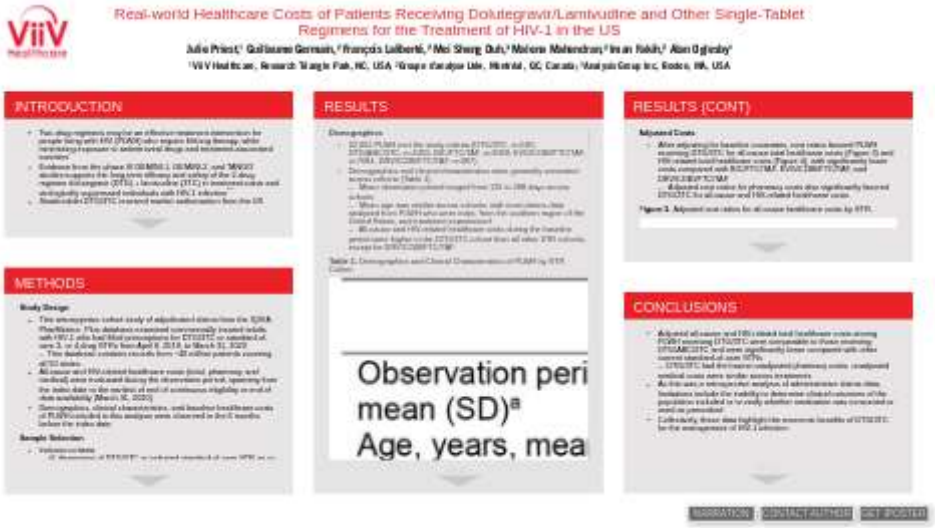
Real-world Healthcare Costs of Patients Receiving Dolutegravir/Lamivudine and Other Single-Tablet Regimens for the Treatment of HIV-1 in the US



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INTRODUCTION

- Two-drug regimens may be an effective treatment intervention for people living with HIV (PLWH) who require lifelong therapy, while minimizing exposure to antiretroviral drugs and treatment-associated toxicities[1]
- Evidence from the phase III GEMINI-1, GEMINI-2, and TANGO studies supports the long-term efficacy and safety of the 2-drug regimen dolutegravir (DTG) + lamivudine (3TC) in treatment-naive and virologically suppressed individuals with HIV-1 infection[2-6]
- Single-tablet DTG/3TC received market authorization from the US Food and Drug Administration (FDA) in 2019 and is currently the lowest priced, integrase-based, single-tablet regimen (STR) based on wholesale acquisition costs[7,8]
- The objective of this study was to evaluate healthcare costs of PLWH receiving treatment with DTG/3TC compared with those receiving treatment with current standard-of-care 3- or 4-drug STRs

METHODS

Study Design

- This retrospective cohort study of adjudicated claims from the IQVIA PharMetrics® Plus database examined commercially insured adults with HIV-1 who had filled prescriptions for DTG/3TC or standard-of-care 3- or 4-drug STRs from April 8, 2019, to March 31, 2020
  – This database contains records from ~40 million patients covering all 50 states
- All-cause and HIV-related healthcare costs (total, pharmacy, and medical) were evaluated during the observation period, spanning from the index date to the earliest of end of continuous eligibility or end of data availability (March 31, 2020)
- Demographics, clinical characteristics, and baseline healthcare costs of PLWH included in this analysis were observed in the 6 months before the index date

Sample Selection

- Inclusion criteria
  – ≥1 dispensing of DTG/3TC or selected standard-of-care STR on or after April 8, 2019 (ie, the date of FDA approval for DTG/3TC)
  - The index date was defined as the date of first pharmacy claim for DTG/3TC; if none, the index date was defined as the first pharmacy claim for other selected standard-of-care STRs
  - Selected standard-of-care STRs included DTG/abacavir (ABC)/3TC, bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF), elvitegravir (EVG)/cobicistat (COBI)/FTC/TAF, and darunavir (DRV)/COBI/FTC/TAF
  – ≥6 months of continuous health insurance coverage before the index date (defined as the baseline period)
  – ≥1 diagnosis of HIV-1 in the primary or secondary position at any time during the study period
  – ≥18 years of age at the index date
- Exclusion criteria
  – Dispensing of DTG twice daily (BID), DRV BID, enfuvirtide, etravirine/maraviroc, or ibalizumab any time before the index date
  – Diagnosis of HIV-2 in the primary or secondary position any time during the period of continuous health insurance coverage
  – Diagnosis of chronic hepatitis B virus in the primary or secondary position during the baseline period or on the index date

Data Analysis

- All-cause and HIV-related healthcare costs were reported per-patient-per-month (PPPM) to account for varying lengths of follow-up
- Cost ratios were estimated using multivariable models adjusting for differences in baseline characteristics between cohorts
- Analyses were further stratified by PLWH who were classified as treatment naive or treatment experienced

RESULTS

Demographics

- 22,061 PLWH met the study criteria (DTG/3TC, n=590; DTG/ABC/3TC, n=4355; BIC/FTC/TAF, n=9068; EVG/COBI/FTC/TAF, n=7081; DRV/COBI/FTC/TAF, n=967)
- Demographics and clinical characteristics were generally consistent across cohorts (Table 1)
  - Mean observation period ranged from 135 to 288 days across cohorts
  - Mean age was similar across cohorts, with most claims data analyzed from PLWH who were male, from the southern region of the United States, and treatment experienced
  - All-cause and HIV-related healthcare costs during the baseline period were higher in the DTG/3TC cohort than all other STR cohorts, except for DRV/COBI/FTC/TAF

Table 1. Demographics and Clinical Characteristics of PLWH by STR Cohort

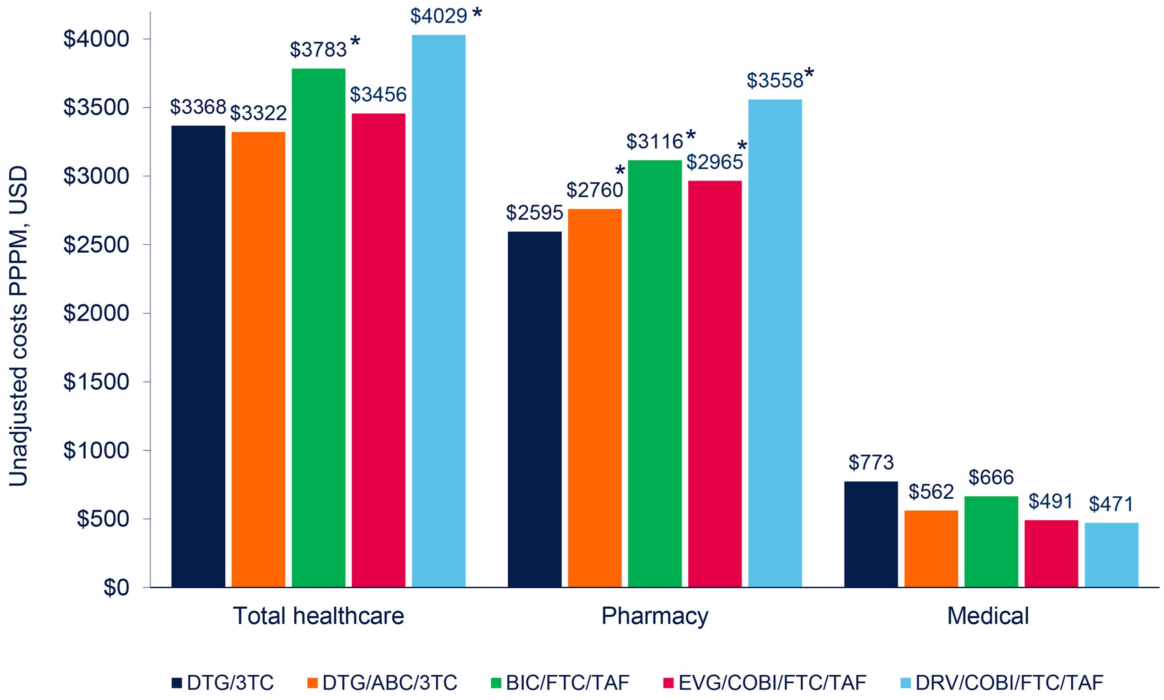
	DTG/3TC (N=590)	DTG/ABC/3TC (N=4355)	BIC/FTC/TAF (N=9068)	EVG/COBI/FTC/TAF (N=7081)	DRV/COBI/FTC/TAF (N=967)
Observation period, days, mean (SD)[a]	135 (84)	288 (92)	252 (110)	288 (93)	234 (111)
Age, years, mean (SD)[b]	46 (12)	46 (12)	46 (12)	46 (11)	46 (11)
Sex, female, n (%)[b]	92 (16)	684 (16)	1469 (16)	1111 (16)	192 (20)
Region, n (%)[b]					
South	454 (77)	3117 (72)	6038 (67)	4433 (63)	746 (77)
Midwest	66 (11)	576 (13)	1408 (16)	1324 (19)	118 (12)
West	37 (6)	297 (7)	627 (7)	524 (7)	32 (3)
Northeast	33 (6)	365 (8)	995 (11)	800 (11)	71 (7)
Treatment status, n (%)					
Treatment naive[c]	76 (13)	265 (6)	1427 (16)	368 (5)	90 (9)
Treatment experienced[d]	514 (87)	4090 (94)	7641 (84)	6713 (95)	877 (91)
Quan-Charlson comorbidity index, mean (SD)[e]	3.6 (1.8)	3.6 (1.8)	3.7 (1.8)	3.5 (1.8)	3.8 (1.7)
Baseline total healthcare costs, USD, mean (SD)[e]					
All-cause	$18,004 ($30,695)	$15,969 ($20,538)	$17,310 ($28,596)	$16,261 ($18,555)	$19,203 ($24,125)
HIV-related[f]	$15,222 ($27,941)	$13,029 ($9644)	$13,724 ($16,885)	$13,688 ($11,331)	$16,334 ($19,329)
Proportion of observation period covered with the index medication, mean (SD)[g]	0.91 (0.17)	0.83 (0.22)	0.88 (0.19)	0.81 (0.24)	0.83 (0.22)

ABC, abacavir; BIC, bictegravir; COBI, cobicistat; DRV, darunavir; DTG, dolutegravir; EVG, elvitegravir; FTC, emtricitabine; PLWH, people living with HIV; SD, standard deviation; TAF, tenofovir alafenamide; 3TC, lamivudine; USD, US dollars. [a]The observation (follow-up) period spanned from the index date until the earliest end of continuous eligibility or end of data availability. [b]Evaluated on the index date. [c]Treatment naive was defined as PLWH with no antiretroviral regimens (ie, no single- or multiple-tablet regimens; prevention therapies were allowed) during the 6-month baseline period. [d]Treatment experienced was defined as PLWH with antiretroviral regimens (ie, single- or multiple-tablet regimens) during the 6-month baseline period. [e]Evaluated during the 6-month baseline period, excluding the index date. [f]HIV-related claims were identified as claims with a primary or secondary diagnosis of HIV. [g]Calculated as the total number of days with medication supplied, after adjusting for overlapping dispensings (ie, shifting early refills to the end of the current dispensing), divided by the number of days in the observation period.

Unadjusted Costs

- Mean all-cause total healthcare costs were significantly lower among PLWH receiving DTG/3TC compared with those receiving BIC/FTC/TAF or DRV/COBI/FTC/TAF (Figure 1)
  - Mean all-cause pharmacy costs were significantly lower for those receiving DTG/3TC compared with all other cohorts
  - Mean all-cause medical costs were not significantly different across all cohorts

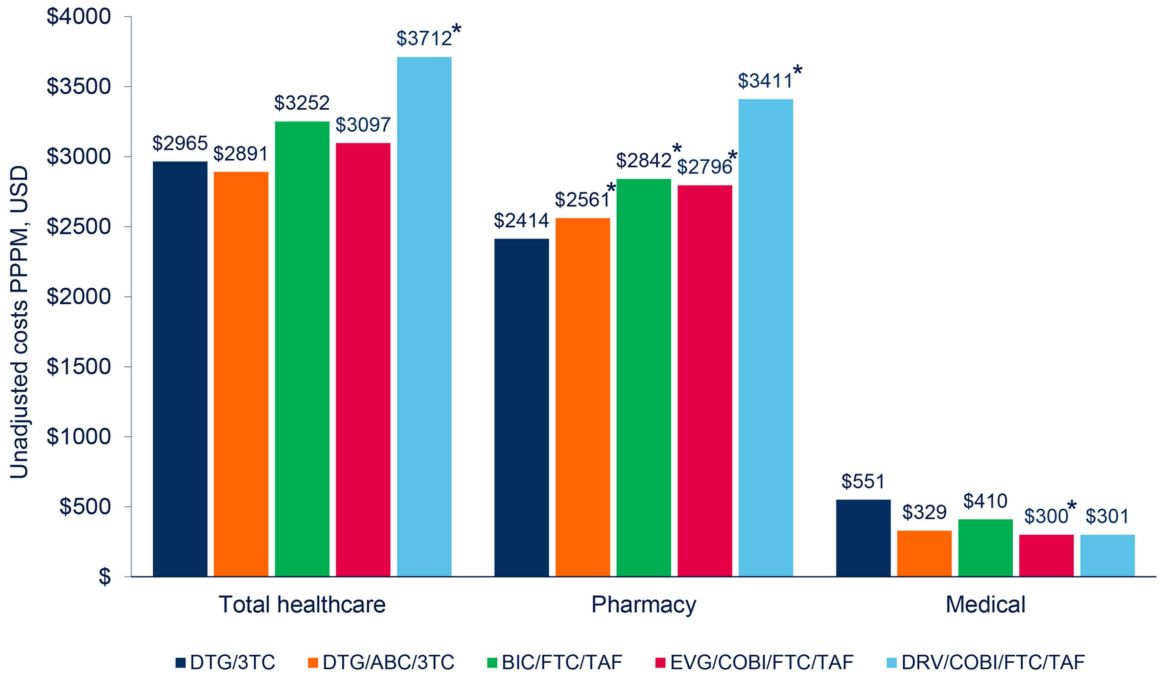
Figure 1. Unadjusted all-cause healthcare costs by STR.



ABC, abacavir; BIC, bictegravir; COBI, cobicistat; DRV, darunavir; DTG, dolutegravir; EVG, elvitegravir; FTC, emtricitabine; PPPM, per-patient-per-month; STR, single-tablet regimen; TAF, tenofovir alafenamide; 3TC, lamivudine. *P<0.05 when compared with DTG/3TC within cost domain (ie, comparisons within all-cause total healthcare, pharmacy, and medical costs).

- Mean HIV-related total healthcare costs were significantly lower among PLWH receiving DTG/3TC compared with those receiving DRV/COBI/FTC/TAF (Figure 2)
  - Mean HIV-related pharmacy costs were significantly lower for those receiving DTG/3TC compared with all other cohorts, with the largest differences among those receiving BIC/FTC/TAF and DRV/COBI/FTC/TAF
  - Mean HIV-related medical costs were not significantly different across cohorts, except for DTG/3TC vs EVG/COBI/FTC/TAF (P=0.044)

Figure 2. Unadjusted HIV-related healthcare costs by STR.



HIV-related claims were identified as claims with a primary or secondary diagnosis of HIV. ABC, abacavir; BIC, bictegravir; COBI, cobicistat; DRV, darunavir; DTG, dolutegravir; EVG, elvitegravir; FTC, emtricitabine; PPPM, per-patient-per-month; STR, single-tablet regimen; TAF, tenofovir alafenamide; 3TC, lamivudine. *P<0.05 when compared with DTG/3TC within cost domain (ie, comparisons within HIV-related total healthcare, pharmacy, and medical costs).

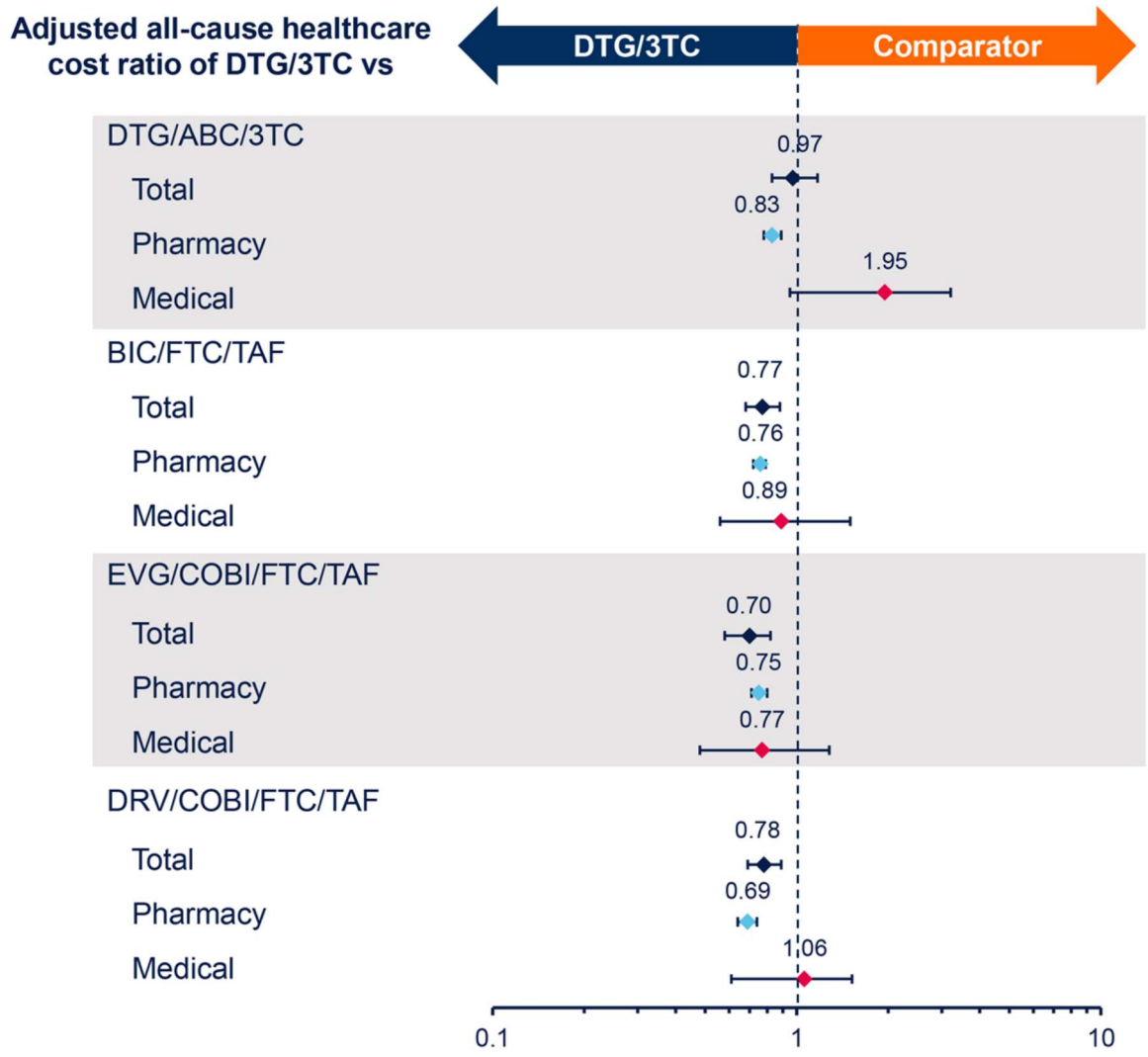
- Across all comparisons, cost differences in all-cause and HIV-related healthcare costs were primarily driven by significantly lower pharmacy costs
- Similar trends were observed among the subgroups of treatment-naive and treatment-experienced PLWH

RESULTS (CONT)

Adjusted Costs

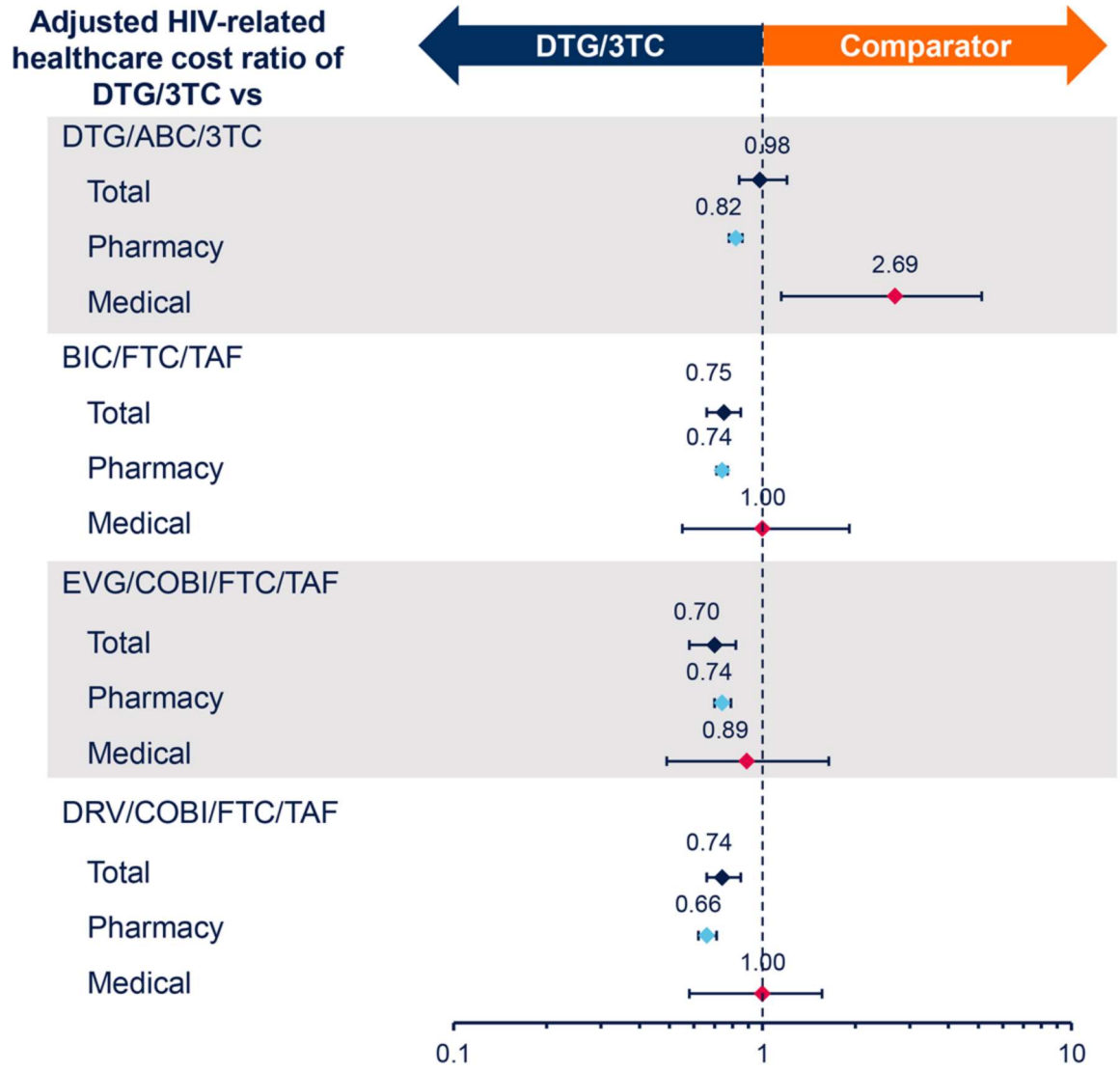
- After adjusting for baseline covariates, cost ratios favored PLWH receiving DTG/3TC for all-cause total healthcare costs (Figure 3) and HIV-related total healthcare costs (Figure 4), with significantly lower costs compared with BIC/FTC/TAF, EVG/COBI/FTC/TAF, and DRV/COBI/FTC/TAF
  – Adjusted cost ratios for pharmacy costs also significantly favored DTG/3TC for all-cause and HIV-related healthcare costs

Figure 3. Adjusted cost ratios for all-cause healthcare costs by STR.



ABC, abacavir; BIC, bictegravir; COBI, cobicistat; DRV, darunavir; DTG, dolutegravir; EVG, elvitegravir; FTC, emtricitabine; STR, single-tablet regimen; TAF, tenofovir alafenamide; 3TC, lamivudine.

Figure 4. Adjusted cost ratios for HIV-related healthcare costs by STR.



ABC, abacavir; BIC, bictegravir; COBI, cobicistat; DRV, darunavir; DTG, dolutegravir; EVG, elvitegravir; FTC, emtricitabine; STR, single-tablet regimen; TAF, tenofovir alafenamide; 3TC, lamivudine.

CONCLUSIONS

- Adjusted all-cause and HIV-related total healthcare costs among PLWH receiving DTG/3TC were comparable to those receiving DTG/ABC/3TC and were significantly lower compared with other current standard-of-care STRs
  – DTG/3TC had the lowest unadjusted pharmacy costs; unadjusted medical costs were similar across treatments
- As this was a retrospective analysis of administrative claims data, limitations include the inability to determine clinical outcomes of the population included or to verify whether medication was consumed or used as prescribed
- Collectively, these data highlight the economic benefits of DTG/3TC for the management of HIV-1 infection

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