

Efficacy and Safety Outcomes With BIC/LEN Single-Tablet Regimen in People With HIV and Renal Impairment in Phase 3 of ARTISTRY-1

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Conclusions

- In participants with baseline renal impairment enrolled in Phase 3 of ARTISTRY-1, bictegravir/lenacapavir (BIC/LEN) was highly efficacious and generally well tolerated through Week 48, including in those with severe renal impairment (estimated glomerular filtration rate [eGFR] 15.0-29.9 mL/min)
- Median eGFR was generally stable in both treatment groups (BIC/LEN vs complex regimen), regardless of baseline renal function
- Overall, renal adverse events (AEs) were uncommon, and none led to discontinuation of BIC/LEN
- These results support BIC/LEN as a single-tablet regimen (STR) option for people with HIV and kidney disease or declining renal function

Plain Language Summary

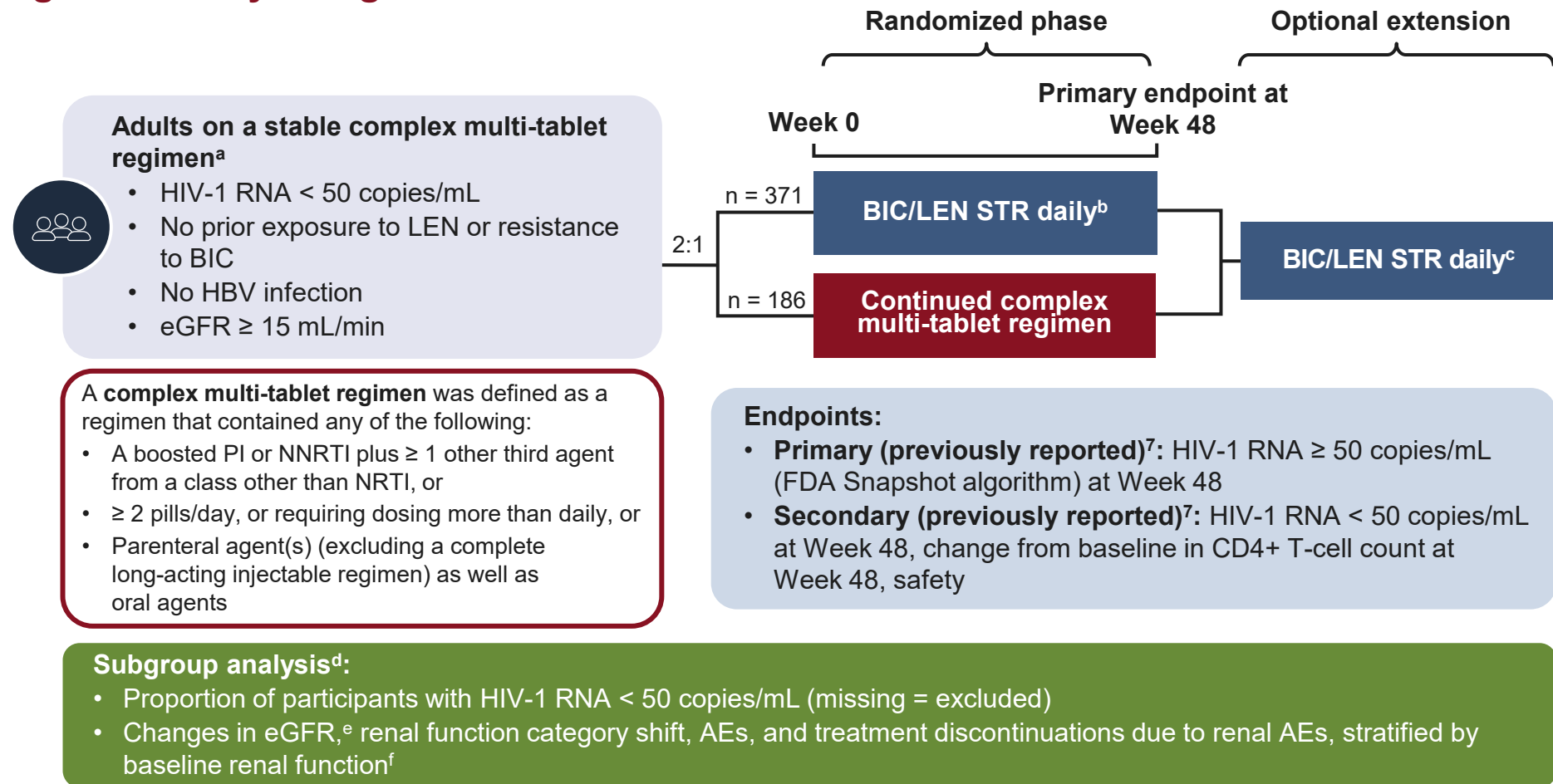
- Many people with human immunodeficiency virus (HIV) also have kidney problems
- BIC/LEN is a new HIV treatment that combines two medicines (bictegravir and lenacapavir) in a single tablet taken once a day
- The ARTISTRY-1 study looked at how well BIC/LEN worked in people with HIV who switched from taking several tablets each day (a complex regimen)
- In this analysis from ARTISTRY-1, researchers looked at how well BIC/LEN worked and how safe it was in people with HIV and kidney problems who switched from complex regimens
- BIC/LEN was highly effective at keeping the amount of HIV in the blood low, including in people with severe kidney problems
- Few people had kidney-related side effects and none stopped HIV treatment because of kidney-related side effects
- These results suggest that BIC/LEN could be a good treatment option for people with HIV and kidney problems, including those with severe kidney problems

Objective

- To evaluate 48-week efficacy and safety outcomes in a subgroup of people with HIV and renal impairment at baseline in Phase 3 of the ARTISTRY-1 study, including those with an eGFR as low as 15.0 mL/min

Methods

Figure 1. Study Design



^aDue to antiretroviral resistance, intolerance, drug-drug interactions, or contraindication to existing STRs. ^bBIC/LEN 75/50 mg, with oral loading dose of LEN 600 mg on Days 1 and 2 of treatment. ^cBIC/LEN 75/50 mg. ^dAll participants who took ≥ 1 dose of the study drug (BIC/LEN or complex regimen) were included in this analysis (full analysis set). ^eCalculated using the Cockcroft-Gault formula. ^fRenal function was categorized as severe renal impairment (eGFR 15.0-29.9 mL/min), moderate renal impairment (eGFR 30.0-59.9 mL/min), mild renal impairment (eGFR 60.0-89.9 mL/min), or normal renal function (eGFR ≥ 90.0 mL/min). ^gAE, adverse event; BIC, bictegravir; CD4, cluster of differentiation 4; eGFR, estimated glomerular filtration rate; FDA, US Food and Drug Administration; HBV, hepatitis B virus; LEN, lenacapavir; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside/nucleotide reverse transcriptase inhibitor; PI, protease inhibitor; STR, single-tablet regimen.

Results

Table 1. Baseline Demographics and Clinical Characteristics

	BIC/LEN				Complex Regimen			
	Baseline eGFR, ^a mL/min				Baseline eGFR, ^a mL/min			
	15.0-29.9 n = 3	30.0-59.9 n = 56	60.0-89.9 n = 157	≥ 90.0 n = 155	15.0-29.9 n = 3	30.0-59.9 n = 26	60.0-89.9 n = 88	≥ 90.0 n = 69
Age, years, median (range)	69 (65-76)	67 (54-84)	62 (41-79)	57 (22-74)	56 (49-60)	66 (41-75)	61 (35-75)	55 (24-75)
Assigned female at birth, n (%)	1 (33)	13 (23)	30 (19)	20 (13)	1 (33)	4 (15)	14 (16)	17 (25)
Race, ^b n (%)								
White	1 (33)	37 (66)	121 (77)	101 (65)	2 (67)	18 (69)	63 (72)	41 (59)
Black	2 (67)	13 (23)	19 (12)	30 (19)	0	4 (15)	11 (13)	18 (26)
Asian	0	3 (5)	5 (3)	8 (5)	1 (33)	1 (4)	3 (3)	4 (6)
Other ^c	0	3 (5)	4 (3)	5 (3)	0	1 (4)	1 (1)	1 (1)
Hispanic or Latine, ^d n (%)	0	11 (20)	36 (23)	33 (21)	0	5 (19)	18 (20)	19 (28)
Medical history of chronic kidney disease, ^e n (%)	2 (67)	21 (38)	21 (13)	5 (3)	3 (100)	13 (50)	11 (13)	2 (3)
eGFR, mL/min, median (Q1, Q3)	26 (25, 28)	53 (46, 55)	76 (67, 81)	108 (98, 122)	21 (20, 30)	47 (40, 52)	74 (67, 83)	111 (99, 126)
TDF-containing regimen at baseline, n (%)	0	2 (4)	8 (5)	15 (10)	1 (33)	1 (4)	4 (5)	2 (3)

^aCalculated using the Cockcroft-Gault formula. ^bLocal regulators did not allow the collection of race information for 19 participants in the BIC/LEN group and 17 in the complex regimen group; percentages were calculated using total number of participants as the denominator. ^cCategory includes American Indian or Alaska Native, Native Hawaiian, Pacific Islander, and Other. ^dLocal regulators did not allow the collection of ethnicity information for 21 participants in the BIC/LEN group and 16 in the complex regimen group; percentages were calculated using total number of participants as the denominator. ^eGrouped term on standardized MedDRA query narrow search. BIC/LEN, bictegravir/lenacapavir; eGFR, estimated glomerular filtration rate; MedDRA, Medical Dictionary for Regulatory Activities; Q, quartile; TDF, tenofovir disoproxil fumarate.

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Results (cont.)

Virologic Outcomes

- At Week 48, ≥ 99% of participants in both treatment groups had HIV-1 RNA < 50 copies/mL (missing = excluded), irrespective of baseline renal function (**Table 2**)

Table 2. Virologic Suppression at Week 48

	BIC/LEN				Complex Regimen			
	Baseline eGFR, ^a mL/min				Baseline eGFR, ^a mL/min			
	15.0-29.9 n = 3 ^b	30.0-59.9 n = 53 ^b	60.0-89.9 n = 154 ^b	≥ 90.0 n = 152 ^b	15.0-29.9 n = 1 ^b	30.0-59.9 n = 24 ^b	60.0-89.9 n = 86 ^b	≥ 90.0 n = 67 ^b
HIV-1 RNA < 50 c/mL, n (%)	3 (100)	53 (100)	152 (99)	151 (99)	1 (100)	24 (100)	85 (99)	67 (100)

^aCalculated using the Cockcroft-Gault formula. ^bIncludes participants with data available at Week 48. BIC/LEN, bictegravir/lenacapavir; DRAE, drug-related adverse event; eGFR, estimated glomerular filtration rate;

Safety Outcomes

- BIC/LEN was generally well tolerated across all renal function categories, with no discontinuations of study drug due to renal AEs (**Table 3**)
- There were no instances of proximal renal tubulopathy or Fanconi syndrome

Table 3. Adverse Events and Discontinuations Through Week 48

	BIC/LEN				Complex Regimen			
	Baseline eGFR, ^a mL/min				Baseline eGFR, ^a mL/min			
	15.0-29.9 n = 3	30.0-59.9 n = 56	60.0-89.9 n = 157	≥ 90.0 n = 155	15.0-29.9 n = 3	30.0-59.9 n = 26	60.0-89.9 n = 88	≥ 90.0 n = 69
AEs^b	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)
DRAEs^b	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) ^c	0	0	0	0
Renal AEs^{b,d}	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
Renal DRAEs^{b,d}	0	0	0	0	0	0	0	0
Select renal AEs								
Acute kidney injury ^e	0	1 (2)	2 (1)	0	1 (33)	2 (8)	0	1 (1)
Chronic kidney disease	0	1 (2)	1 (< 1)	0	0	3 (12)	0	1 (< 1)
Blood creatinine increased ^f	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
Proteinuria	0	0	0	1 (< 1)	0	0	0	0
Discontinuation of study drug due to renal AEs	0	0	0	0	0	0	0	0

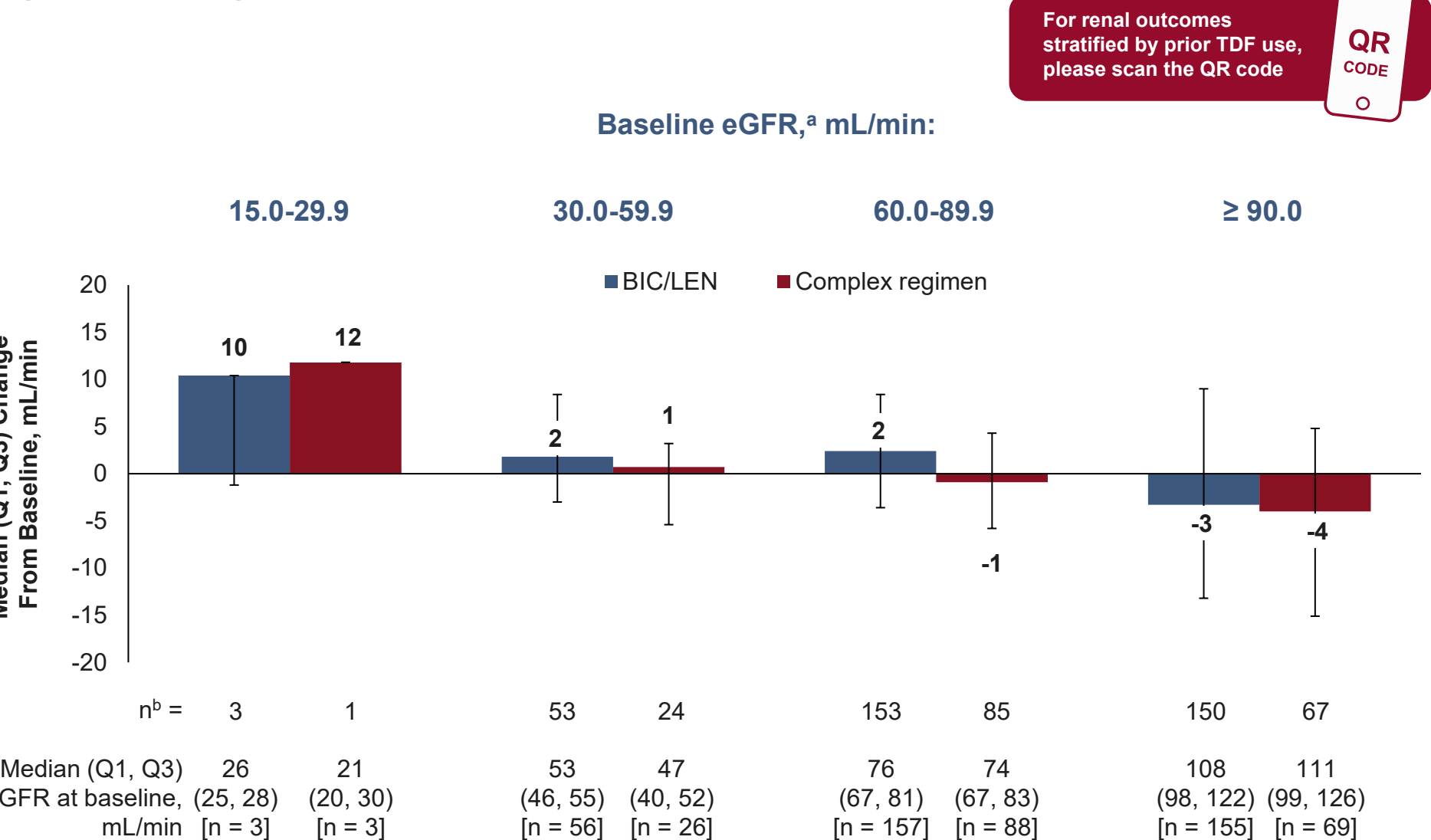
Data are n (%).
^aCalculated using the Cockcroft-Gault formula.
^bParticipants may have reported more than one AE.
^cNewly diagnosed diabetes mellitus.
^dRenal AEs were identified by the standard MedDRA search term "Keep Under Review" list.
^eAmong participants with acute kidney injury recorded as an AE (n = 7), reasons and subsequent outcome as reported by the investigator were: transient and resolved without intervention (n = 2); acute kidney injury on chronic kidney disease related to hypotension, transient and returned to baseline (n = 1); stable creatinine, weight loss accounted for decreased eGFR (n = 2); occurred during hospital admission with femoral neck fracture in addition to ischemic stroke, non-ST-elevation myocardial infarction, and postoperative anemia (n = 1); associated with episodes of diarrhea and vomiting (n = 1).
^fCreatinine increase was reported as the MEDRA Preferred Term "Blood creatinine increased" and is therefore presented as an adverse event rather than a laboratory parameter.
AE, adverse event; BIC/LEN, bictegravir/lenacapavir; DRAE, drug-related adverse event; eGFR, estimated glomerular filtration rate; MedDRA, Medical Dictionary for Regulatory Activities.

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Renal Outcomes

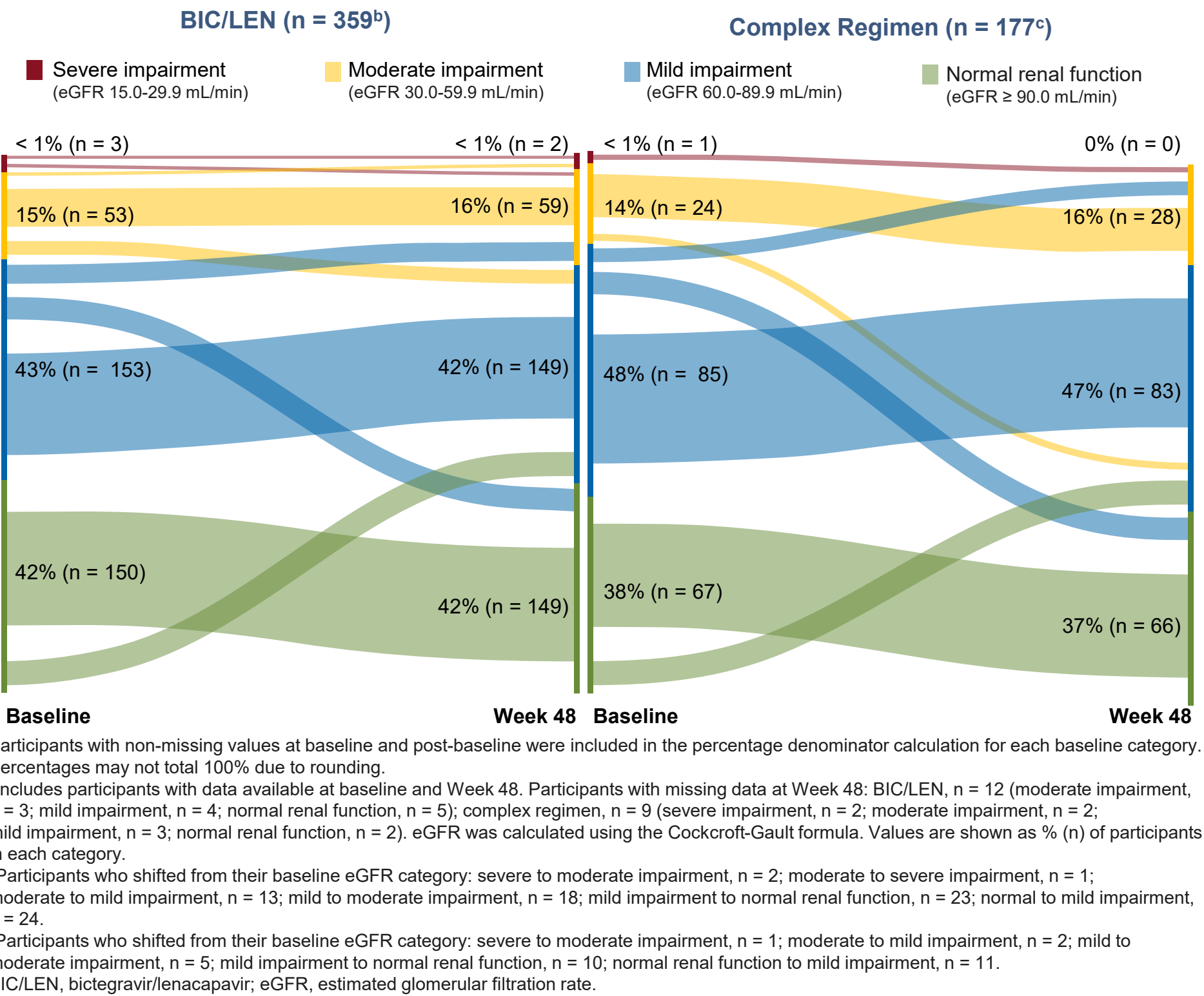
- Median eGFR was generally stable through Week 48 across both treatment groups and all renal function categories (**Figure 2**). Most participants remained in the same baseline eGFR category or shifted to a less severe category at Week 48 (**Figure 3**)

Figure 2. Change From Baseline at Week 48 in eGFR^a



^aCalculated using the Cockcroft-Gault formula.
^bNumber of participants with available data at baseline and Week 48. BIC/LEN, bictegravir/lenacapavir; eGFR, estimated glomerular filtration rate; Q, quartile; TDF, tenofovir disoproxil fumarate.

Figure 3. Sankey Flow Diagrams of Renal Function Category Shift From Baseline^a



Participants with non-missing values at baseline and post-baseline were included in the percentage denominator calculation for each baseline category. Percentages may not total 100% due to rounding.
^aIncludes participants with data available at baseline and Week 48. Participants with missing data at Week 48: BIC/LEN, n = 12 (moderate impairment, n = 3; mild impairment, n = 4; normal renal function, n = 5); complex regimen, n = 9 (severe impairment, n = 2; moderate impairment, n = 2; mild impairment, n = 3; normal renal function, n = 2). eGFR was calculated using the Cockcroft-Gault formula. Values are shown as % (n) of participants in each category.
^bParticipants who shifted from their baseline eGFR category: severe to moderate impairment, n = 2; moderate to severe impairment, n = 1; moderate to mild impairment, n = 13; mild to moderate impairment, n = 18; mild impairment to normal renal function, n = 23; normal to mild impairment, n = 24.
^cParticipants who shifted from their baseline eGFR category: severe to moderate impairment, n = 1; moderate to mild impairment, n = 2; mild to moderate impairment, n = 5; mild impairment to normal renal function, n = 10; normal renal function to mild impairment, n = 11. BIC/LEN, bictegravir/lenacapavir; eGFR, estimated glomerular filtration rate.

References: 1. DHHS. <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new> (accessed July 16, 2026). 2. McCutcheon K, et al. *Circ Res*. 2024;134:1636-60. 3. EACS. <https://eacs.sanfordguide.com/en/eacs-hiv/art/eacs-initial-regimens-arv-naive-adults> (accessed July 16, 2026). 4. Gandhi RT, et al. *JAMA*. 2025;333:609-28. 5. Acosta RK, et al. *Antimicrob Agents Chemother*. 2019;63:e02533-18. 6. Dvory-Sobol H, et al. *Curr Opin HIV AIDS*. 2022;17:15-21. 7. Orkin O, et al. *Lancet*. 2026;407:1249-58.