GILEAD | Medical Information

Biktarvy® (BIC/FTC/TAF) Use in Bariatric Surgery

This document is in response to your request for information regarding the use of Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) in individuals who have undergone bariatric surgery, including gastric bypass or gastric sleeve surgery.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

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

Literature Search

A literature search was conducted in Ovid MEDLINE, BIOSIS Previews, and Embase databases for studies published between 1946 and March 3, 2026, using search terms that included bictegravir, tenofovir alafenamide, emtricitabine, bariatric, gastric bypass, gastric sleeve surgery, and other related search terms. Relevant citations were identified and are summarized below.

Case Reports on BIC/FTC/TAF Use After Bariatric Surgery

Please note that 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. Additionally, 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.[1]

BIC/FTC/TAF Use in a Patient After Sleeve Gastrectomy[2]

A 42-year-old male African American patient with HIV underwent a laparoscopic sleeve gastrectomy for weight loss management. Before the surgery, the patient had a BMI of 41.8 kg/m^2 and was virologically suppressed (HIV RNA was <20 c/mL) on EFV/FTC/TDF 600/200/300 mg daily with a CD4 count of 795 cells/mm^3. After the procedure, the patient was switched to BIC/FTC/TAF to modernize his regimen. At 4 months after the surgery, the patient had a BMI of 37 kg/m^2 and was virologically suppressed with a CD4 count of 621 cells/mm^3. The patient maintained virologic suppression for 24 months, and no adverse effects or complications were reported.

BIC/FTC/TAF Use With Mineral Supplements in a Patient After Sleeve Gastrectomy[3]

A 56-year-old female patient presented with a new diagnosis of HIV-1 with no mutations on baseline genotyping. The patient's past medical history included a laparoscopic sleeve gastrectomy 3 years prior, and her medication list included vitamin D_3 2000 units daily and calcium citrate 500 mg daily. At baseline, her HIV-1 RNA was 139,790 c/mL, and her CD4 cell count was 544 cells/mm^3; BIC/FTC/TAF treatment was initiated within 5 days of diagnosis. The patient was instructed to take the BIC/FTC/TAF and calcium citrate at the same time and with food. Within 3 weeks of BIC/FTC/TAF initiation, her HIV-1 RNA decreased to 67 c/mL, and her CD4 cell count increased to 756 cells/mm^3. After 3 weeks of BIC/FTC/TAF treatment, a dietician was consulted, and calcium citrate was increased to 600 mg twice daily, and a multivitamin with minerals (200 mg calcium, 11 mg zinc, 50 mg magnesium, and 18 mg iron) twice daily and vitamin B_{12} 500 mcg once daily were added. The patient was instructed to take BIC/FTC/TAF with calcium citrate 600 mg with breakfast; the first multivitamin ≥4 hours later; the second dose of calcium citrate 600 mg with dinner; and the second multivitamin, vitamin D_3, and vitamin B_{12} at bedtime. Eight weeks later, the patient reported complete adherence to the regimen and had an undetectable viral load (HIV-1 RNA <40 c/mL) and a CD4 cell count of 821 cells/mm^3. Three months later, the patient continued to report 100% adherence, maintained an undetectable viral load, and had a CD4 cell count of 839 cells/mm^3.

ARV Use in Patients After Gastrectomy or Gastric Bypass[4]

A retrospective case series reported the virologic failure rate (HIV viral load ≥200 c/mL) within 12 months after bariatric weight loss surgery (gastrectomy or Roux-en-Y gastric bypass) among patients living with HIV. The series included 18 patients who were virologically suppressed on various ARV regimens prior to their surgeries. Two patients in the case series received BIC/FTC/TAF post-surgery; neither of these patients experienced virologic failure within 12 months after their surgeries. No other details specific to these 2 patients were reported. One patient who was receiving E/C/F/TDF experienced virologic failure within 12 months after undergoing a sleeve gastrectomy.

BIC/FTC/TAF Use in a Patient After Gastrectomy and Gastric Bypass

A 64-year-old female patient with HIV was diagnosed with gastric cancer and underwent Billroth II gastrectomy, followed by a Roux-en-Y reconstruction. Prior to the gastrectomy, the patient had been on stable ARV treatment since 1998, with virologic suppression on raltegravir 400 mg twice daily plus abacavir 600 mg and lamivudine 300 mg once daily, which was started 5 years before the gastric cancer diagnosis. Her CD4 cell count was 905 cells/mm^3, and her HIV RNA was <30 c/mL. Following the gastrectomy, the patient was switched to BIC/FTC/TAF in order to reduce the pill burden. Concomitant medications at the time were pantoprazole and methadone. BIC/FTC/TAF was well tolerated without any adverse effects, and HIV RNA was <30 c/mL through 6 months post-surgical intervention. The last CD4 cell count was 839 cells/mm^3.[5]

Two months after the patient initiated BIC/FTC/TAF therapy, a PK analysis was performed. Blood plasma samples were collected predose (C_{trough}) and at 1, 2, 4, and 8 hours after the oral intake of BIC/FTC/TAF without food. C_{trough} was also used as the 24-hour result. There was a decrease in BIC PK parameters and an increase in FTC and TAF parameters in

comparison with population means (Table 1). Changes in BIC, FTC, and TAF PK did not have a clinical impact on ARV efficacy or safety in this patient.[5]

Table 1. Comparison of BIC/FTC/TAF PK Parameters[5,6]

PK Parameters		Case Patient With Gastrectomy	Population Mean[a] (CV%)
BIC	AUC_{0-24}, ng·h/mL	57,463	102,000 (26.9)
	C_{max}, ng/mL	4260	6150 (22.9)
	C_{trough}, ng/mL	1301	2610 (35.2)
FTC	AUC_{0-24}, ng·h/mL	21,485	12,300 (29.2)
	C_{max}, ng/mL	3191	2130 (34.7)
	C_{trough}, ng/mL	164.4	96 (37.4)
TAF	AUC_{0-24}, ng·h/mL	1218	142 (17.3)
	C_{max}, ng/mL	1059	121 (15.4)
	C_{trough}, ng/mL	N/A	N/A

[a]Multiple-dose PK parameters based on population PK analysis following oral administration of BIC/FTC/TAF in HIV-1 infected adults.

References

1. Nissen T, Wynn R. The Clinical Case Report: A Review of Its Merits and Limitations. *BMC Res Notes.* 2014;7:264. https://www.ncbi.nlm.nih.gov/pubmed/24758689
2. Badowski M, Kassem S, Labedz M, et al. Virologic outcomes of antiretroviral therapy in patients with HIV-1 following bariatric surgery: A case series and review of the literature. *Int J STD AIDS.* 2024;35(2):103-111.
3. Buscemi L, Mossholder B. Achievement of virologic suppression with HIV antiretroviral therapy in a patient also taking multiple daily cation supplement doses: A case report and review of the literature [Accepted Manuscript]. *Am J Health Syst Pharm.* 2023;80.
4. Kaip EA, Nguyen NY, Cocohoba JM. Antiretroviral Therapy Efficacy Post-Bariatric Weight Loss Surgery: A Case Series of Persons Living with Human Immunodeficiency Virus. *Obes Surg.* 2022;32(5):1523-1530.
5. Tempestilli M, D'Avolio A, De Nicolo A, Agrati C, Antinori A, Cicalini S. Pharmacokinetics of bictegravir, emtricitabine and tenofovir alafenamide in a gastrectomized patient with HIV. *J Antimicrob Chemother.* 2021;76(12):3320-3322.
6. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. US Prescribing Information. Foster City, CA.

Abbreviations

ARV=antiretroviral
AUC_{0-24}=area under the curve from time 0 to 24 hours
BIC=bictegravir
C_{max}=maximum concentration
C_{trough}=trough concentration
c/mL=copies/mL
CV=coefficient of variation
E/C/F/TDF=elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate
EFV=efavirenz
FTC=emtricitabine
PK=pharmacokinetic(s)
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:

☎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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