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GILEAD | Medical Information

Biktarvy® (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® (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.

Summary

Product Labeling[1]

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 VS 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 VS 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 to BIC/FTC/TAF

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.[2]

Real-World Data on Switching TE Patients With Viremia to BIC/FTC/TAF

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

- Of participants with detectable viremia at BIC/FTC/TAF initiation, 87% of the participants with data available at baseline and Month 24 (n=75) achieved virologic suppression at Month 24 (M=E analysis).[4]

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.[5]

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.[6]

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% reachieved and maintained virologic suppression for the entire observation period.[7]

In a retrospective analysis of data from the ICONA cohort, the 1-year cumulative probability of achieving virologic suppression was 74.8% (95% CI: 52.6–92.2) in the 20 PWH with detectable HIV-1 RNA at the time of switch to BIC/FTC/TAF. Overall, 2 discontinuations due to VF and 4 discontinuations due to toxicity were reported.[8]

Clinical Data on Switching TE Patients With Viremia to BIC/FTC/TAF

BASE Study in Participants With SUD[2]

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[2]

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	35 (81.4)/6 (14)/2 (4.6)/7 (16.3)
Overall HIV-1 RNA, median (range), c/mL		55,800 (1212–2,280,000)
CD4 count, median (range), cells/mcL		460 (40–1653)
TE participants, n (%)		31 (72.1)

Key Demographics and Characteristics		BIC/FTC/TAF (N=43)
HIV-1 RNA, median (range), c/mL		43,700 (1212–2,280,000)
Previous ART regimen, n (%)	INSTI + 2 NRTIs	22 (71)
	PI + 2 NRTIs	9 (29)
Genotypic drug resistance, n (%)	Any	19 (44.2)
	NNRTI-based	12 (28)
	M184V/I	5 (11.6)
	PI-based	1 (2.3)
	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 ≥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.

Real-World Data on Switching TE Patients With Viremia to BIC/FTC/TAF

BICSTaR Study

Study design[3]

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.

TE participants with preexisting PRMs and detectable viremia at baseline[3]

The primary analysis was in VS participants, but the effectiveness of BIC/FTC/TAF in participants with viremia at the time of switching to BIC/FTC/TAF was also assessed. Overall, 87 participants were viremic when switched to BIC/FTC/TAF; 11 participants had preexisting PRMs (≥1 preexisting NRTI resistance mutation, n=5), and 7 had a history of VF.

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 ≥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.

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TE participants with detectable viremia at baseline[4]

The effectiveness, safety, and patient-reported outcomes through 24 months of BIC/FTC/TAF were evaluated in TE participants with detectable levels of viremia (HIV-1 RNA ≥50 c/mL) at the time of BIC/FTC/TAF initiation.

In the M=E analysis of 75 participants with available baseline and Month 24 data, virologic suppression was achieved by 67% at Month 3, 76% at Month 6, 79% at Month 12, and 87% at Month 24. The median (Q1, Q3) HIV-1 RNA among the 10 participants with detectable viremia at Month 24 was 1.93 (1.79, 3.37) $\log_{10}$ c/mL.

Among the 59 participants with available data at BL and Month 24, CD4 counts improved by a median of 113 cells/mcL; in the 53 participants with available data at both time points, the median CD4/CD8 ratio increased by 0.2 (each, *P*=0.002).

Overall, 69 of 107 participants (64%) experienced ≥1 AE within 24 months of treatment initiation. TRAEs occurred in 12 participants (11%), including mild, moderate, and severe events in 7 (7%), 6 (6%), and 1 (1%) participant, respectively. Six participants (6%) discontinued BIC/FTC/TAF due to TRAEs; depression was the only TRAE that led to discontinuation in ≥1% (n=2 [2%]). Five participants (5%) discontinued treatment due to lack of efficacy; last on-treatment HIV-1 RNA viral loads ranged from 55 c/mL to 180 c/mL between Days 165 and 309. Two deaths (2%) were reported: 1 due to pulmonary insufficiency following trauma and 1 due to an unknown cause.

Of the 53 participants with SF-36 scores available at baseline and Month 24, the Mental Component Summary median score increased from 48.9 at baseline by 2.8 points at Month 24 (*P*=0.006); Physical Component Summary scores remained stable, with a median change of -0.4 points. The median treatment satisfaction score, as measured by the HIVSTQ status questionnaire, was 53 at baseline (n=94) and increased to 57.5 at Month 24 (n=48).

Retrospective Subanalysis of the BICTARG Study[5]

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[6]

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[7]

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)[7]

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_{10} c/mL		4.4 (3.6–4.7)	4.4 (3.7–5)
CD4 count at switch, median (IQR), cells/mm^3		232 (146–418)[a]	390 (244–624)[a]
Duration of HIV diagnosis before switch, median (IQR), years		8 (3–11)[b]	4 (2–5)[b]
Duration of follow-up after switch, median (IQR), weeks		95 (63–114)[c]	70 (30–123)[c]
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)

[a]*P*=0.049; [b]*P*=0.007; [c]*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 reachieve 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 reachieved 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.

Retrospective Study of the ICONA Cohort[8]

A retrospective analysis of data from the ICONA cohort assessed outcomes of PWH who switched from a two-drug regimen to BIC/FTC/TAF (N=60). Primary objectives included the cumulative probability of virologic suppression in patients with detectable HIV-1 RNA (HIV-1 ≥50 c/mL) at baseline and the cumulative probability of BIC/FTC/TAF discontinuation due to toxicity or VF. At baseline, 45 patients (75%) were male, the median (IQR) age was

49 (38–57) years, and the median (IQR) number of previous ART regimens was 4 (3–6). At the time of switch, 20 patients had detectable HIV-1 RNA, and 13 of these patients had low-level viremia (HIV-1 RNA 50–200 c/mL). Genotypic resistance testing was performed in 11 of the 20 patients with detectable HIV-1 RNA; no INSTI-R was detected.

Overall, the median (IQR) follow-up duration after switching to BIC/FTC/TAF was 10.9 (3.6–24.7) months. Among the 20 patients with detectable HIV-1 RNA at the time of switch to BIC/FTC/TAF, the 1-year cumulative probability of achieving virologic suppression was 74.8% (95% CI: 52.6–92.2). Overall, 2 discontinuations due to VF and 4 discontinuations due to toxicity (neuropsychiatric adverse event, tachycardia, weight gain, and unspecified toxicity; each, n=1) were reported, with a 1-year cumulative probability of BIC/FTC/TAF discontinuation due to virologic failure or toxicity of 10.7% (95% CI: 0.5–24.5).

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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
DTG=dolutegravir
FTC=emtricitabine
HIVTSQ=HIV Treatment Satisfaction Questionnaire
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
PP=per protocol
PRM=primary resistance mutation
PWH=people with HIV
Q=quartile
RAM=resistance-associated mutation
RT=reverse transcriptase
SAE=serious adverse event
SF-36=36-Item Short Form Health Survey
SUD=substance use disorder
TAF=tenofovir alafenamide
TAM=thymidine analog mutation
TDF=tenofovir disoproxil fumarate
TE=treatment-experienced
TFV=tenofovir
TRAE=treatment-related adverse event
VF=virologic failure
VS=virologically suppressed

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.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

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

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