Gilead Sciences, Inc. is providing this document to you, a US Healthcare Professional, in response to your unsolicited request for medical information.

GILEAD | Medical Information

Bixlenvo™ (bictegravir/lenacapavir) Use in Patients With Renal Impairment Not on Dialysis

This document is in response to your request for information regarding Bixlenvo™ (bictegravir/lenacapavir [BIC/LEN]) and its use in patients with renal impairment who are not on dialysis.

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: www.gilead.com/-/media/files/pdfs/medicines/hiv/BIXLENVO/BIXLENVO_pi.

Summary

Product Labeling[1]

No dosage adjustment of BIC/LEN is recommended in patients with mild, moderate or severe renal impairment (estimated CrCl ≥15 mL/min). BIC/LEN has not been studied in patients with ESRD (estimated CrCl <15 mL/min).

No clinically relevant differences in the PK of BIC were observed between participants with severe renal impairment (CrCl 15 to <30 mL/min, estimated by CG method) and participants with normal renal function. In a study of VS participants with ESRD (estimated CrCl <15 mL/min, by CG method) receiving chronic hemodialysis who were receiving a BIC-containing regimen, median BIC C_{trough} values were lower compared to participants with normal renal function. Despite significantly lower BIC C_{trough} values in this population, virologic suppression was maintained in this study.

There were no clinically significant differences in the PK of LEN in participants with severe renal impairment. The effect of ESRD (including dialysis) on the PK of LEN is unknown. As LEN is >98.5% protein bound, dialysis is not expected to alter exposures of LEN.

Clinical Data on BIC/LEN Use in Renal Impairment

ARTISTRY-1: Participants with $eGFR_{CG}$ ≥15 mL/min who were not on renal replacement therapy were permitted in a phase 2/3 study that evaluated the safety and efficacy of switching to BIC/LEN vs continuing a complex ART regimen in VS PWH.[2,3]

- During the phase 2 and phase 3 portions of the study, 23% and 14%, respectively, of participants had a history of CKD.[2,3]
- During the phase 3 portion of the study, 1% of participants in the BIC/LEN arm had CrCl >15 to ≤30 mL/min and 15% of participants in the BIC/LEN arm had CrCl >30 to <60 mL/min.[3]
- In a subgroup analysis of participant outcomes by baseline renal function, ≥99% of participants across renal function categories and treatment groups were VS at Week 48.

BIC/LEN was generally well tolerated, and there were no renal TRAEs or discontinuations due to renal AEs.[4]

ARTISTRY-2: Participants with $eGFR_{CG}$ ≥30 mL/min were permitted to enroll in a phase 3 study that evaluated the safety and efficacy of switching to BIC/LEN STR vs continuing BIC/FTC/TAF in VS PWH.[5]

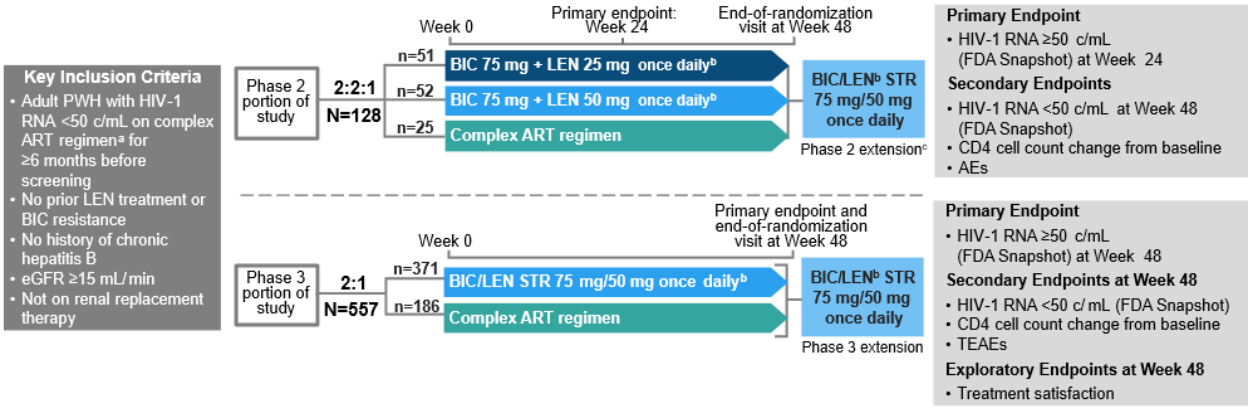
- At baseline, 5% and 6% of participants in the BIC/LEN and BIC/FTC/TAF groups had CKD, respectively.[5] Through Week 48, safety outcomes were generally similar across treatment groups and among participants with baseline CKD.[6]

Clinical Data on BIC/LEN Use in Participants With Renal Impairment Not on Dialysis

ARTISTRY-1: Switching to BIC/LEN vs Complex ART

ARTISTRY-1 is an ongoing, randomized, multicenter, open-label, phase 2/3 study (NCT05502341) evaluating the efficacy and safety of switching to BIC/LEN versus continuing a baseline complex ART regimen in VS PWH. Efficacy and safety outcomes were not reported separately for participants with CKD.[2,3]

Figure 1. ARTISTRY-1 Phase 2/3: Study Design[2,7,8]



Abbreviations: CD4=cluster of differentiation 4; NNRTI=non-nucleos(t)ide reverse transcriptase inhibitor; NRTI=nucleos(t)ide reverse transcriptase inhibitor; OLE=open-label extension; PI=protease inhibitor.
[a]Due to viral resistance, intolerance, or contraindication to existing STRs. Regimens contained the following: a boosted PI or NNRTI + ≥1 other third agent from a class other than NRTIs, or ≥2 pills/day or a dosing frequency >once daily, or parenteral ART (excluding a complete long-acting injectable regimen) plus oral ART.
[b]LEN oral loading doses (600 mg for 2 days) given after participants switched from their complex ART regimen.
[c]All participants reached Week 48 and completed end-of-randomization visit before entering the OLE phase.

Phase 2 of ARTISTRY-1

During the phase 2 portion of the study, participants were randomly assigned to switch to BIC + LEN (oral) or to continue their complex ART regimen. After the randomized period, participants could continue on to the extension period and receive BIC/LEN STR (Figure 1).[2,9]

Table 1. Phase 2 of ARTISTRY-1:
Renal-Related Baseline Demographics and Disease Characteristics[7]

Key Demographics and Characteristics	BIC 75 mg + LEN 25 mg (n=51)	BIC 75 mg + LEN 50 mg (n=52)	Complex ART Regimen (n=25)
Age, median (range), years	62 (26–79)	62 (34–76)	58 (41–70)
CKD,[a] n (%)	12 (23.5)	14 (26.9)	5 (20)
$eGFR_{CG}$,[a] median (IQR), mL/min	80.4 (70–99.5)	82.7 (65.4–98.2)	81.2 (70.4–102.1)

[a]Grouped terms in broad scope.

Switching to BIC 75 mg + LEN 50 mg demonstrated non-inferior efficacy compared with staying on a baseline complex ART regimen by FDA Snapshot analysis at the Week 24 primary endpoint (HIV-1 RNA ≥50 c/mL: 1.9% vs 0%, respectively; difference, 1.9%; 95% CI: -12.2% to 10.7%; *P*>0.99).[2]

TRAEs through Week 48 occurred in 17.6% of participants (9/51) in the BIC 75 mg + 25 mg group, 5.8% of participants (3/52) in the BIC 75 mg + 50 mg group, and none of the participants in the complex ART regimen group.[7] Two participants discontinued treatment due to TEAEs considered related to the study drugs through Week 48: 1 participant in the BIC 75 mg + LEN 25 mg group, due to Grade 1 nausea, and 1 participant in the BIC 75 mg + LEN 50 mg group with a history of nausea and vomiting, due to Grade 3 worsening vomiting.[2,9]

At Week 24, Grade 3 or 4 renal-related laboratory abnormalities that occurred in ≥3 participants in any treatment group included low CrCl in participants with preexisting CKD (BIC 75 mg + LEN 25 mg, n=1 [2%]; BIC 75 mg + LEN 50 mg, n=6 [11.5%]; complex ART regimen, n=2 [12%]).[10] Laboratory abnormalities were not reported at Week 48.[7,9]

Phase 3 of ARTISTRY-1

For the phase 3 portion of the study, participants were randomly assigned (2:1) to receive BIC/LEN STR (n=371) or continue their stable complex ART regimen (n=186) for 48 weeks.

Table 2. Phase 3 of ARTISTRY-1:
Renal-Related Baseline Demographics and Disease Characteristics[3]

Key Demographics and Characteristics		BIC/LEN 75 mg/50 mg (n=371)	Complex ART Regimen (n=186)
Age, median (range), years		60 (22–84)	60 (24–75)
CKD,[a] n (%)		49 (13)	29 (16)
CrCl, mL/min	Median (IQR)	82.9 (66.4–103.2)	82.4 (65.4–100.2)
	>15 to ≤30, n (%)	3 (1)	3 (2)
	>30–60, n (%)	56 (15)	26 (14)
	≥60, n (%)	312 (84)	157 (84)

[a]Grouped terms on standardized MedDRA query narrow search.

Switching to BIC/LEN demonstrated non-inferior efficacy compared with staying on a baseline complex ART regimen by FDA Snapshot analysis at the Week 48 primary endpoint (HIV-1 RNA ≥50 c/mL: 1% vs 1%, respectively; difference, -0.3%; 95.002% CI: -2.3% to 1.8%).[3]

Through Week 48, TRAEs were reported in 14% of participants (53/371) in the BIC/LEN group and 2% of participants (3/186) in the complex ART group. AEs led to discontinuation of the study drug in 2% of participants (6/371) in the BIC/LEN group and 1% of participants (1/186) in the complex ART group.[3] Refer to Table 3 for renal-related AEs by baseline eGFR and Table 4 for Grade ≥3 renal-related laboratory abnormalities through Week 48.[11]

Table 3. Phase 3 of ARTISTRY-1: Renal-Related AE Through Week 48 (Safety Analysis Set)[11]

Safety Outcome, n (%)	eGFR >15 to ≤30 mL/min		eGFR >30 to <60 mL/min		eGFR ≥60 mL/min	
	BIC/LEN (n=3)	Complex ART Regimen (n=3)	BIC/LEN (n=56)	Complex ART Regimen (n=26)	BIC/LEN (n=312)	Complex ART Regimen (n=157)
Any renal-related AE[a]	0	1 (33)[b]	2 (4)[c]	7 (27)[d]	15 (5)[e]	7 (4)[f]

[a]Multiple AEs were counted once per participant for each preferred term.
[b]AKI.
[c]AKI and CKD (each, n=1).
[d]CKD (n=3); AKI, hyperkalemia (each, n=2); pollakiuria, blood Cr increased, and toxic nephropathy (each, n=1).
[e]AKI, pollakiuria, hypokalemia, nocturia (each, n=2); CKD, hematuria, encephalopathy, GFR decreased, glycosuria, hypocalcemia, oliguria, proteinuria (each, n=1).
[f]Renal CrCl decreased (n=2), AKI, CKD, blood Cr increased, hematuria, blood phosphate decreased, crystalluria, hypophosphatemia, and pericarditis (each, n=1).

Table 4. Phase 3 of ARTISTRY-1: Renal-Related Laboratory Abnormalities Through Week 48 (Safety Analysis Set)[11]

Grade ≥3 Laboratory Abnormalities (≥2% of Participants in Either Group), n (%)	BIC/LEN 75 mg/50 mg (n=371)	Complex ART Regimen (n=183)
CrCl decreased	46 (12)	29 (16)
Direct bilirubin level increased[a]	36 (10)	11 (6)
Increased Cr level	11 (3)	11 (6)

[a]All abnormalities were Grade 3.

Baseline renal function subgroup analysis[4]

A subgroup analysis assessed outcomes of participants with baseline renal impairment, including participants with an eGFR ≥15 mL/min. Endpoints included the proportion of VS participants at Week 48 and changes renal parameters (ie, $eGFR_{CG}$, renal function category shift, and treatment discontinuations due to renal AEs) stratified by baseline renal function.

At Week 48, VS was achieved by ≥99% of participants in both treatment groups, regardless of baseline renal function (Table 5).

Table 5. Phase 3 of ARTISTRY-1: Virologic Suppression at Week 48 by Baseline Renal Function (Missing=Excluded)[4]

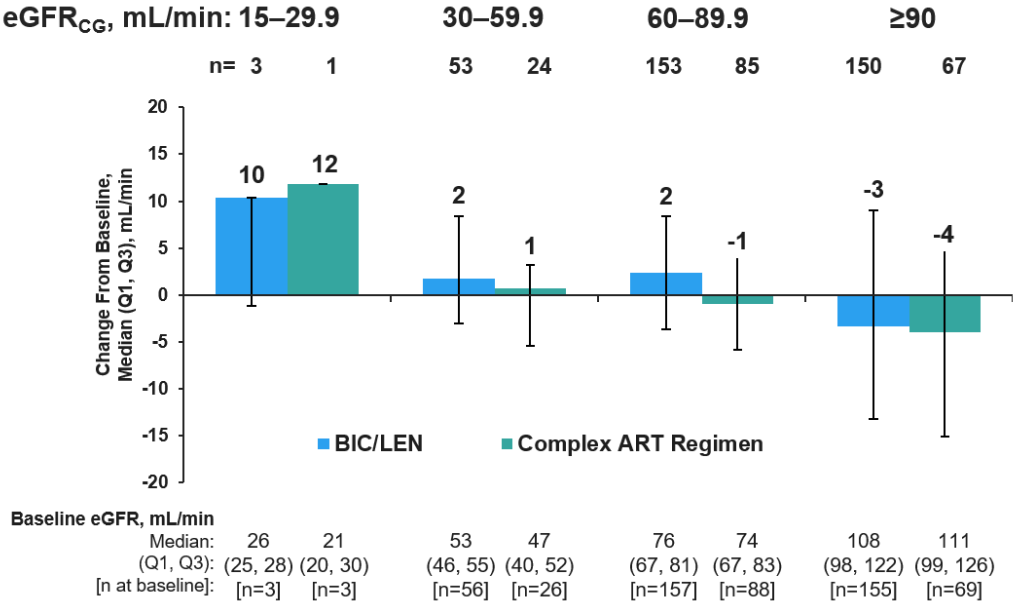
Participants, n (%)	BIC/LEN 75 mg/50 mg				Complex ART Regimen			
	Baseline $eGFR_{CG}$, mL/min				Baseline $eGFR_{CG}$, mL/min			
	15–29.9 (n=3)	30–59.9 (n=53)	60–89.9 (n=154)	≥90 (n=152)	15–29.9 (n=1)	30–59.9 (n=24)	60–89.9 (n=86)	≥90 (n=67)
HIV-1 RNA <50 c/mL	3 (100)	53 (100)	152 (99)	151 (99)	1 (100)	24 (100)	85 (99)	67 (100)

Note: Only included participants with available Week 48 data.

From baseline to Week 48, $eGFR_{CG}$ was generally consistent across baseline renal function categories in both treatment groups (Figure 2), and most participants either remained in the same renal function category or improved to a less severe renal function category at Week 48.

Gilead Sciences, Inc. is providing this document to you, a US Healthcare Professional, in response to your unsolicited request for medical information.

Figure 2. Phase 3 of ARTISTRY-1:
Changes in $eGFR_{CG}$ From Baseline to Week 48 by Baseline Renal Function Category[4]



Abbreviation: Q=quartile.
Note: Included participants with available data at both baseline and at Week 48.

Through Week 48, there were no reports of proximal renal tubulopathy, Fanconi syndrome, or renal TRAEs in either treatment group. BIC/LEN was generally well tolerated regardless of baseline renal function category, and no participants discontinued study drug due to renal AEs (Table 6).

Table 6. Phase 3 of ARTISTRY-1:
Safety Outcomes Through Week 48 by Baseline Renal Function Category[4]

Safety Outcome, n (%)	BIC/LEN 75 mg/50 mg Baseline $eGFR_{CG}$, mL/min				Complex ART Regimen Baseline $eGFR_{CG}$, mL/min			
	15–29.9 (n=3)	30–59.9 (n=56)	60–89.9 (n=157)	≥90 (n=155)	15–29.9 (n=3)	30–59.9 (n=26)	60–89.9 (n=88)	≥90 (n=69)
Any-grade AEs	2 (67)	41 (73)	126 (80)	136 (88)	2 (67)	23 (88)	77 (88)	55 (80)
Grade ≥3	0	5 (9)	26 (17)	20 (13)	1 (33)	6 (23)	12 (14)	7 (10)
Serious	0	7 (13)	24 (15)	21 (14)	0	6 (23)	8 (9)	8 (12)
Any-grade TRAEs	0	6 (11)	22 (14)	25 (16)	0	0	3 (3)	0
Grade ≥3	0	0	0	2 (1)	0	0	0	0
Serious	0	0	0	1 (<1)[a]	0	0	0	0
Any-grade renal AEs	0	2 (4)	7 (4)	8 (5)	1 (33)	7 (27)	6 (7)	1 (1)
Grade ≥3	0	0	2 (1)	1 (<1)	1 (33)	1 (4)	3 (3)	0
Serious	0	0	2 (1)	0	0	0	1 (1)	0

Intended for U.S. Healthcare Professionals only
Last Updated: 04 Nov 2026

Gilead Sciences, Inc. is providing this document to you, a US Healthcare Professional, in response to your unsolicited request for medical information.

Safety Outcome, n (%)	BIC/LEN 75 mg/50 mg				Complex ART Regimen			
	Baseline $eGFR_{CG}$, mL/min				Baseline $eGFR_{CG}$, mL/min			
	15–29.9 (n=3)	30–59.9 (n=56)	60–89.9 (n=157)	≥90 (n=155)	15–29.9 (n=3)	30–59.9 (n=26)	60–89.9 (n=88)	≥90 (n=69)
Select renal AEs								
AKI[b]	0	1 (2)	2 (1)	0	1 (33)	2 (8)	0	1 (1)
CKD	0	1 (2)	1 (<1)	0	0	3 (12)	0	1 (<1)
Proteinuria	0	0	0	1 (<1)	0	0	0	0
Blood Cr increased[c]	0	0	0	0	0	1 (4)	1 (1)	0
Toxic nephropathy	0	0	0	0	0	1 (4)	0	0
Hypophosphatemia	0	0	0	0	0	0	1 (1)	0

[a]New diagnosis of diabetes mellitus.
[b]Causes and outcomes were as follows: transient and resolved without intervention (n=2); stable creatinine and weight loss accounted for decreased eGFR (n=2); AKI on CKD related to hypotension that was transient and returned to baseline (n=1); occurred during hospitalization for femoral neck fracture, ischemic stroke, non-ST elevation myocardial infarction, and postoperative anemia (n=1); and associated with episodes of diarrhea and vomiting (n=1).
[c]The MedDRA preferred term "blood creatinine increase" was used to report creatinine increase; thus, it was categorized as an AE vs laboratory parameter.

Age subgroup analysis[12,13]

In a subgroup analysis that assessed participant outcomes by age (<65 years and ≥65 years), a greater proportion of participants aged ≥65 years had lower baseline CrCl values than those aged <65 years. Among participants aged ≥65 years, 25% to 26% had a baseline CrCl of ≥30 to <60 mL/min and 0% to 3% had a baseline CrCl of ≥15 to <30 mL/min; among participants aged <65 years, 8% to 10% had a baseline CrCl of ≥30 to <60 mL/min and 0% to 1% of participants had a baseline CrCl of ≥15 to <30 mL/min. CrCl remained stable among most participants through Week 48, with only modest shifts between adjacent CrCl categories.

ARTISTRY-2: Switching to BIC/LEN vs BIC/FTC/TAF

ARTISTRY-2 is an ongoing, double-blind, multicenter, randomized, controlled, phase 3 study (NCT06333808) evaluating the efficacy and safety of switching to BIC/LEN (n=384) vs continuing BIC/FTC/TAF (n=193) in VS PWH.[5] Participants with $eGFR_{CG}$ ≥30 mL/min were permitted to enroll in the study.[14] At baseline, median age of participants was 49 years, and 5% of participants (20/383) and 6% (12/191) in the BIC/LEN and BIC/FTC/TAF groups, respectively, had CKD. Efficacy and safety outcomes were not reported separately for participants with CKD.[5]

In the overall population, switching to BIC/LEN demonstrated non-inferior efficacy compared with staying on a baseline regimen of BIC/FTC/TAF by FDA Snapshot analysis at the Week 48 primary endpoint (HIV-1 RNA ≥50 c/mL: 1.3% vs 1%, respectively; difference, 0.3%; 95.002% CI: -1.9 to 2.4%).[5]

Through Week 48, safety outcomes were generally similar across treatment groups and among participants with CKD at baseline (Table 7).[6]

Table 7. ARTISTRY-2: Safety Outcomes Overall and in Participants With Baseline CKD[6]

Safety Outcome, n (%)	Overall		CKD	
	BIC/LEN (n=383)	BIC/FTC/TAF (n=191)	BIC/LEN (n=20)	BIC/FTC/TAF (n=12)
Any-grade AEs	288 (75)	141 (74)	16 (80)	8 (67)
Grade ≥3	38 (10)	15 (8)	2 (10)	1 (8)
Serious AEs	27 (7)	13 (7)	1 (5)	0
Any-grade TRAEs	40 (10)	23 (12)	5 (25)	0
Grade ≥3	1 (<1)[a]	0	0	0
Serious TRAEs	0	0	0	0
AEs that led to treatment discontinuation	6 (2)	3 (2)	1 (5)	1 (8)
Death	0	1 (1)	0	0

[a]Grade 3 rhabdomyolysis that resolved with continued treatment without a dose change or interruption and was subsequently recategorized as a Grade 1 AE after the cutoff date for this analysis.
Note: Grade severity was defined by the Division of AIDS Toxicology Grading Scale v2.1.

References

1. Enclosed, Gilead Sciences Inc. BIXLENVO™ (bictegravir and lenacapavir) tablets, for oral use. U.S. Prescribing Information. Foster City, CA. 2026.
2. Mounzer K, Slim J, Ramgopal M, et al. Efficacy and Safety of Switching to Daily Bictegravir Plus Lenacapavir From a Complex HIV Treatment Regimen: A Randomized, Open-Label, Multicenter Phase 2 Study (ARTISTRY-1). *Clin Infect Dis.* 2025;80(4):881-888.
3. Orkin C, Ruane PJ, Hedgcock M, et al. Switch to single-tablet bictegravir-lenacapavir from a complex HIV regimen (ARTISTRY-1): a randomised, open-label, phase 3 clinical trial. *The Lancet.* 2026.
4. Hedgcock M, Cahn P, Antinori A, et al. Efficacy and Safety Outcomes With BIC/LEN Single-Tablet Regimen in People With HIV and Renal Impairment in Phase 3 of ARTISTRY-1 [Poster P-1045]. Paper presented at: IDWeek; October 21-24, 2026; Washington, DC.
5. Meissner EG, Ramgopal M, Ruane PJ, et al. Safety and efficacy of switching to bictegravir-lenacapavir versus continuing bictegravir-emtricitabine-tenofovir alafenamide in virologically suppressed people with HIV-1 (ARTISTRY-2): a double-blind, multicentre, randomised, controlled, phase 3, non-inferiority trial. *Lancet HIV.* 2026;13(8):e538-e547.
6. Ramgopal M, Hung CC, Mills AM, et al. Metabolic and Safety Outcomes With BIC/LEN Single-Tablet Regimen in People With HIV and Comorbidities in ARTISTRY-2 [Poster P-23]. Paper presented at: IDWeek; October 21-24, 2026; Washington, DC.
7. Mounzer K, Slim J, Ramgopal M, et al. Efficacy and Safety of Bictegravir Plus Lenacapavir: 48-Week Outcomes in People With HIV-1 Who Are Virologically Suppressed on Complex Antiretroviral Regimens at Baseline [Supplement]. *Open Forum Infectious Diseases.* 2025;12(11):1-8.
8. Orkin C, Ruane PJ, Hedgcock M, et al. Switch to single-tablet bictegravir-lenacapavir from a complex HIV regimen (ARTISTRY-1): a randomised, open-label, phase 3 clinical trial. *Lancet.* 2026;407(10535):1249-1258.
9. Mounzer K, Slim J, Ramgopal M, et al. Efficacy and Safety of Bictegravir Plus Lenacapavir: 48-Week Outcomes in People With HIV-1 Who Are Virologically Suppressed on Complex Antiretroviral Regimens at Baseline. *Open Forum Infectious Diseases.* 2025;12(11):ofaf615.
10. Mounzer K, Slim J, Ramgopal M, et al. Efficacy and Safety of Switching to Daily Bictegravir Plus Lenacapavir From a Complex HIV Treatment Regimen: A Randomized, Open-Label, Multicenter Phase 2 Study (ARTISTRY-1) [Supplementary Materials]. *Clin Infect Dis.* 2025.
11. Orkin C, Ruane PJ, Hedgcock M, et al. Switch to single-tablet bictegravir-lenacapavir from a complex HIV regimen (ARTISTRY-1): a randomised, open-label, phase 3 clinical trial [Supplementary appendix]. *Lancet.* 2026;407(10535):1249-1258.

12. Bloch M, Gaultier C, Trottier B, et al. Efficacy and Safety of BIC/LEN Single-Tablet Regimen in Virologically Suppressed People With HIV Aged ≥ 65 Years: Week 48 Analysis of Participants in the Phase 3 Portion of ARTISTRY-1 [Poster TUPEB096]. Paper presented at: The 26th International AIDS Conference (AIDS); July 26–31, 2026; Rio de Janeiro, Brazil.
13. Bloch M, Gaultier C, Trottier B, et al. Efficacy and Safety of BIC/LEN Single-Tablet Regimen in Virologically Suppressed People With HIV Aged ≥ 65 Years: Week 48 Analysis of Participants in the Phase 3 Portion of ARTISTRY-1 [Poster TUPEB096] Supplementary Materials. Paper presented at: The 26th International AIDS Conference (AIDS); July 26-31, 2026; Rio de Janeiro, Brazil.
14. Meissner EG, Ramgopal M, Ruane PJ, et al. Safety and efficacy of switching to bictegravir-lenacapavir versus continuing bictegravir-emtricitabine-tenofovir alafenamide in virologically suppressed people with HIV-1 (ARTISTRY-2): a double-blind, multicentre, randomised, controlled, phase 3, non-inferiority trial [Supplementary appendix]. *Lancet HIV.* 2026;13(8):e538-e547.

Abbreviations

AE=adverse event
AKI=acute kidney injury
ART=antiretroviral therapy
ARV=antiretroviral
BIC=bictegravir
c/mL=copies/mL
CG=Cockcroft-Gault
CKD=chronic kidney disease
C_{trough}=lowest observed drug concentration
ESRD=end-stage renal disease
FTC=emtricitabine
LEN=lenacapavir
MedDRA=Medical Dictionary for Regulatory Activities
PK=pharmacokinetic(s)
PWH=people with HIV-1
STR=single-tablet regimen
TAF=tenofovir alafenamide
TEAE=treatment-emergent adverse event
TRAE=treatment-related adverse event
VS=virologically suppressed

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Bixlenvo US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/BIXLENVO/BIXLENVO_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

Data Privacy

The Medical Information service at Gilead Sciences may collect, store, and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers, and regulatory authorities located in countries besides your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact gilead.privacy@gilead.com.

BIXLENVO, GILEAD, and the GILEAD logo are trademarks of Gilead Sciences, Inc., or its related companies.
© 2026 Gilead Sciences, Inc.