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Biktarvy® (BIC/FTC/TAF) Efficacy by Adherence Subgroups

This document is in response to your request for information regarding the efficacy of the single-tablet regimen (STR) Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) in people with HIV (PWH) by adherence subgroups.

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Summary

Clinical Data on Efficacy of BIC/FTC/TAF by Adherence Subgroups

In a pooled analysis of 5 trials evaluating BIC/FTC/TAF vs DTG + 2 NRTIs, PWH who were treated with BIC/FTC/TAF had high rates of virologic suppression (96–99%, using LOCF imputation) at Weeks 48, 96, and 144, regardless of the level of adherence.[1]

In post hoc pooled analyses that evaluated outcomes of Hispanic/Latine vs non-Hispanic/Latine and Black vs non-Black participants in Studies 1489 and 1490, median adherence rates were high across all subgroups (96.3–97.7%), and all participants with low adherence had VL <50 c/mL at Week 240 (M=E analysis).[2]

In a phase 3 study that evaluated the safety and efficacy of switching to BIC/FTC/TAF in VS PWH who identified as Black American, high rates of virologic suppression (98–100% using a LOCF imputation) were maintained through Week 72 in all adherence subgroups.[3]

Real-World Data on Effectiveness of BIC/FTC/TAF by Adherence Subgroups

In retrospective studies of VS PWH who switched to BIC/FTC/TAF or DTG-containing STRs or MTRs in the Trio Health HIV EMR and dispensing database, virologic suppression rates remained high and were similar between all groups despite the differences in adherence.[4,5]

In the BICSTaR study, an ongoing, prospective, observational cohort study in PWH who receive BIC/FTC/TAF in clinical practice, virologic suppression was high (92–100%) at 24 months, regardless of adherence pattern.[6]

A retrospective cohort study in Italy evaluating BIC/FTC/TAF forgiveness reported that a PDC as low as 0.75 was sufficient for >90% of patients to obtain a VL of <50 or <200 c/mL.[7]

Clinical Data on the Efficacy of BIC/FTC/TAF by Adherence Subgroups

Pooled Analysis of Adherence in Studies of BIC/FTC/TAF vs DTG + 2 NRTIs

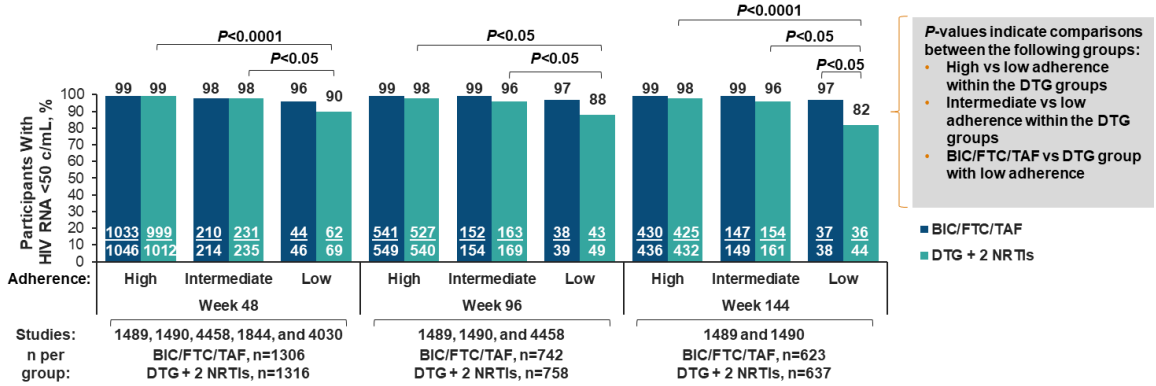
Study design and demographics[1]

A retrospective analysis of five double-blind, placebo-controlled, phase 3 studies (1489, 1490, 4458, 1844, and 4030) of ARV-naive and VS PWH who received BIC/FTC/TAF (n=1306) or DTG + 2 NRTIs (n=1316) assessed the effect of adherence on virologic outcomes. Adherence (calculated by dividing the number of pills taken by the total number of pills prescribed) was analyzed at Weeks 48, 96, or 144 and was categorized into three subgroups: high (≥95%), intermediate (≥85% to <95%), and low (<85%). Virologic outcomes were evaluated using the last available on-treatment VL (LOCF imputation). Participants underwent post-BL resistance testing if they had confirmed virologic failure (defined as VL ≥50 c/mL at two consecutive visits without resuppression on study drug) or a VL ≥200 c/mL at the last visit. BL demographics were generally similar between treatment groups.

Results

At Weeks 48, 96, and 144, overall rates of virologic suppression at last visit were high in both treatment groups (BIC/FTC/TAF, 99%; DTG + 2 NRTIs, 97–98%).[8] Through Week 48, low adherence (<85%) was observed in 4% of participants in the BIC/FTC/TAF group (median adherence, 78%) and 5% in the DTG + 2 NRTIs group (median adherence, 80%). Compared with participants with high and intermediate adherence, those with low adherence were younger, more often Black, and more often ARV-naive (P≤0.02). Participants who received BIC/FTC/TAF had high rates of virologic suppression, regardless of the level of adherence, whereas virologic suppression rates were significantly lower among participants treated with DTG + 2 NRTIs who had <85% adherence than among those with intermediate or high adherence (Figure 1). Among participants with low adherence, the virologic suppression rate at Week 144 was significantly higher in those who received BIC/FTC/TAF than in those who received DTG + 2 NRTIs (P<0.05).[1]

Figure 1. Pooled Analysis: Virologic Suppression in Treatment Groups by Time Point and Adherence Category[1]



Note: Adherence subgroups were defined as follows: high, ≥95%; intermediate, ≥85% to <95%; low, <85%.

No participants who received BIC/FTC/TAF had treatment-emergent resistance through Week 144. Two participants who received DTG/ABC/3TC had emergent M184V identified at Week 168, with noted adherence rates of 93% and 86% at Week 144; both were resuppressed after being switched to open-label BIC/FTC/TAF.[1]

Safety outcomes were not provided for this pooled analysis.

Pooled Analyses of Adherence in Hispanic/Latine and Black Participants in Studies 1489 and 1490[2]

Two post hoc pooled analyses evaluated efficacy and safety outcomes of Hispanic/Latine (n=155) vs non-Hispanic/Latine (n=477) and Black (n=211) vs non-Black (n=421) participants who received BIC/FTC/TAF in Studies 1489 and 1490. Adherence was calculated by total number of pills taken divided by total number of pills prescribed up to Week 240; adherence categories were ≥95% (high), ≥85% to <95%, and <85% (low).

Median adherence rates were high across all subgroups of participants: Black, 96.3%; non-Black, 97.7%; Hispanic/Latine, 97.5%; non-Hispanic/Latine, 97.2%. Black participants were more likely to have lower adherence than non-Black participants (*P*=0.0074); however, all 10 Black participants and all 9 non-Black participants with low adherence had a VL <50 c/mL at Week 240 (M=E analysis). The proportion of Hispanic/Latine participants in each adherence category was similar to the proportion of non-Hispanic/Latine participants, and at Week 240, all 4 Hispanic/Latine participants and all 15 non-Hispanic/Latine participants with low adherence had a VL <50 c/mL (M=E analysis).

Adherence Analysis in the BRAAVE 2020 Study[3]

A phase 3, randomized, multicenter study evaluated the safety and efficacy of switching to BIC/FTC/TAF (n=330) or continuing a BL regimen of 2 NRTIs plus a third agent (n=165) in PWH who were VS; located in the US; and self-identified as Black, Black American, or mixed race, including Black. The primary efficacy endpoint was the proportion of participants with plasma VL ≥50 c/mL at Week 24 by FDA Snapshot analysis. After Week 24, participants in the continuing BL regimen group were switched to BIC/FTC/TAF.

Switching to BIC/FTC/TAF was noninferior to continuing the BL regimen of 2 NRTIs plus a third agent at Week 24. High rates of virologic suppression (98–100%, using an M=E analysis) were maintained through Week 72 in participants who received BIC/FTC/TAF, regardless of adherence levels. Through Week 72, 100% of participants (362/363) with ≥95% adherence, 98% of participants (102/104) with ≥80% to <95% adherence, and 100% of participants (15/15) with <80% adherence had a VL <50 c/mL at their last visit (LOCF). No treatment-emergent resistance was detected.

Through Week 72, all-grade AEs that occurred in ≥5% of participants who received BIC/FTC/TAF at any time (n=493) included upper respiratory tract infection, syphilis, headache, pain in extremity, arthralgia, hypertension, and nasopharyngitis. AEs led to study drug discontinuation in 12 participants through Week 72.[9]

Real-World Data on the Effectiveness of BIC/FTC/TAF by Adherence Subgroups

Trio Health Studies

A retrospective study using data from the Trio Health HIV network assessed outcomes of PWH who switched to BIC/FTC/TAF (n=4571) or a DTG-based STR (DTG/3TC, DTG/RPV, DTG/ABC/3TC; n=1697). Adherence was assessed by PDC, and suboptimal adherence was defined as <80%. Compared with those who received a DTG-based STR, patients who received BIC/FTC/TAF were significantly younger, more likely to be Black or African American, and had lower rates of virologic suppression at switch.[4]

More patients who received BIC/FTC/TAF had suboptimal adherence than those who received DTG-based STRs (total cohort, 45% vs 29%, respectively; *P*<0.05; matched sample, 35% vs 30%; *P*=0.03); however, rates of virologic suppression were not significantly different (total cohort, 89% vs 93%; matched sample, 94% vs 93%; *P*=0.25).[4]

A retrospective observational study evaluated data on HIV suppression from the Trio Health HIV EMR and dispensing database in VS stable patients who switched to STRs (BIC/FTC/TAF, DTG/3TC/ABC) or MTRs (DTG + FTC/TAF, DTG + FTC/TDF, DTG + 3TC + ABC). PDC ≥80% and ≥95% were used to measure adherence. At BL, there were significant differences across treatment groups in gender, race, and proportion of patients with CD4 <200 cells/mcL.[5]

Of the 2229 patients, 51% (n=1130) switched to BIC/FTC/TAF, 23% (n=520) switched to DTG/3TC/ABC, and 26% (n=579) switched to DTG MTRs. Patients who switched to BIC/FTC/TAF were found to be significantly more adherent at PDC ≥80% and PDC ≥95% than patients who received DTG/3TC/ABC and DTG MTR. At Month 6, virologic suppression rates remained high (86–96%) and were similar between all groups despite the differences in adherence. Accounting for differences within groups at BL, an association was found between adherence and virologic suppression for DTG regimens but not for BIC/FTC/TAF.[5]

BICSTaR Study[6]

BICSTaR is a large, ongoing, multicountry, prospective, observational cohort study in PWH that is evaluating the efficacy, safety, and tolerability of BIC/FTC/TAF in clinical practice. A subanalysis was conducted in 1496 TE participants with any VAS/missed doses data through 24 months to identify patterns of treatment adherence in TE participants switching to BIC/FTC/TAF, to identify significant associations between each treatment pattern and BL characteristics, and to determine effectiveness outcomes according to adherence pattern. Self-reported adherence data were collected at BL, 6 months, 12 months, and 24 months using a VAS adherence questionnaire and a report of missed doses in the last 4 and 30 days.

In an M=E analysis at 24 months, virologic suppression was high (92–100%) in all groups, regardless of adherence pattern. Among participants who reported missing ≥4 doses of BIC/FTC/TAF in the last month at 6 months (n=25), 12 months (n=31), and 24 months (n=34), virologic suppression was maintained through 24 months in 92%, 100%, and 94% of participants, respectively.

BIC/FTC/TAF Forgiveness to Imperfect Adherence[7]

A retrospective cohort study in Italy was conducted to assess overall adherence in PWH treated with BIC/FTC/TAF and to determine rates of virologic suppression associated with different levels of adherence. The analysis included 420 patients who were treated with BIC/FTC/TAF from January 2020 to August 2022 and had obtained a minimum of 2 refills. Adherence was assessed by PDC, and VLs were obtained from EMRs. Patients were categorized according to virologic response: TND (undetectable), VL <50 c/mL, or VL <200 c/mL. Forgiveness in this study was calculated as the possibility to reach and maintain one of the three virologic thresholds for any degree of imperfect adherence.

Overall adherence was high, with a median (IQR) PDC of 0.97 (0.91–1). The mean adherence rate among patients with a steady VL <50 or <200 c/mL was 0.94 (95% CI: 0.93–0.95). Overall virologic success rate was also high, with only 17 measures (2.2%) of VL >200 c/mL and 56 measures (7.11%) of VL >50 c/mL over 873 person-years. Forgiveness with BIC/FTC/TAF was observed with a PDC as low as 0.75. An adherence level of 0.75 was sufficient to achieve a VL of <50 or <200 c/mL in >90% of patients and to reach the TND threshold in >60% of patients. In a logistic regression analysis, PDC significantly correlated with the VL <200 c/mL threshold (P<0.0001) and with achieving and maintaining a VL <50 c/mL (P-value not reported). Achievement of a TND VL was significantly associated with PDC (P<0.0001), number of chronic pathologies (P<0.001), and duration of time with HIV (P=0.05).

References

1. Andreatta K, Sax PE, Wohl D, et al. Efficacy of bictegravir/emtricitabine/tenofovir alafenamide versus dolutegravir-based three-drug regimens in people with HIV with varying adherence to antiretroviral therapy. *Journal of Antimicrobial Chemotherapy.* 2024.
2. 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.
3. Andreatta K, D'Antoni ML, Chang S, et al. High efficacy of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in Black adults in the United States, including those with pre-existing HIV resistance and suboptimal adherence. *J Med Virol.* 2024;96(10):e29899.
4. Elion RA, Moyle G, Gruber J, et al. Persistence and Virologic Outcomes of People with HIV (PWH) with Suboptimal Adherence on B/F/TAF or Dolutegravir-Based Single-Tablet Regimens. [Poster #P-382]. Paper presented at: IDWeek; October 19–22, 2025; Atlanta, GA.
5. Sax PE, Althoff KN, Eron JJ, et al. Impact of Adherence on Viral Suppression with Bictegravir- and Dolutegravir (DTG)- Containing Triple Therapy in Clinical Practice. [Poster P029]. Paper presented at: HIV Drug Therapy Glasgow; October 5-8, 2020; Virtual.
6. Boffito M, Brunetta J, Levy I, et al. Real-World Effectiveness in Treatment-Experienced People With HIV Switching to B/F/TAF With Distinct Patterns of Self-Reported Adherence [Poster P068]. Paper presented at: HIV Glasgow; November 10-13, 2024; Glasgow, UK.
7. Maggiolo F, Taramasso L, Valenti D, et al. B/F/TAF forgiveness to non-adherence. *Sex Transm Infect.* 2024;100(7):418-422.
8. Andreatta K, Sax PE, Wohl D, et al. Efficacy of bictegravir/emtricitabine/tenofovir alafenamide versus dolutegravir-based three-drug regimens in people with HIV with varying adherence to antiretroviral therapy [Supplementary Material]. *Journal of Antimicrobial Chemotherapy.* 2024.
9. Kumar P, Stephens JL, Wurapa AK, et al. Week 72 Outcomes and COVID-19 Impact From the BRAAVE 2020 Study: a Randomized Switch to B/F/TAF in Black American Adults With HIV [Poster 802]. Paper presented at: 11th International AIDS Society (IAS) Conference on HIV Science Virtual; 18-21 July, 2021.

Abbreviations

3TC=lamivudine
ABC=abacavir
AE=adverse event
ARV=antiretroviral
BIC=bictegravir
BL=baseline
c/mL=copies per mL
CD4=cluster of differentiation 4
DTG=dolutegravir
EMR=electronic medical record
FTC=emtricitabine
LOCF=last observation carried forward
M=E=missing=excluded
MTR=multitablet regimen
NRTI=nucleos(t)ide reverse transcriptase inhibitor
PDC=proportion of days covered
PWH=people with HIV
RPV=rilpivirine
STR=single-tablet regimen
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate
TE=treatment experienced
TND=target not detected
VAS=visual analog scale
VL=viral load
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

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