GILEAD | Medical Information

Bixlenvo™ (bictegravir/lenacapavir) Use in Dialysis

This document is in response to your request for information regarding the use of Bixlenvo™ (bictegravir/lenacapavir [BIC/LEN]) in individuals on dialysis. There are no data on BIC and LEN use in peritoneal 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.

Product Labeling[1]

Use in Specific Populations

Renal impairment

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).

Clinical Pharmacology

Pharmacokinetics

Patients with renal impairment

No clinically relevant differences in the pharmacokinetics of BIC were observed between participants with severe renal impairment (CrCl 15 to <30 mL/min, estimated by Cockcroft-Gault method) and participants with normal renal function. In a study of VS participants with ESRD (estimated CrCl <15 mL/min, by Cockcroft-Gault 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 pharmacokinetics of LEN in participants with severe renal impairment. The effect of ESRD (including dialysis) on the pharmacokinetics of LEN is unknown. As LEN is greater than 98.5% protein bound, dialysis is not expected to alter exposures of LEN.

Clinical Data

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 BIC/LEN versus continuing a baseline complex ART regimen in VS PWH.[2,3] Participants were eligible for the study if they had an eGFR ≥15 mL/min according to the Cockcroft-Gault equation for CrCl and were not receiving renal replacement therapy. Participants with CrCl <15 mL/min by Cockcroft-Gault equation at screening were excluded from enrolling in the study.[4]

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 vs continuing BIC/FTC/TAF in VS PWH.[5] Participants with eGFR ≥30 mL/min according to the Cockcroft-Gault equation for CrCl were eligible for enrollment in the study.[6]

Available Data on BIC/LEN Use in Dialysis

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published between 1946 and August 10, 2026 using search terms that included bictegravir, lenacapavir, dialysis, dialyses, renal replacement therapy, and other related search terms. No relevant citations were identified.

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. 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.
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.
6. 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.

Abbreviations

ART=antiretroviral therapy
BIC=bictegravir
ESRD=end-stage renal disease
FTC=emtricitabine
LEN=lenacapavir
PWH=people with HIV-1
STR=single-tablet regimen
TAF=tenofovir alafenamide
VS=virologically suppressed

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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

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