demographics

BICSTaR is an ongoing, multinational, prospective, observational cohort study evaluating the real-world effectiveness, safety, and tolerability of BIC/FTC/TAF in PWH in the clinical setting, including in 1083 TE PWH. The primary analysis was in VS participants, but the effectiveness of BIC/FTC/TAF in participants with viremia at baseline was also assessed. Overall, 87 participants were viremic when switched to BIC/FTC/TAF; 11 participants had preexisting PRMs ( $\geq 1$  preexisting NRTI resistance mutation,  $n=5$ ), and 7 had a history of VF.

#### Results

Among participants who had viremia at baseline, 100% of participants with preexisting PRMs (9/9) and 85% of participants without preexisting PRMs (44/52) achieved virologic suppression at Month 12 (M=E analysis). Of the 52 participants with viremia at baseline without preexisting PRMs, 8 had HIV-1 RNA  $\geq 50$  c/mL at Month 12 (range, 129–6120 c/mL).

Safety data were not reported for the subgroup of participants who were viremic at baseline.

### Retrospective Subanalysis of the BICTARG Study<sup>4</sup>

#### Study design and demographics

A subanalysis of the retrospective, observational BICTARG study (N=2356) in Argentina examined virologic suppression rates (plasma HIV-1 RNA  $< 50$  c/mL) in PWH with a history of VF ( $n=185$ ; 7.8%) who were treated with BIC/FTC/TAF from October 2019 to December 2021. Baseline characteristics were the following: Hispanic/Latin ethnicity, 100%; male, 69.6%; median (IQR) age, 48 (43–54) years; comorbidities, 57.6%. Of the 185 patients with a history of VF, 28 had ongoing VF, and 174 had any RAM at baseline,

with NRTI mutations present in 111 patients (representing 64% of any RAMs) at baseline. A total of 92 patients had M184V/I mutations, and 31 had M184V/I + TAMs.

## Results

Overall, virologic suppression rates were 96% at Week 24 and 94% at Week 48. At Week 48, 94% of patients with a history of VF and 85% of patients with both a history of and ongoing VF were VS. A total of 93% of patients with any RAM and 95% of patients with NRTI RAMs were VS. Virologic suppression rates among patients with M184V/I mutations were 74% at baseline, 94% at Week 24, and 97% at Week 48. Among patients with M184V/I + TAMs, the rates were 75%, 96%, and 95%, respectively. No cases of VF occurred with BIC/FTC/TAF treatment, and no new RAMs emerged during follow-up. No safety data were reported.

## Retrospective Study on Switching to BIC/FTC/TAF<sup>5</sup>

### Study design and demographics

A single-center, retrospective study was conducted to compare the clinical outcomes over a 3-year period between PWH who were VS (ie, HIV RNA <50 c/mL) and those who were not VS when they were switched to BIC/FTC/TAF. Among the 76/163 PWH (46.6%) who were not VS when switched to BIC/FTC/TAF, 39 patients (51.3%) were male, the median (IQR) viral load at switch was 7405 (321–84,525) c/mL, and the median (IQR) age was 42 (29–54) years.

## Results

The mean (IQR) duration of BIC/FTC/TAF exposure in the overall population of suppressed and non-suppressed patients was 20 (14–30) months. Of the 76 patients who were not VS at switch, 36.8% achieved virological suppression, 19.7% experienced low-level viremia (ie, HIV RNA 50–199 c/mL), and 43.4% experienced VF (ie, HIV-1 RNA >200 c/mL on ≥2 assessments).

A safety analysis was not conducted among the patients who were not suppressed at switch. In the overall population, 19/163 patients (11.6%), including 10 patients who were not suppressed at switch, discontinued BIC/FTC/TAF after a median (IQR) of 178 (92–272) days; sleep and gastrointestinal disturbances were the most common complaints, in addition to 1 occurrence of a drug-associated rash. Three patients in the overall population discontinued BIC/FTC/TAF due to persistent viremia, 2 of whom developed new INSTI RAMs. Of the 2 patients with INSTI RAMs, 1 developed additional mutations in RT. The study authors concluded that patients who were not suppressed at switch and did not achieve viral suppression had a 1/24 chance of developing integrase resistance.

## Retrospective Study: Switching to BIC/FTC/TAF or DTG + 2 NRTIs<sup>6</sup>

### Study design and demographics

A single-center, retrospective cohort study was conducted in Taiwan among PWH aged ≥20 years who had received HIV care and were prescribed ≥3 months of ART between January 2016 and March 2022. Eligible patients had available plasma HIV RNA levels, had

a history of achieving virologic suppression on ART (ie, HIV RNA <50 c/mL) before a virologic rebound (ie, HIV RNA >1000 c/mL), and were switched to either BIC/FTC/TAF or DTG + 2 NRTIs after a virologic rebound. All included PWH were followed from the day of the ARV regimen switch until the last available HIV RNA level testing before a censoring event. Censoring events included changes to the core agents (BIC or DTG) of ART, death, LTFU (no clinic visits or drug refills for >6 months), or the conclusion of the observation period, whichever happened first. The primary endpoint was the proportion of patients who reachieved virologic suppression and maintained it within the first 48 weeks of switching ARV regimens. Additional endpoints include the proportions of PWH who achieved virologic suppression beyond 48 weeks.

**Table 2. Baseline Demographics and Disease Characteristics (Chen et al)<sup>6</sup>**

Key Demographics and Characteristics		BIC/FTC/TAF (n=40)	DTG + 2 NRTIs (n=39)
Age, median (IQR), years		38.1 (33.8–46)	36.3 (29.7–40.9)
Male, n (%)		38 (95)	37 (94.9)
HIV RNA at switch, median (IQR), log <sub>10</sub> c/mL		4.4 (3.6–4.7)	4.4 (3.7–5)
CD4 count at switch, median (IQR), cells/mm <sup>3</sup>		232 (146–418) <sup>a</sup>	390 (244–624) <sup>a</sup>
Duration of HIV diagnosis before switch, median (IQR), years		8 (3–11) <sup>b</sup>	4 (2–5) <sup>b</sup>
Duration of follow-up after switch, median (IQR), weeks		95 (63–114) <sup>c</sup>	70 (30–123) <sup>c</sup>
ARV regimen used before switch, n (%)	PI-based	5 (12.5)	0
	NNRTI-based	5 (12.5)	32 (82.1)
	INSTI-based	30 (75)	7 (17.9)
Genotypic resistance results, n/N (%)	NRTI-related RAMs	15/36 (41.7)	15/34 (44.1)
	M184I/V mutation	12/36 (33.3)	13/34 (38.2)
	INSTI-related RAMs	6/36 (16.7)	2/34 (5.9)
NRTI choices at switch, n (%)	TDF + FTC	0	10 (25.6)
	Abacavir + lamivudine	0	28 (71.8)

<sup>a</sup>P=0.049; <sup>b</sup>P=0.007; <sup>c</sup>P=0.39.

## Results

Within the first 48 weeks after switching ARV regimens, 79.7% of patients (63/79) reachieved virologic suppression (BIC/FTC/TAF, 82.5% [33/40]; DTG + 2 NRTIs, 76.9% [30/39]; *P*=0.78). When extending beyond 48 weeks, a total of 89.9% of patients reachieved and maintained virologic suppression during the entire observation period (BIC/FTC/TAF, 95% [38/40]; DTG + 2 NRTIs, 84.6% [33/39]; *P*=0.15).

In the BIC/FTC/TAF group, 7 patients (17.5%) did not achieve virologic suppression within the first 48 weeks; 5 patients continued treatment and achieved virologic suppression, and 2 patients were LTFU. Among patients in the DTG + 2 NRTIs group, 9 (23.1%) did not initially achieve virologic suppression within the first 48 weeks: 4 patients continued treatment and achieved virologic suppression, 4 patients were LTFU, and 1 patient was switched at Week 70 to a boosted darunavir-based ART. Genotypic resistance testing was performed on 5/16 patients from both groups who did not re achieve virologic suppression within the first 48 weeks of switching, and no emerging RAMs to INSTIs or NRTIs were detected.

In both groups, 88.6% of patients (70/79) had available genotypic resistance data prior to switching to BIC/FTC/TAF or DTG + 2 NRTIs. Of these patients, 45.7% (32/70) had documented or archived NRTI or INSTI RAMs. A total of 93.8% of patients (15/16) in the BIC/FTC/TAF group and 81.3% of patients (13/16) in the DTG group re achieved virologic



suppression ( $P=0.6$ ). The study found that the predicted genotypic susceptibility score was not associated with virologic success after the switch for both groups.

Safety outcomes were not reported.

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## References

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3. Trottier B, Bonnet F, García-Delatoro MG, et al. Real World Effectiveness and Tolerability of Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) in Treatment Experienced People With HIV and a History of Antiretroviral Drug Resistance Mutations [Poster 1628848]. Paper presented at: ID Week 2023; October 11-15, 2023; Boston, MA.
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5. King L, Mackie N, C. F. Switching to Biktary: real-world single centre outcomes over 3 years. Paper presented at: Spring Conference of the British HIV Association (BHIVA); April 24-26, 2023; Gateshead, United Kingdom.
6. Chen GJ, Sun HY, Chang SY, et al. Effectiveness of second-generation integrase strand-transfer inhibitor-based regimens for antiretroviral-experienced people with HIV who had viral rebound. *Journal of Microbiology, Immunology and Infection*. 2023:1-8.

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## Abbreviations

AE=adverse event  
ART=antiretroviral therapy  
ARV=antiretroviral  
BIC=bictegravir  
BICSTaR=Bictegravir  
Single-Tablet Regimen  
c/mL=copies/mL  
CD4=cluster of  
differentiation 4  
CVF=confirmed virologic  
failure  
DRAE=drug-related adverse  
event  
DTG=dolutegravir  
FTC=emtricitabine  
INSTI=integrase strand  
transfer inhibitor  
INSTI-R= integrase strand  
transfer inhibitor resistance

LTFU=lost to follow-up  
M=E=missing equals  
excluded  
NNRTI=non-nucleos(t)ide  
reverse transcriptase  
inhibitor  
NNRTI-R=non-nucleos(t)ide  
reverse transcriptase  
inhibitor resistance  
NRTI=nucleos(t)ide reverse  
transcriptase inhibitor  
NRTI-R= nucleos(t)ide  
reverse transcriptase  
inhibitor resistance  
PI=protease inhibitor  
PI-R=protease inhibitor  
resistance  
PP=per protocol  
PRM=primary resistance  
mutation

PWH=people with HIV  
RAM=resistance-associated  
mutation  
RT=reverse transcriptase  
SAE=serious adverse event  
SUD=substance use  
disorder  
TAF=tenofovir alafenamide  
TAM=thymidine analog  
mutation  
TDF=tenofovir disoproxil  
fumarate  
TE=treatment-experienced  
TFV=tenofovir  
VF=virologic failure  
VS=virologically suppressed

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## Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Biktarvy US Prescribing Information available at:

[www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy\\_pi](http://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi).

## Follow-Up

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☎ 1-866-MEDI-GSI (1-866-633-4474) or 🌐 [www.askgileadmedical.com](http://www.askgileadmedical.com)

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Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or

🌐 [www.gilead.com/utility/contact/report-an-adverse-event](http://www.gilead.com/utility/contact/report-an-adverse-event)

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 [www.accessdata.fda.gov/scripts/medwatch](http://www.accessdata.fda.gov/scripts/medwatch)

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