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Biktarvy® (BIC/FTC/TAF) Use in Patients With Severe Renal Impairment and Hemodialysis

This document is in response to your request for information regarding the use of Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) in patients with severe renal impairment (eGFR <30 mL/min/1.73m^2), including those requiring hemodialysis (HD).

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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 not recommended in individuals with severe renal impairment (estimated CrCl of 15 to <30 mL/min); or ESRD (estimated CrCl <15 mL/min) who are not receiving chronic HD; or no ARV treatment history and ESRD who are receiving chronic HD.

Clinical Data on BIC/FTC/TAF Use in Participants With Severe Renal Impairment and HD

In a phase 3b study (Study 1825), the following outcomes were evaluated in participants with an eGFR <15 mL/min on HD who switched from E/C/F/TAF to BIC/FTC/TAF during the OLE phase[2,3]:

- All participants who switched to BIC/FTC/TAF (n=10) maintained HIV-1 RNA <50 c/mL at Week 48 (M=E analysis). Most AEs were Grade 1 or 2 in severity.
- Mean BIC C_{trough} levels were lower in participants on HD than historical mean values of PWH with normal kidney function or mild or moderate kidney impairment, but C_{trough} levels of BIC were 4- to 7-fold higher than the $paEC_{95}$ against wild-type HIV-1 virus for BIC.
- Most AEs were Grade 1 or 2 in severity, and 3 participants had SAEs, all of which were deemed unrelated to BIC/FTC/TAF. No AEs led to BIC/FTC/TAF discontinuation.

In a phase 1 study, BIC AUC_∞ was approximately 27% lower in participants with an eGFR of 15 to 29 mL/min than in healthy volunteers with normal renal function. No correlation was observed between the AUC_∞ or C_{max} and $eGFR_{CG}$. Overall, BIC was well tolerated.[4]

In a case series of 6 patients on HD who switched to BIC/FTC/TAF-containing regimens, all patients achieved or maintained virologic suppression, and no patients reported AEs.[5]

Clinical Data on BIC/FTC/TAF Use in Participants With Severe Renal Impairment and HD

Study GS-US-292-1825: BIC/FTC/TAF in PWH With ESRD on Chronic HD

Study design and demographics

A phase 3b, open-label, multicenter, single-arm study was conducted to evaluate the safety, tolerability, PK, and efficacy of E/C/F/TAF in virologically suppressed (HIV-1 RNA <50 c/mL) PWH who were on a stable ARV regimen for ≥6 consecutive months and had ESRD (eGFR <15 mL/min) on chronic HD for ≥6 months. Participants switched from their current ARV regimen to E/C/F/TAF and received treatment for ≥96 weeks. Following regulatory approval of BIC/FTC/TAF by the FDA, the study protocol was amended to allow eligible US participants to switch to BIC/FTC/TAF in the OLE phase for 48 weeks (N=10).[2]

During the OLE, BIC/FTC/TAF safety was assessed by AEs and laboratory abnormalities, and efficacy was assessed by the proportion of participants who were virologically suppressed. PK sampling was conducted at Weeks 4, 24, and 48.[2]

The median (range) age of participants who switched to BIC/FTC/TAF was 55 (34–63) years. The median (IQR) $eGFR_{CG}$ at BIC/FTC/TAF start was 11.6 (6.8–17.3) mL/min, and the median (range) time on HD was 4 (2–16) years.[3]

Virologic outcomes at Week 48[2]

Virologic suppression was maintained in all 10 participants (100%; 95% CI: 69.2–100%) according to an M=E analysis, with a median (range) duration of BIC/FTC/TAF exposure of 48 (47–52) weeks. The median (range) change from baseline to Week 48 in CD4 count and percentage (n=9) was -121 (-296 to -45) cells/mcL and 1.5% (-5.2 to 8.8%), respectively. From baseline to Week 48, the median (range) treatment adherence rate was 88.5% (76.1–99.1%).

PK results at Week 48[2]

Mean BIC C_{trough} values at Weeks 4, 24, and 48 are presented in Table 1. C_{trough} levels of BIC were lower in participants on HD than the historical mean (%CV) level of 2610 ng/mL (35.2%) in PWH with normal kidney function or mild-to-moderate kidney impairment. C_{trough} levels of BIC stayed 4- to 7-fold higher than the $paEC_{95}$ (162 ng/mL) against wild-type HIV-1 virus for BIC.

Table 1. Study 1825: Mean BIC C_{trough} Values at Weeks 4, 24, and 48[2]

Mean (Range), ng/mL; %CV	Week 4 (n=5)	Week 24 (n=2)	Week 48 (n=3)
BIC C_{trough}	919 (293.5–1810); 83.1	674 (288–1060); 81	1097 (632–1510); 40.2

Safety results at Week 48[2,3]

All participants had ≥1 AE during the OLE phase, and most AEs were Grade 1 or 2 in severity (Table 2). One participant had >1 Grade 3 AE, and 3 participants had SAEs; none were considered related to BIC/FTC/TAF. No AEs led to BIC/FTC/TAF discontinuation,

and no deaths were reported. Five participants (50%) had ≥1 Grade 3 or 4 laboratory abnormality.

Table 2. Study 1825: AEs and Laboratory Abnormalities (Safety Analysis Set)[2,3]

AEs and Laboratory Abnormalities, n (%)		BIC/FTC/TAF (n=10)
Any AEs		10 (100)
AEs occurring in >1 participant	Dyspnea	2 (20)
	Hypertension	2 (20)
Grade 3 or 4 AE		1 (10)[a]
Study drug-related AE		1 (10)[b]
SAEs		3 (30)[c]
Any Grade 3 or 4 laboratory abnormalities		5 (50)[d]

[a]One participant reported multiple Grade 3 AEs that were not considered treatment related, including abdominal wall hematoma, cervical spinal stenosis, congestive cardiac failure, hypertensive emergency, hypertensive urgency, pneumonia, respiratory syncytial viral pneumonia, spinal stenosis, and vascular access site hemorrhage.
[b]One participant reported Grade 2 nausea and Grade 1 malaise.
[c]Included the following: tendon rupture, hyperkalemia, and dyspnea (n=1); angina pectoris, acute myocardial infarction, and skin ulcer (n=1); and vascular access site hemorrhage, pneumonia, respiratory syncytial viral pneumonia, hypertensive urgency, abdominal wall hematoma, cervical spine stenosis, hypertensive emergency, congestive heart failure, and spinal stenosis (n=1). None were considered treatment related.
[d]Included the following: increased amylase (n=2), increased γ-glutamyltransferase (n=1), increased C (n=1), increased fasting LDL (n=1), increased lipase (n=1), and serum potassium (hyperkalemia; n=1).

Patient-reported outcomes at Week 48[2,3]

All participants were “satisfied” or “very satisfied” with BIC/FTC/TAF treatment, with a median (range) HIVTSQ score of 58 (52–60) at baseline (n=10) and 59 (51–60) at Week 48 (n=9). SF-36 scores showed minimal change, with a median (range) change from baseline to Week 48 of 0.5 (-12.9 to 9.5) in the mental component score and -4.9 (-12.2 to 4.9) in the physical component score.

Study of BIC in Participants With Severe Renal Impairment

Study design and demographics

A phase 1, open-label, single-dose, parallel-design study assessed the PK profile, safety, and tolerability of BIC in participants with severe renal impairment ($CrCl_{CG}$, 15–29 mL/min). Participants with chronic stable renal impairment not on dialysis (n=10) and healthy volunteers with normal renal function ($CrCl_{CG}$ ≥90 mL/min; n=8) were eligible to participate in this study. At screening, all were required to have BMI values of 18 to 40 kg/m^2. Participants with severe renal impairment were matched to healthy volunteers with normal renal function based on gender, age, and BMI. Participants and healthy volunteers received a moderate-fat breakfast followed by a single dose of BIC 75 mg (not commercially available). PK assessments were conducted during the 144-hour period after dose administration. Safety was assessed throughout the study and during the follow-up period.[4,6]

The mean (range) age was 62 (22–75) years in the severe renal impairment group and 56 (22–67) years in the normal renal function group. The mean (range) $CrCl_{CG}$ was 24 (22–26) mL/min in the severe renal impairment group and 107 (90–131) mL/min in the normal renal function group.[4]

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PK results[4]

The BIC AUC_{∞} was approximately 27% lower in participants with severe renal impairment than in healthy volunteers with normal renal function (Table 3). No correlation was observed between the AUC_{∞} or C_{max} and $eGFR_{CG}$.

Table 3. Summary of BIC PK Parameters (Zhang et al)[4]

Parameter	Severe Renal Impairment (n=10)	Normal Renal Function (n=8)	GLSM Ratio, % (90% CI)
AUC_{∞}, mean (CV), h·ng/mL	138,170 (44.4)	170,106 (24.8)	72.6 (48.8–108.1)
C_{max}, mean (CV), ng/mL	5977 (34.8)	7228 (29.5)	80.3 (59.6–108.3)
$t_{1/2}$, median (Q1, Q3), h	17.7 (12.1, 21.9)	19.2 (18, 21.2)	–
F_u, mean (CV)	0.75 (72)	0.49 (9.3)	–
Free AUC_{∞}, mean (CV), h·ng/mL	831 (32.1)	825 (24.7)	99.3 (79.5–124)
Free C_{max}, mean (CV), ng/mL	38 (21.6)	35 (28.4)	109.8 (87.5–137.9)

Abbreviations: F_u=unbound fraction; GLSM=geometric least squares mean; Q=quartile; $t_{1/2}$=terminal half-life.

Safety[4]

Overall, BIC was well tolerated, and all AEs were Grade 1 in severity. There were 2 AEs, 1 drug-related AE, and no SAEs in each study group. There were 10 laboratory abnormalities in the severe renal impairment group (Grade 1/2/3: 2/4/4) and 4 in the normal renal function group (Grade 1/2/3: 2/2/0).

Case Series

There are limitations in the interpretation of case reports. Case reports cannot be generalized. Unlike controlled clinical trials, causality cannot be inferred based on uncontrolled observational data. In addition, incidence or prevalence cannot be estimated due to the lack of a representative population sample. Other limitations of case reports include the retrospective design and publication bias.[7]

BIC/FTC/TAF in patients on HD[5]

A retrospective, single-center case series identified 6 patients on HD who switched to BIC/FTC/TAF-containing regimens between January 2018 and October 2022 (Table 4).

After switching to a BIC/FTC/TAF-containing regimen, all patients achieved or maintained virologic suppression, and no patients reported AEs. Patient 1 reported an increased quality of life after switching to BIC/FTC/TAF.

Table 4. Case Series: Summary of Patients on HD Who Switched to BIC/FTC/TAF-Containing Regimens[5]

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Age, gender, race	51 y, F, Puerto Rican	70 y, M, White	56 y, M, AA	60 y, F, AA	59 y, F, AA	57 y, M, AA
Reason for switch	Non-adherence	DDI[a]	DDI, potential resistance[b]	Variable adherence, resistance[c]	Variable adherence, resistance, intolerance[d]	Viremia despite adherence, transplant candidate[e]

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		Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Prior regimen		ABC 2 ×/d, DTG 1 ×/d, 3TC 1 ×/d	DTG 1 ×/d, RPV 1 ×/d, ZDV 3 ×/d, 3TC 1 ×/d	E/C/F/TAF 1 ×/d	ABC 1 ×/d, DOR 1 ×/d, DTG 1 ×/d	ABC 2 ×/d, DTG 2 ×/d, RPV 1 ×/d, TDF 1 ×/wk	ABC 2 ×/d, ATV 1 ×/d, DTG 1 ×/d, RTV 1 ×/d
Post-switch regimen		BIC/FTC/ TAF 1 ×/d	BIC/FTC/ TAF 1 ×/d	BIC/FTC/ TAF 1 ×/d	BIC/FTC/ TAF 1 ×/d, DOR 1 ×/d	BIC/FTC/ TAF 1 ×/d, RPV 1 ×/d	BIC/FTC/ TAF 1 ×/d, DOR 1 ×/d
Virologic suppression parameters							
1 y before switch	Absolute CD4	127 cells/mcL	239 cells/mcL	693 cells/mcL	261 cells/mcL	157 cells/mcL	367 cells/mcL
	CD4%	27	24	43	16	13	39
	HIV-1 RNA	244 c/mL	<30 c/mL	<30 c/mL	490 c/mL	56 c/mL	<30 c/mL
Within 30 d of switch	Absolute CD4	21 cells/mcL	326 cells/mcL	1254 cells/mcL	353 cells/mcL	308 cells/mcL	300 cells/mcL
	CD4%	6	28	54	29	19	41
	HIV-1 RNA	87,197 c/mL	52 c/mL	<30 c/mL	<30 c/mL	<30 c/mL	55 c/mL
1 y after switch	Absolute CD4	185 cells/mcL	269 cells/mcL	948 cells/mcL	726 cells/mcL	462 cells/mcL	366 cells/mcL
	CD4%	25	34	54	34	27	48
	HIV-1 RNA	<30 c/mL	<30 c/mL	<30 c/mL	<30 c/mL	<30 c/mL	66 c/mL[f]

Abbreviations: 1 x/d=one time per day; 2 ×/d=two times per day; 3 ×/d=three times per day; 3TC=lamivudine; AA=African American; ABC=abacavir; ATV=atazanavir; COBI=cobicistat; DDI=drug-drug interaction; DOR=doravirine; DTG=dolutegravir; EVG=elvitegravir; F=female; GI=gastrointestinal; INSTI-R=integrase strand transfer inhibitor resistance; M=male; NNRTI-R=non-nucleos(t)ide reverse transcriptase inhibitor resistance; NRTI-R=nucleos(t)ide reverse transcriptase inhibitor resistance; RPV=rilpivirine; RTV=ritonavir; TDF=tenofovir disoproxil fumarate; ZDV=zidovudine.

[a]Patient 2 was admitted for a GI bleed and required initiation of proton pump inhibitor treatment, which is contraindicated with concomitant RPV.

[b]Patient 3 was receiving amlodipine and metoprolol tartrate, each of which had the potential to interact with COBI. The patient was also receiving calcium acetate supplementation, which interacts with EVG. There was also a potential for resistance to EVG.

[c]Patient 4 had a history of NRTI-R (M41L and M184V mutations), NNRTI-R (K103R, V179D, and G190A mutations). There was also an increased cardiovascular risk with ABC.

[d]Patient 5 had variable adherence to her ARV regimen, and self-discontinued ABC and TDF 2 months prior to the switch. She also had a history of NRTI-R (M184V), NNRTI-R (K103N), and INSTI-R (Q148 and G190S), and severe GI symptoms with protease inhibitors.

[e]Patient 6 had low-level viremia and occasionally had an undetectable viral load, no resistance, and no concerns for DDIs (calcium supplement dosing was separated from DTG). The patient was required to have an undetectable viral load prior to being considered for a kidney transplant.

[f]Patient 6 had two consecutive undetectable viral load measurements about 2.5 years after the regimen switch.

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Abbreviations

AE=adverse event
ARV=antiretroviral
AUC_{∞}=area under the curve to time infinity
BIC=bictegravir
c/mL=copies/mL
CD4=cluster of differentiation 4
C_{max}=peak concentration
CG=Cockcroft–Gault equation
C_{trough}=trough concentration
CV=coefficient of variation
E/C/F/TAF=elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide
ESRD=end-stage renal disease
FTC=emtricitabine
HD=hemodialysis
HIVTSQ=HIV Treatment Satisfaction Questionnaire
M=E=missing=excluded
OLE=open-label extension
$paEC_{95}$=protein-adjusted 95% effective concentration
PK=pharmacokinetic(s)
PWH=people with HIV-1
SAE=serious adverse event
SF-36=36-Item Short Form Health Survey
TAF=tenofovir alafenamide

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:

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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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