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## An Evaluation of Weight Gain in Patients Treated with Dolutegravir vs. Other Core Agents

### Final Study Report

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*I have read this report and confirm that to the best of my knowledge this report accurately describes the conduct and results of study [208943].*

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## Table of Contents

1. Executive Summary.....	4
2. Background and Rationale .....	10
2.1. Background .....	10
2.2. Rationale .....	11
3. Study Objectives .....	12
3.1. Primary Objectives .....	12
3.2. Secondary Objectives.....	12
4. Methods.....	12
4.1. Study Design.....	12
4.2. Exposure Definition.....	14
4.3. Outcomes Definition .....	14
4.3.1. Weight/BMI/Lipids.....	14
4.3.2. Lipodystrophy .....	16
4.4. Analyses .....	16
4.4.1. Primary objectives.....	16
4.4.1.1. Describe BMI categories, weight, lipodystrophy, and lipid panels at core agent initiation and at 6, 12, and 24 months following initiation .....	16
4.4.1.2. Association between core agent and BMI among ART-experienced patients.....	17
4.4.1.3. Addendum: Association between core agent and BMI among ART-experienced, suppressed patients.....	17
4.4.2. Secondary objectives .....	17
4.4.2.1. Describe BMI categories, weight, lipodystrophy, and lipid panels at core agent initiation and at 6, 12, and 24 months following initiation among patients who were suppressed at switch (stable switch) .....	17
5. Results.....	18
6. Conclusion.....	31
7. Acknowledgements.....	33
8. References .....	35

## 1. Executive Summary

### Background

Body composition has been a concern for patients with HIV since the initial manifestations of severe muscle wasting in the pre-antiretroviral (ART) era [1-4]. However, these concerns have evolved over time as studies have observed increases in weight among people living with HIV since the introduction of ART [5-7]. Lipodystrophy was associated with primarily older ART regimens but is still observed with some regimens containing newer agents including protease inhibitors (PIs) such as darunavir (DRV) or atazanavir (ATV), integrase strand transfer inhibitors (INSTIs) such as raltegravir (RAL), and non-nucleoside reverse transcriptase inhibitors (NNRTIs) such as rilpivirine (RPV) [8-11]. In the current ART era, weight gain has been attributed to the effect of the treatment rather than simply an improvement in health with increases in weight following initiation of ART reported in multiple studies [5, 6, 12, 13]. The relative impact on weight gain of most common core ART agents has yet to be determined.

Raised disproportionality analysis (DPA) scores for both DTG and DTG/ABC/3TC were detected through the routine pharmacovigilance. An evaluation of clinical trial data, spontaneous case reports, and published studies could not rule out an association between DTG exposure and weight gain. The cumulative analysis led to a recommendation for a label change indicating weight gain as an uncommon adverse drug reaction (ADR). This study, utilizing data from a large real-world population of treated HIV patients, sought to provide additional information to support the signal evaluation.

### Primary Objectives

- 1) Among new users of DTG, RPV, RAL, BIC\*, EVG/c and DRV(/r/c): To describe BMI categories, weight, lipid levels (e.g. total cholesterol, HDL, LDL, triglycerides), and lipodystrophy at core agent initiation and at 6, 12, and 24 months after core agent initiation, stratified by ART-naïve, ART-experienced, and ART-experienced, suppressed at core agent initiation.
- 2) Among all ART-experienced new users of DTG vs. RPV, RAL, BIC\*, EVG/c or DRV (/r/c): To estimate the association between specific core agent initiation and changes in BMI at 6, 12, and 24 months after core agent initiation.

### Secondary Objectives

- 1) Among ART-experienced patients who were suppressed at switch (stable switch) to DTG, RPV, RAL, BIC\*, EVG/c, or DRV(/r/c): To describe BMI categories, weight, and lipid panel levels (e.g. total cholesterol, HDL, LDL, triglycerides) at core agent initiation, and at 6, 12, and 24 months after core agent initiation.

\*BIC was excluded from this study due to the small number of patients initiating BIC who met inclusion criteria (n=5).

### Methods

#### Study Population

Four study populations were identified from the OPERA Observational Database. All study populations were derived from the overall OPERA population, which included HIV-positive patients aged 18 years or older, prescribed DTG, RPV, RAL, BIC, EVG/c, or DRV(/r/c) as part of a 3-drug regimen for the first time between 01AUG2013 and 31DEC2017, who were not exposed to >1 core agent of interest concurrently, were not pregnant at baseline, were male or female (not transgender), and had  $\geq 1$  baseline viral load

available. Patients also had to have  $\geq 1$  measurement for weight available within 3 months before or at core agent initiation, with BMI in the plausible range ( $\geq 10$  and  $\leq 50$ ), and at least one follow-up measurement with plausible weight available during the follow-up period of interest, where plausible weight and change in weight were defined as  $< 500$  kg and  $< 450$  kg, respectively.

Three study populations were derived from the overall study population and included those with a follow-up weight measurement at 6 months, 12 months, and 24 months following core agent initiation. Descriptive analyses were stratified by ART experience at core agent initiation. ART-naïve patients were defined as patients with no evidence of prior ART exposure and with baseline viral load result  $\geq 1000$  copies/mL. ART-experienced patients were defined as patients with a history of ART prior to initiation of the core agent of interest, or a baseline viral load of  $< 1000$  copies/mL. ART-experienced, suppressed patients were defined as ART-experienced patients with a baseline viral load  $< 200$  copies/mL.

#### Outcomes Definition

Weight (in kg), BMI, and lipid levels including total cholesterol, HDL, LDL, and triglycerides were assessed at baseline, and at 6 months, 12 months and 24 months after core agent initiation. Baseline weight, BMI, and lipids were identified as the closest measurement to index date using measurements within 3 months prior to or on index date. BMI/weight/lipids at 6 months were assessed using measurements closest to 6 months after core agent initiation, between  $> 3$  and  $\leq 9$  months, in a subset of the population restricted to patients with a BMI measurement during this time window. BMI/weight/lipids at 12 months were assessed using measurements closest to 12 months after core agent initiation, between  $> 9$  and  $\leq 15$  months, in a subset of the population restricted to patients with a BMI measurement during this time window. BMI/weight/lipids at 24 months were assessed using measurements closest to 24 months after core agent initiation, between  $> 21$  and  $\leq 27$  months, in a subset of the population restricted to patients with a BMI measurement during this time window. BMI categories were also assessed at baseline, as well as changes in BMI category at 6 months, 12 months, and 24 months after core agent initiation (Table 1).

#### Statistical Analyses

All descriptive analyses were conducted among ART-naïve, ART-experienced and ART-experienced, suppressed patients. Baseline demographic and clinical characteristics at the time of ART initiation were summarized using medians and interquartile ranges (IQR) for continuous variables and counts and percentages for categorical variables. Baseline BMI, BMI categories, weight, lipodystrophy, and lipid levels at the time of ART initiation were summarized using medians and interquartile ranges for continuous variables and counts and percentages for categorical variables. Lipid levels (total cholesterol, HDL, LDL, triglycerides), weight and change in weight, BMI and change in BMI, and incident lipodystrophy at 6, 12, and 24 months after initiation were summarized using medians and interquartile ranges for continuous variables and counts and percentages for categorical variables. Pairwise comparisons between DTG and each of the other core agent groups at baseline and at 6, 12, and 24 months after initiation were evaluated by the Pearson's Chi-square test (categorical), Fisher's exact test (few events), or Wilcoxon Rank-Sum test (continuous). Patients without the lab values of interest at each time point were excluded from evaluation at that time point. BMI and lipids were assessed categorically, as the proportion of patients in each category at baseline and at 6, 12, and 24 months after core agent initiation. Change in BMI category, absolute change in weight, and percentage change were also assessed at 6 months, 12 months, and 24 months after core agent initiation.

Statistical modeling was performed among ART-experienced patients. Adjusted linear regression models were used to assess the association between core agent and mean changes in BMI at 6, 12, and 24 months. Baseline variables included in the adjusted models were selected a priori based on the literature, including baseline age, sex, race/ethnicity, BMI, lipodystrophy, endocrine disorders, hypertension, concomitant medications associated with weight gain and weight loss [14, 15], viral load, CD4 cell count, substance abuse, and tenofovir alafenamide (TAF) use. Continuous variables were modeled using restricted cubic splines. Inverse probability-of-censoring (IPC) weights were used to account for patients who discontinued treatment, were lost to follow-up, died, became pregnant, or unavailability of a BMI measurement during the time windows of interest, and were constructed using logistic regression models. This analysis was stratified by baseline BMI categories (underweight, normal weight, overweight, obese). Estimates from these models can be interpreted as the difference between the mean change in BMI between DTG and other core agents (e.g. and estimate of 0.2 is interpreted as: BMI increased by an estimated 0.2kg more on average with core agent A than with DTG).

## Results

### POPULATION IDENTIFICATION

There were 21,559 patients in the overall study population after inclusion criteria were met. However, due to the limited number of patients initiating BIC as the first of the core agents of interest (n=5), these patients were excluded from further analyses, which resulted in a total of 21,554 patients in the overall study population used for analysis. Among all patients, 6,246 were considered treatment-naïve, 15,308 were considered treatment-experienced, and 10,653 were considered treatment-experienced, suppressed.

### ART-NAÏVE PATIENTS

#### Descriptive results

Among 6246 ART-naïve PLWH, demographics and weight by group varied significantly at baseline.

RPV users had higher baseline weight and BMI values (median [IQR] = 77.1kg [68.0, 90.7] and 25.9 [22.6, 30.3], respectively) compared to DTG users (median [IQR] = 73.9kg [65.3, 85.7] and 24.8 [22.0, 28.3], respectively).

At 6, 12 and 24 months, mean and median increases in weight showed more variability than mean and median increase in BMI. Patterns were similar between the two measures. Median weight gain was greater with DRV(/r/c), but smaller with RPV, compared to DTG at 6 months (DRV(/r/c): 2.1kg; RPV: 1.4kg vs. DTG: 1.8kg) and 12 months (DRV(/r/c): 3.6kg; RPV: 1.8kg vs. DTG: 2.6kg). At 24 months, median weight gain was smaller with both EVG/c and RPV than with DTG (EVG/c: 3.6kg; RPV: 2.7kg vs. DTG: 4.1kg).

Of PLWH with normal or overweight BMI at baseline, 15% to 33% increased by at least one BMI category at 12 months after regimen initiation. Of underweight PLWH at baseline, the majority increased to a normal BMI at 12 months. Obese PLWH at baseline could not increase category, by definition. Weight gain varied across thresholds:  $\geq 3$  kg (37% to 53%),  $\geq 5$  kg (23% to 41%),  $\geq 5\%$  (30% to 49%; Figure 5).



DRV (/r/c) users were more likely and RPV users were less likely to have a weight increase  $\geq 5$  kg compared to DTG users at 6 months (DRV(/r/c): 28.4%; RPV: 15.7% vs. DTG: 23.2%), 12 months (DRV(/r/c): 41.4%; RPV: 23.2% vs. DTG: 32.7%) and 24 months (DRV(/r/c): 44.0%; RPV: 33.2% vs. DTG: 42.7%).

## ART-EXPERIENCED PATIENTS

### Descriptive results

Among 15,308 ART-experienced PLWH, demographics and weight by group varied significantly at baseline. Baseline weight and BMI values were higher for RAL users (median [IQR] = 79.5kg [69.9, 91.2] and 26.2 [23.3, 29.8], respectively) and RPV users (median [IQR] = 79.4kg [70.3, 90.7] and 26.2 [23.2, 29.8], respectively) compared to DTG users (median [IQR] = 78.0 [68.1, 89.8] and 25.9 [23.1, 29.3], respectively).

Median increases in weight were smaller with RAL and DRV(/r/c) than with DTG at 6 months (RAL: 0.7kg; DRV: 0.7kg vs. DTG: 1.0kg) and 12 months (RAL: 0.9kg; DRV(/r/c): 1.0kg vs. DTG: 1.5kg). Only RAL users had a smaller increase in weight than DTG users at 24 months (RAL: 0.9kg vs. DTG: 1.8kg). At 12 months following core agent initiation, only differences between DRV (/r/c) users and DTG users were significant (p-value = 0.0013).

There was not a clear trend in the pattern of categorical weight changes between core agents for any of the follow-up period.

### Statistical modeling of the association between core agent initiation and changes in BMI

At **6 months** following core agent initiation among ART-experienced patients, after adjustment for confounding, the mean increase in BMI was lower for EVG/c, RAL, and DRV(/r/c) users compared to DTG users (EVG/c: -0.16kg [-0.25, -0.07], RAL: -0.23 kg [-0.40, -0.05], DRV(/r/c): -0.22 kg [-0.34, -0.09]). When stratifying by baseline BMI category, among those with a normal baseline BMI, EVG/c, RPV, and DRV(/r/c) users had a lower mean increase in BMI at 6 months compared to DTG users (EVG/c: -0.18 kg [-0.28, -0.07], RPV: -0.21 kg [-0.34, -0.08], DRV(/r/c): -0.16 kg [-0.31, -0.01]). EVG/c and DRV(/r/c) users who were overweight at baseline had a lower mean increase in BMI compared to DTG users (EVG/c: -0.12 kg [-0.25, 0.00], DRV(/r/c): -0.22 kg [-0.39, -0.05]). There were no differences in changes in BMI between core agent groups among underweight or obese ART-experienced patients at 6 months following core agent initiation.

At **12 months** following core agent initiation in ART-experienced patients, the average increase in BMI was lower for RAL users compared to DTG users in adjusted estimates (-0.24 kg [0.48, 0.00]). In weighted estimates, there were no statistically significant differences in BMI increases between core agent groups. In analyses stratified by baseline BMI category, EVG/c users and DRV (/r/c) users who were a normal weight at baseline had a lower increase in BMI compared to DTG users (EVG/c: -0.23 kg [-0.37, -0.10], DRV(/r/c): -0.20 kg [-0.41, 0.00]). However, in weighted estimates, the difference in mean increase in BMI was only statistically significant for EVG/c users compared to DTG users (-0.23 kg [-0.36, -0.09]). Among patients who were obese at baseline, RAL users had a lower average increase in BMI compared to DTG users in both unweighted and weighted estimates (unweighted: -0.81 kg [-1.44, -0.18], weighted: -0.76 kg [-1.43, -0.08]). There were no differences in mean increases in BMI change between core agent groups among underweight and overweight ART-experienced patients at 12 months following core agent initiation.

At **24 months** following core agent initiation, there were no differences between core agent groups in mean increases in BMI in adjusted estimates among all ART-experienced patients. In analyses stratified by baseline BMI category, EVG/c and RAL users who were a normal weight at baseline had a lower average increase in BMI compared to DTG users (EVG/c: -0.39 kg [-0.61, -0.17], RAL: -0.54 kg [-1.01, -0.07]). There were no differences in mean BMI increases between core agent groups among underweight, overweight, or obese ART-experienced patients at 24 months following core agent initiation.

#### ART-EXPERIENCED, SUPPRESSED PATIENTS

##### Descriptive results

Compared to ART-experienced, suppressed DTG users, EVG/c and RPV users were younger, and RAL users were older at baseline. RAL and RPV users were more likely to be female compared to DTG users. EVG/c and RPV users were less likely to be on concomitant medications associated with weight gain, while RAL users were more likely to use such medications compared to DTG users. EVG/c, DRV(/r/c), and RPV users were all less likely to be on concomitant medications associated with weight loss compared to DTG users. DRV(/r/c) users had higher baseline weight and BMI values (median [IQR] = 80.9kg [71.2, 91.3] and 26.6 [23.9, 30.2], respectively) compared to DTG users (79.4kg [69.4, 90.7] and 26.2 [23.4, 29.5], respectively).

In the ART-experienced, suppressed subgroup, RAL and DRV(/r/c) users experienced smaller mean increases in weight, but RPV users experienced a larger increase in weight than DTG users at 6 months (RAL: 0.5kg; DRV(/r/c): 0.5kg; RPV: 1.3kg vs. DTG: 0.9kg), 12 months (RAL: 0.5kg; DRV(/r/c): 0.5kg; RPV: 1.8kg vs. DTG: 1.4kg) and 24 months (RAL: 0.8kg; DRV(/r/c): 0.8kg; RPV: 2.0kg vs. DTG: 1.8kg). RAL and DRV(/r/c) users were less likely to have a weight increase  $\geq 5$  kg compared to DTG users at 6 months (RAL: 10.3%; DRV(/r/c): 10.8% vs. DTG: 13.2%), 12 months (RAL: 23.9%; DRV(/r/c): 21.8% vs. DTG: 26.4%), and 24 months (RAL: 23.0%; DRV(/r/c): 22.4% vs. DTG: 25.5%).

##### Statistical modeling of the association between core agent initiation (Addendum)

At 6 months following core agent initiation among ART-experienced, suppressed patients, the average increase in BMI was lower for EVG/c, RAL, and DRV (/r/c) users compared to DTG users (EVG/c: -0.15kg [-0.25, -0.06], RAL: -0.22kg [-0.39, -0.06], DRV (/r/c): -0.30kg [-0.44, -0.17]), with similar results for inverse probability of censoring weighted estimates. In analyses stratified by baseline BMI category, among those with normal baseline BMI, all groups experienced a lower increase in BMI on average compared to DTG users (EVG/c: -0.20kg [-0.32, -0.08], RAL: -0.23kg [-0.45, -0.01], RPV: -0.16kg [-0.29, -0.03], DRV(/r/c): -0.20kg [-0.38, -0.03]), with consistent results obtained for weighted estimates. EVG/c and DRV (/r/c) users who were overweight at baseline had a lower mean increase in BMI compared to DTG users (EVG/c: -0.15kg [-0.28, -0.01], DRV (/r/c): -0.26kg [-0.45, -0.06]). However, in weighted estimates, the difference in mean BMI increases was only statistically significant for EVG/c users compared to DTG users (-0.15kg [-0.27, -0.01]). Among those who were obese at baseline, the mean increase in BMI was higher for RPV users and lower for DRV (/r/c) users compared to DTG users in both unweighted (RPV: 0.36kg [0.06, 0.64], DRV (/r/c): -0.49kg [-0.85, -0.14]) and weighted (RPV: 0.38kg [0.09, 0.66], DRV (/r/c): -0.44kg [-0.79, -0.08]) estimates. There were no differences in mean BMI increases between core agent groups among underweight ART-experienced patients at 6 months following core agent initiation.

At 12 months following core agent initiation in ART-experienced, suppressed patients, only DRV(/r/c) was associated with a lower increase in BMI than DTG in both unweighted (-0.31kg [-0.49, -0.12]) and weighted estimates (-0.30kg [-0.49, -0.11]). In analyses stratified by baseline BMI category, EVG/c and DRV(/r/c) users who were normal weight at baseline had a lower average increase in BMI compared to DTG users in both unweighted (EVG/c: -0.27kg [-0.43, -0.11], DRV(/r/c): -0.26kg [-0.50, -0.03]) and weighted estimates (EVG/c: -0.24kg [-0.47, 0.00], DRV(/r/c): -0.24kg [-0.47, 0.00]). Among those who were overweight at baseline, the average increase in BMI was lower for DRV (/r/c) users compared to DTG users (-0.32kg [-0.57, -0.06]). IPC weighting could not be performed in this subgroup due to large weights. There were no differences in the average increase in BMI between core agent groups among underweight or obese ART-experienced patients at 12 months following core agent initiation.

At 24 months following core agent initiation, ART-experienced, suppressed individuals on DRV(/r/c) had a lower average increase in BMI than those on DTG (unweighted: -0.29kg [-0.57, -0.01], weighted: -0.30kg [-0.58, -0.01]). In analyses stratified by baseline BMI category, EVG/c, RAL, and DRV (/r/c) users who were normal weight at baseline had a lower increase in BMI compared to DTG users in both unweighted (EVG/c: -0.34kg [-0.58, -0.10], RAL: -0.56kg [-1.03, -0.08], DRV(/r/c): -0.50kg [-0.88, -0.09]) and weighted (EVG/c: -0.30kg [-0.53, -0.06], RAL: -0.52kg [-1.01, -0.03], DRV(/r/c): -0.50kg [-0.89, -0.10]) estimates. There were no differences in the average increase in BMI between core agent groups among underweight, overweight, or obese ART-experienced patients at 24 months following core agent initiation.

## Conclusions

In this study, weight gains at 6, 12, and 24 months following initiation were relatively small for all core agent groups even after two years of follow up. Among all ART-experienced patients, EVG/c, RAL and DRV(/r/c) users had lower increases in BMI on average than DTG users at 6 months following initiation. Only RAL users had a lower mean increase in BMI than DTG users at 12 months following initiation. There were no differences in average increases in BMI at 24 months following initiation for EVG/c, RAL, RPV, and DRV (/r/c) users compared to DTG users. However, it must be noted that different patients were included in the analyses of each time point, based on the availability of a BMI measurement at 6-, 12- or 24-months following core agent initiation. Inverse probability of censoring weighting attempted to control for potential biases arising from this study design. In addition, a strong assumption of linearity was made by assessing changes in BMI at 3 subsequent time points in different models. Linear models assume that the slope of change in BMI is constant over the entire follow-up time. If this assumption held, estimates would be consistent across models between each time points. However, this cannot be assessed easily due to the use of different populations for each set of models. While an extensive list of conditions and medications known to increase and decrease weight were evaluated and controlled for in this analysis, recreational marijuana use was not assessed.

## 2. Background and Rationale

### 2.1. Background

Highly active antiretroviral therapy (ART) has changed human immunodeficiency virus (HIV) infection from a fatal illness to a chronic disease [16, 17]. Since the mid-1990's, regimens containing multiple antiretroviral drugs from at least two classes have been the standard of care in HIV treatment [18]. Combination therapy presents multiple barriers to viral replication and limits the development of drug-resistant mutations [18].

Integrase strand transfer inhibitors (INSTI) are the newest tool for prolonging survival and improving quality of life for people with HIV [19]. This class of medications includes raltegravir (RAL), elvitegravir (EVG), dolutegravir (DTG) and bictegravir (BIC). INSTIs appear to result in a more rapid decline in viral load and higher increases in CD4 counts when compared to protease inhibitors (PI) or efavirenz (EFV) based regimens [20-27].

Body composition has been a concern for patients with HIV since the initial manifestations of severe muscle wasting in the pre-ART era [1-4]. However, these concerns have evolved over time as studies have observed increases in weight among people living with HIV since the introduction of ART [5-7]. Lipodystrophy was associated with primarily older ART regimens but is still observed with some regimens containing newer agents including PIs such as darunavir (DRV) or atazanavir (ATV), INSTIs such as RAL, and non-nucleoside reverse transcriptase inhibitors (NNRTI) such as rilpivirine (RPV) [8-11].

Apart from irregular body fat deposition, weight gain was attributed to an improvement in health initially, especially among those severely immunocompromised. More recently, it has been appreciated that obesity and body mass index (BMI) have been increasing in HIV populations over time both before the initiation of ART and after [7]. In a sample of 14,084 patients living with HIV in the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD), the percentage of patients who were obese at ART initiation increased from 9% to 18% between 1998 and 2010 [5]. In the Swiss HIV Cohort Study, overweight/obesity prevalence increased from 13% in 1990 to 38% in 2012 [28].

In the current ART era, weight gain has been attributed to the effect of the treatment rather than simply an improvement in health with increases in weight following initiation of ART reported in multiple studies [5, 6, 12, 13]. In the NA-ACCORD, 22% of patients with normal BMI at baseline became overweight and 18% of patients who were overweight at baseline became obese after just three years of ART [5]. Out of 1,255 HIV patients enrolled in the U.S. Military Natural History Study between 1985–2004 and followed up to 2007, 62% gained weight after HIV diagnosis, among whom BMI increased by 2.3 kg/m<sup>2</sup> on average from baseline to last visit (average rate of 0.55 kg/m<sup>2</sup> per year). The average weight gain was 7.3 kg with an average rate of 1.71 kg per year [6]. Among 1,600 HIV patients initiating ART in the Swiss HIV Cohort Study, BMI increased on average by 0.92 kg/m<sup>2</sup> per year (95% CI: 0.83, 1.0) in the first year of ART and 0.31 kg/m<sup>2</sup> per year (0.29, 0.34) during years 1–4 [28]. Among 1,160 women in the Women's Interagency HIV Study (WIHS), median BMI increases over 5 years were 0.21 kg/m<sup>2</sup> (90% CI: –1.33, 0.42) for normal baseline BMI, 0.39 kg/m<sup>2</sup> (90% CI: 0.15, 0.66) for overweight, 0.31 kg/m<sup>2</sup> (90% CI: –1.18, 0.67) for obese, and –0.36 kg/m<sup>2</sup> (90% CI: –2.04, 1.08) for morbidly obese women [12]. In the Veterans Aging Cohort Study (VACS), 4,311 ART-naïve patients initiating ART between 2000-2008 gained a median of 2.7 kg (IQR: –1.3 to 7.7) [13].

In addition, duration of ART exposure may also impact weight gain. Between 1999 and 2004 in the Multicenter AIDS Cohort Study (1,059 men living with HIV) and the WIHS cohorts (1,455 women living with HIV), a shorter duration of ART was associated with lower BMI [7]. These studies suggest that both ART initiation in general and time since initiation are associated with increases in BMI and weight [5-7, 12, 13].

To our knowledge, four recent studies have reported on weight or BMI increases associated with specific core agents [29-32]. One cohort study included 462 European patients on DTG for more than six months and observed a significant increase in weight (mean increase: 3 kg) and BMI (mean increase: 1 kg/m<sup>2</sup>) over follow-up; 20% of the patients experienced >10% increase in weight [30]. However, the follow-up timepoints varied between patients and the study did not include a comparison group. Another cohort study following 495 patients virologically suppressed on EFV/tenofovir disoproxil fumarate (TDF)/emtricitabine (FTC) from the Vanderbilt Comprehensive Care Clinic found that weight change over an 18-month period was highest among patients switching to an INSTI-containing regimen (2.9 kg) when compared to switching to a PI-containing regimen (0.7 kg) or continuation with EFV/TDF/FTC (0.9 kg) [29]. The greatest change was observed for patients switching to DTG/abacavir (ABC)/lamivudine (3TC) specifically (5.3 kg) [29]. In the SCOLTA cohort, mean BMI increases were estimated among ART-experienced patients at 6 and 12 months following initiation of a new core agent [31]. Mean BMI increase with DTG (n=225) was  $0.18 \pm 0.08$  at 6 months and  $0.30 \pm 0.10$  at 12 months. With RAL (n=382), mean BMI increase was  $0.17 \pm 0.07$  at 6 months and  $0.24 \pm 0.08$  at 12 months. With EVG (n=148), mean BMI increase was  $0.21 \pm 0.07$  at 6 months and  $0.23 \pm 0.10$  at 12 months. With DRV (n=145), mean BMI increase was  $0.32 \pm 0.09$  at 6 months and  $0.41 \pm 0.10$  at 12 months. With RPV (n=218), mean BMI increase was  $0.06 \pm 0.07$  at 6 months and  $0.06 \pm 0.08$  at 12 months [31]. Although small, BMI increases from baseline were statistically significant ( $p < 0.05$ ) for all core agents assessed at both 6 and 12 months with the exception of RPV (6 months:  $p = 0.39$ , 12 months:  $p = 0.51$ ) [31].

In 1,809 ART-naïve patients randomized to ATV/ritonavir (r)/TDF/FTC, DRV/r/TDF/FTC, or RAL/TDF/FTC, weight increased on average by 3.8 kg and BMI by 1.3 kg/m<sup>2</sup> over 96 weeks [32]. Adjusted logistic regression with multiple imputation was performed to predict severe weight gain (i.e.  $\geq 10\%$  increase in weight if  $\geq$  normal BMI at baseline;  $\geq$  overweight at 96 weeks if underweight at baseline) and severe BMI increase (i.e. increase of one or more BMI categories at 96 weeks if  $\geq$  normal baseline BMI;  $\geq$  overweight at 96 weeks if underweight at baseline). Compared to RAL, patients prescribed ATV/r were less likely to experience a severe weight increase (aOR: 0.72, 95% CI: 0.53, 0.99) and those prescribed DRV/r were less likely to experience a severe BMI increase (aOR: 0.73; 95% CI: 0.53, 0.99) [32]. The relative impact on weight gain of most common core ART agents has yet to be determined.

## 2.2. Rationale

Disentangling weight gain due to improved health status from weight gain due to an undesired effect of therapy requires an assessment of a large number of patients who may be progressing toward a stable health status or in whom a stable health status has been achieved and maintained.

Raised disproportionality analysis (DPA) scores for both DTG and DTG/ABC/3TC were detected through the routine pharmacovigilance. An evaluation clinical trial data, spontaneous case reports, and published studies could not rule out an association between DTG exposure and weight gain. The cumulative analysis led to a recommendation for a label change indicating weight gain as an uncommon adverse drug reaction (ADR).

This study, utilizing data from a large real-world population of treated HIV patients, sought to provide additional information to support the signal evaluation.

### 3. Study Objectives

#### 3.1. Primary Objectives

- 1) Among new users of DTG, RPV, RAL, BIC\*, EVG/c and DRV(/r/c): To describe BMI categories, weight, lipid levels (e.g. total cholesterol, HDL, LDL, triglycerides), and lipodystrophy at core agent initiation and at 6,12, and 24 months after core agent initiation, stratified by ART-naïve and ART-experienced at core agent initiation.
- 2) Among all ART-experienced and ART-experienced, suppressed new users of DTG vs. RPV, RAL, BIC\*, EVG/c or DRV (/r/c): To estimate the association between specific core agent initiation and changes in BMI at 6, 12, and 24 months after core agent initiation.

#### 3.2. Secondary Objectives

- 1) Among ART-experienced patients who were suppressed at switch (stable switch) to DTG, RPV, RAL, BIC\*, EVG/c, or DRV(/r/c): To describe BMI categories, weight, and lipid panels levels (e.g. total cholesterol, HDL, LDL, triglycerides) at core agent initiation, and at 6, 12, and 24 months after core agent initiation.

\* BIC was excluded from this analysis due to the small number of patients initiating BIC who met inclusion criteria (n=5).

### 4. Methods

#### 4.1. Study Design

##### Study population

##### Primary population

- HIV-positive patients initiating an ART regimen (stratified by prior ART experience), meeting the following inclusion criteria:
  - HIV+
  - 18 years of age
  - Male or female
  - Prescribed one of the following core agents as part of a 3-drug regimen for the first time between 01AUG2013 and 31DEC2017:
    - DTG
    - RPV
    - RAL
    - EVG/c

- DRV (/r/c)
- BIC
- Not exposed to >1 core agent of interest concurrently
- Women who were not considered pregnant at the baseline date
- Not transgender (potential for weight changes due to hormone use)
- At least one viral load available prior to or at initiation of the regimen of interest
- At least one measurement for weight available within 3 months before or at core agent initiation, with a BMI in the plausible range ( $\geq 10$  and  $\leq 50$ )
- At least one follow-up measurement with plausible weight available during the follow-up period of interest, where plausible weight was <500 kg and change in weight from baseline was <450 kg

ART-naïve patients were defined as patients with no evidence of ART exposure prior to initiation of the core agent of interest and with a baseline viral load of  $\geq 1000$  copies/mL. ART-experienced patients were defined as patients with a history of ART prior to initiation of the core agent of interest, or a baseline viral load of <1000 copies/mL.

Secondary population (ART-experienced, suppressed)

- ART-experienced, suppressed patients were defined as ART-experienced patients with a baseline viral load <200 copies/mL

#### Baseline date

The index date for an eligible patient is defined as the first date of the first regimen of interest ever prescribed to a patient

#### Baseline period

The 12-month baseline period preceding the index date was used to assess patient demographic and clinical characteristics

#### Eligibility period

From 01AUG2013 and 31DEC2017, to allow at least 12 months of potential follow up for all patients

#### Observation period

Patients were observed from their index date until the first of the following censoring events:

- a) End of follow-up (6, 12, or 24 months after core agent initiation)
- b) Loss to follow up, defined as any 12-month period in which no clinical contact is made (cessation of continuous clinical activity)
- c) Discontinuation/addition of a core agent
- d) Pregnancy (patients with pregnancy-related diagnoses were considered pregnant and were censored at three months prior to their first pregnancy-related diagnosis)
- e) Death
- f) Study end (31DEC2018)

Patients who experienced a censoring event within three months on or after the baseline date were excluded.

#### Continuous Clinical Activity

Patients failing to meet the continuous clinical activity requirement (defined as any 12-month period in which no clinical contact is made) were censored 12 months after their last contact. Regimen gaps in therapy of 45 days or less were collapsed for continuity of treatment analysis.

## 4.2. Exposure Definition

First exposure to any core agent of interest (DTG vs. RPV, RAL, BIC\*, EVG/c or DRV(/r/c)), after inclusion in the OPERA database was identified. Prior exposure to other core agents of interest was not allowed, regardless of boosting agent use.

\* The number of BIC users satisfying all inclusion criteria was not sufficient to conduct any analyses and these patients were therefore excluded from the final study population, as shown in **Error! Reference source not found.**

## 4.3. Outcomes Definition

### 4.3.1. Weight/BMI/Lipids

Weight (in kg), BMI, and lipid levels including total cholesterol, HDL, LDL, triglycerides were assessed at baseline, and at 6 months, 12 months, and 24 months after core agent initiation.

BMI and change in BMI were defined as:

- $BMI = weight/height^2$ 
  - Weight measured in kg
  - Height measured in m
- Change in BMI = BMI(follow-up) – BMI(baseline)

Change in weight (kg) and percentage change in weight were defined as:

- Change in weight (kg) = Weight(follow-up) – Weight(baseline)
- $Percentage\ Change\ in\ Weight = \left( \frac{Weight(follow-up) - Weight(baseline)}{Weight(baseline)} \right) * 100$

Total cholesterol level categories were defined as:<sup>1</sup>

- Normal: < 5.2 mmol/L or <200 mg/dl
- Borderline Abnormal: ≥ 5.2 to < 6.2 mmol/L or ≥ 200 to < 240 mg/dl
- Dyslipidemia: ≥ 6.2 to < 7.2 mmol/L or ≥ 240 to < 280 mg/dl
- Severe dyslipidemia: ≥ 7.2 mmol/L or ≥ 280 mg/dl

LDL level categories were defined as:<sup>1</sup>

- Normal: < 2.5 mmol/L or <100 mg/dl
- Borderline Abnormal: ≥ 2.5 to < 3.3 mmol/L or ≥ 100 to < 130 mg/dl

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<sup>1</sup> Cut-offs obtained <https://www.nhlbi.nih.gov/files/docs/guidelines/atp3xsum.pdf>



- Dyslipidemia:  $\geq 3.3$  to  $< 4.1$  mmol/L or  $\geq 130$  to  $< 160$  mg/dl
- Severe dyslipidemia:  $\geq 4.1$  to  $< 4.9$  mmol/L or  $\geq 160$  to  $< 190$  mg/dl
- Very severe dyslipidemia:  $\geq 4.9$  mmol/L or  $\geq 190$  mg/dl

HDL level categories were defined as:<sup>1</sup>

- Normal:  $\geq 1.54$  mmol/L or  $\geq 60$  mg/dl
- Borderline Abnormal:  $\geq 1.03$  to  $< 1.54$  mmol/L or  $\geq 40$  to  $< 60$  mg/dl
- Dyslipidemia:  $< 1.03$  mmol/L or  $< 40$  mg/dl

Triglycerides level categories were defined as:<sup>1</sup>

- Normal:  $< 1.7$  mmol/L or  $< 150$  mg/dl
- Borderline Abnormal:  $\geq 1.7$  to  $< 2.25$  mmol/L or  $\geq 150$  to  $< 200$  mg/dl
- Dyslipidemia:  $\geq 2.25$  to  $< 5.64$  mmol/L or  $\geq 200$  to  $< 500$  mg/dl
- Severe dyslipidemia:  $\geq 5.64$  mmol/L or  $\geq 500$  mg/dl

Baseline weight, BMI, and lipids were identified as the closest measurement to index date using measurements within 3 months prior to or on index date. The time windows for assessing measurements of BMI/weight/lipids at 6, 12, and 24 months after core initiation were defined as:

- BMI/weight/lipids at 6 months: measurements closest to 6 months after core agent initiation, between  $>3$  and  $\leq 9$  months
- BMI/weight/lipids at 12 months: measurements closest to 12 months after core agent initiation, between  $>9$  and  $\leq 15$  months
- BMI/weight/lipids at 24 months: measurements closest to 24 months after core agent initiation, between  $>21$  and  $\leq 27$  months

BMI categories were also assessed at baseline, as well as changes in BMI category at 6 months, 12 months, and 24 months after core agent initiation (Table 1).

*Table 1. Changes in BMI categories*

Baseline	Follow-up
Underweight (BMI: $<18.5$ )	Underweight (BMI: $<18.5$ )
	Normal weight (BMI: $18.5 - 24.9$ )
	Overweight (BMI: $25.0 - 29.9$ )
	Obese (BMI: $\geq 30$ )
Normal weight (BMI: $18.5 - 24.9$ )	Underweight (BMI: $<18.5$ )
	Normal weight (BMI: $18.5 - 24.9$ )
	Overweight (BMI: $25.0 - 29.9$ )
	Obese (BMI: $\geq 30$ )
Overweight (BMI: $25.0 - 29.9$ )	Underweight (BMI: $<18.5$ )
	Normal weight (BMI: $18.5 - 24.9$ )
	Overweight (BMI: $25.0 - 29.9$ )
	Obese (BMI: $\geq 30$ )
Obese (BMI: $\geq 30$ )	Underweight (BMI: $<18.5$ )
	Normal weight (BMI: $18.5 - 24.9$ )

	Overweight (BMI: 25.0 – 29.9)
	Obese (BMI: ≥30)

#### 4.3.2. Lipodystrophy

Baseline (prevalent) lipodystrophy was defined as diagnosis of lipodystrophy within 12 months prior to or on index date. New (incident) lipodystrophy was defined as a new diagnosis of lipodystrophy within 6, 12, or 24 months after core agent initiation. A diagnosis of lipodystrophy was identified in the EMR by searching for diagnosis codes and text consistent with lipodystrophy, lipohypertrophy, lipoaccumulation, hyperadiposity, or lipoatrophy.

#### 4.4. Analyses

All descriptive analyses were conducted among ART-naïve, ART-experienced, and ART-experienced, suppressed patients. Baseline demographic and clinical characteristics at the time of ART initiation were summarized using medians and interquartile ranges for continuous variables and counts and percentages for categorical variables. Pairwise comparisons between DTG and each of the other core agent groups were evaluated by the Pearson's Chi-square test (categorical), Fisher's exact test (few events), or Wilcoxon Rank-Sum test (continuous).

##### 4.4.1. Primary objectives

###### 4.4.1.1. Describe BMI categories, weight, lipodystrophy, and lipid panels at core agent initiation and at 6, 12, and 24 months following initiation

These descriptive analyses were also conducted among ART-naïve, ART-experienced, and ART-experienced, suppressed patients. Baseline BMI, BMI categories, weight, lipodystrophy, and lipid levels at the time of ART initiation were summarized using medians and interquartile ranges for continuous variables and counts and percentages for categorical variables. Lipid levels (total cholesterol, HDL, LDL, triglycerides), weight and change in weight, BMI and change in BMI, and incident lipodystrophy at 6, 12, and 24 months after initiation were summarized using medians and interquartile ranges for continuous variables and counts and percentages for categorical variables. Pairwise comparisons between DTG and each of the other core agent groups at baseline and at 6, 12, and 24 months after initiation were evaluated by the Pearson's Chi-square test (categorical), Fisher's exact test (few events), or Wilcoxon Rank-Sum test (continuous). Patients without the lab values of interest at each time point were excluded from evaluation at that time point.

BMI and lipids were assessed categorically, as the proportion of patients in each category at baseline and at 6, 12, and 24 months after core agent initiation. Change in BMI category, absolute change in weight, and percentage change were also assessed at 6 months, 12 months, and 24 months after core agent initiation.

The incidence proportion of lipodystrophy (reported as a percentage) was calculated as:

- $\left( \frac{\text{Number of new cases of lipodystrophy}}{\text{Number of patients without lipodystrophy at baseline}} \right) * 100$

#### **4.4.1.2. Association between core agent and BMI among ART-experienced patients**

Statistical modeling was performed among ART-experienced patients. Adjusted linear regression models were used to assess the association between core agent and mean changes in BMI at 6, 12, and 24 months. Baseline variables included in the adjusted models were selected a priori, based on the literature, including baseline age, sex, race/ethnicity, BMI, lipodystrophy, endocrine disorders, hypertension, concomitant medications associated with weight gain and weight loss [14, 15], viral load, CD4 cell count, substance abuse, and TAF use. Factors associated with the exposure and the outcome identified in the descriptive analyses were considered for inclusion in the adjusted model if the requirements for confounding were met. Continuous variables were modeled using restricted cubic splines. Inverse probability-of-censoring weights were used to account for patients who discontinued treatment, were lost to follow-up, died, became pregnant, or unavailability of a BMI measurement during the time windows of interest, and were constructed using a logistic regression model.

\*This analysis was stratified by baseline BMI categories (underweight, normal weight, overweight, obese).

#### **4.4.1.3. Addendum: Association between core agent and BMI among ART-experienced, suppressed patients**

In addition to the analyses planned in the protocol, the statistical analyses described in section 4.4.1.2 were also performed among ART-experienced, suppressed patients to assess the association between core agent and mean changes in BMI at 6, 12, and 24 months in ART-experienced, suppressed patients.

### **4.4.2. Secondary objectives**

#### **4.4.2.1. Describe BMI categories, weight, lipodystrophy, and lipid panels at core agent initiation and at 6, 12, and 24 months following initiation among patients who were suppressed at switch (stable switch)**

All analyses noted in section 3.4.1.1 above were performed among the subset of patients who were suppressed at switch to the core agent of interest (stable switch).

## 5. Results

See supplemental materials for detailed output from all analyses.

### POPULATION IDENTIFICATION

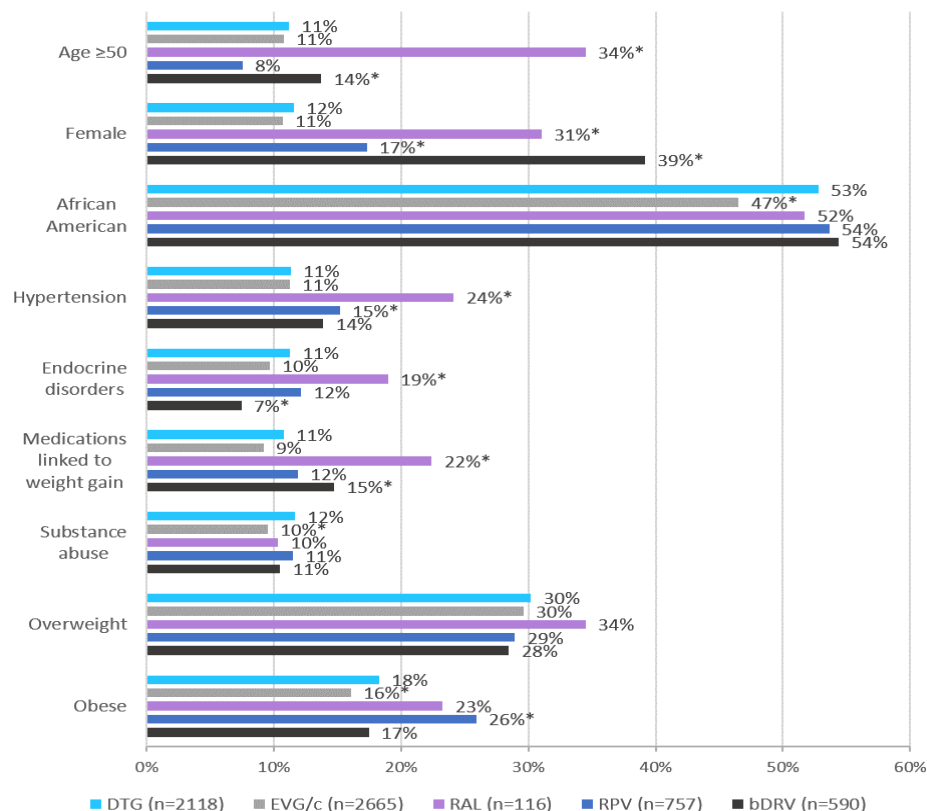
There were 21,559 patients in the overall study population after inclusion criteria were met. However, due to the limited number of patients initiating BIC as the first of the core agents of interest (n=5), these patients were excluded from further analyses, which resulted in a total of 21,554 patients in the overall study population used for analysis. Among all patients, 6,246 were considered treatment-naïve, 15,308 were considered treatment-experienced, and 10,653 were considered treatment-experienced, suppressed.

### ART-NAÏVE PATIENTS

#### Descriptive results

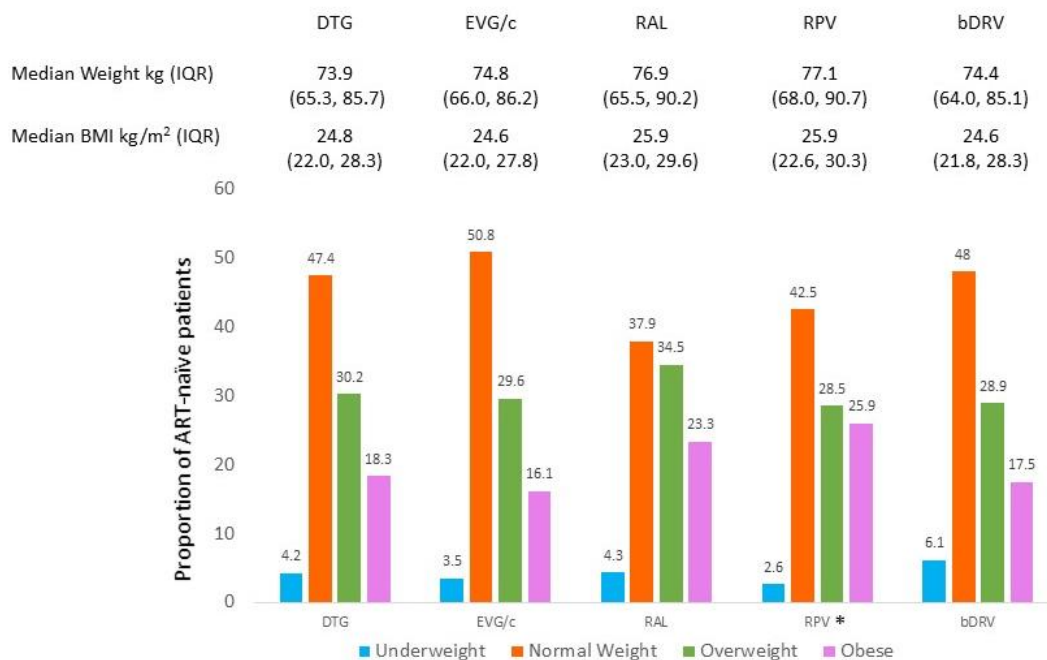
At baseline, ART-naïve RAL and DRV(/r/c) users were older and more likely to be female compared to DTG users (Figure 1). RPV users were also more likely to be female compared to DTG users. RAL and DRV(/r/c) were more likely to be on specific concomitant medications associated with weight gain, while EVG/c users were more likely to be on specific concomitant medications associated with weight loss compared to DTG users. RPV users had higher baseline weight and BMI values (median [IQR] = 77.1kg [68.0, 90.7] and 25.9 [22.6, 30.3], respectively) compared to DTG users (median [IQR] = 73.9kg [65.3, 85.7] and 24.8 [22.0, 28.3], respectively).

Figure 1. Baseline demographic and clinical characteristics for ART-naïve patients (N=6246)



\*Comparison to DTG, p-value <0.05

Figure 2. Baseline weight and BMI for ART-naïve patients



Median weight gain was greater with DRV(/r/c), but smaller with RPV, compared to DTG at 6 months (DRV(/r/c): 2.1kg; RPV: 1.4kg vs. DTG: 1.8kg) and 12 months (DRV(/r/c): 3.6kg; RPV: 1.8kg vs. DTG: 2.6kg). At 24 months, median weight gain was smaller with both EVG/c and RPV than with DTG (EVG/c: 3.6kg; RPV: 2.7kg vs. DTG: 4.1kg). At 6, 12 and 24 months, mean increases in weight showed more variability than mean increase in BMI, patterns were similar (Figures 3-4).

Figure 3. Mean change in weight (kg) and 95% confidence intervals from baseline to 6, 12, and 24 months following core agent initiation

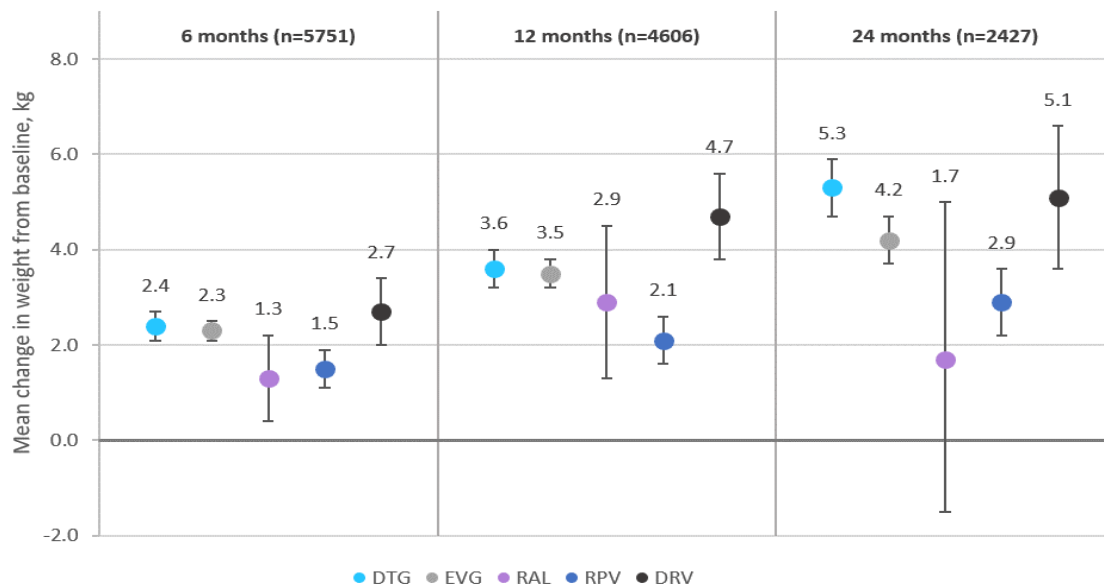
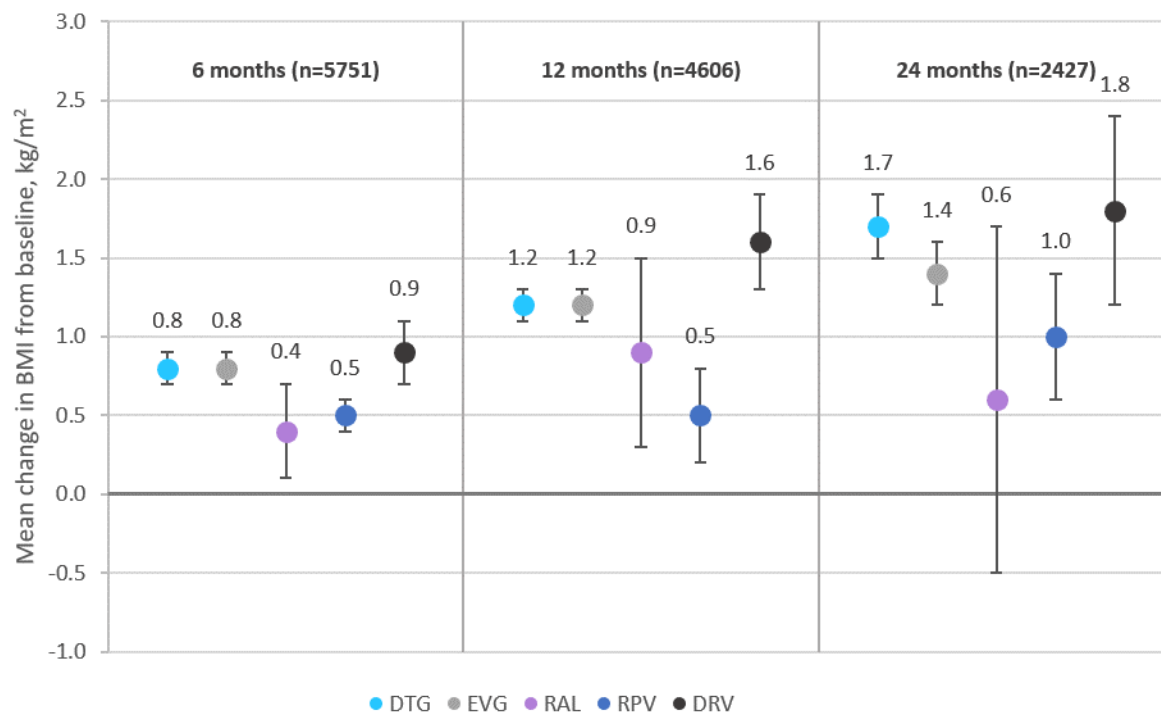


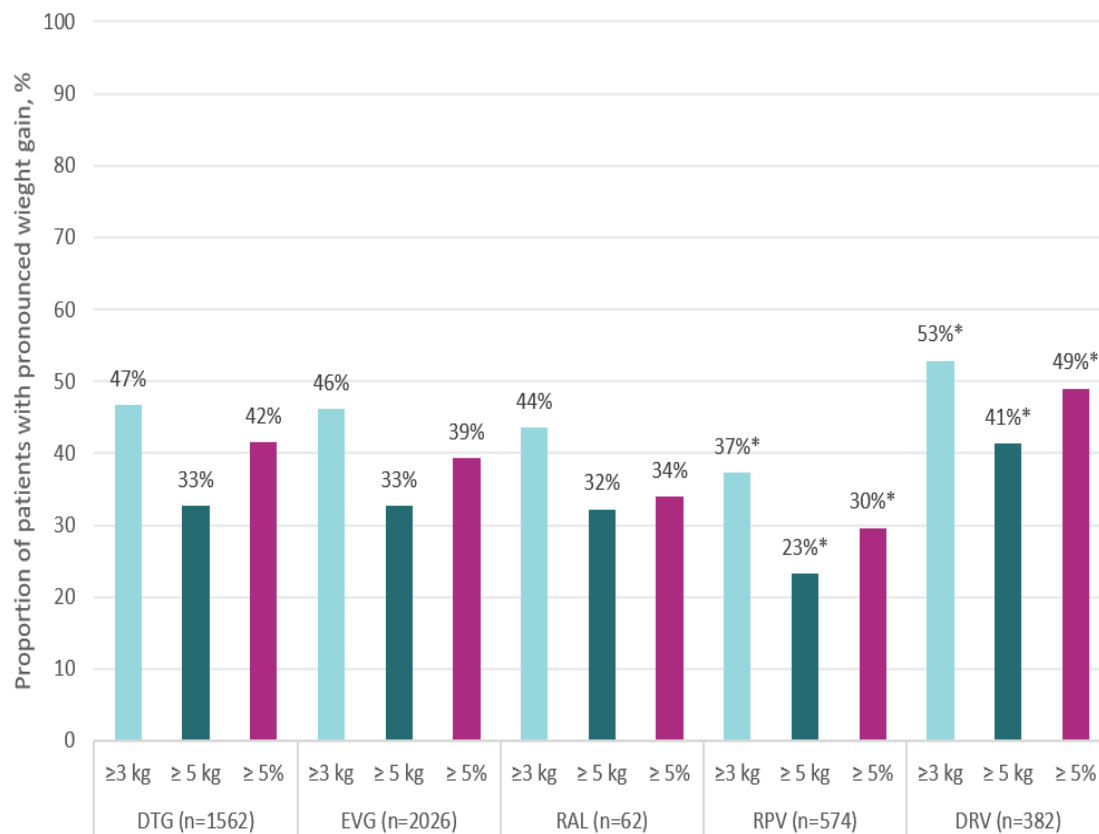
Figure 4. Mean change in BMI ( $\text{kg}/\text{m}^2$ ) and 95% confidence intervals from baseline to 6, 12, and 24 months following core agent initiation



RPV users were more likely to have no pronounced changes in weight (i.e.  $<3$  kg change) compared to DTG users at 6 months (RPV: 58.4% vs. DTG: 51.6%), 12 months (RPV: 47.0% vs. DTG: 40.9%), and 24 months (RPV: 36.3% vs. DTG: 31.1%). DRV (/r/c) users were more likely and RPV users were less likely to

have a weight increase  $\geq 5$  kg compared to DTG users at 6 months (DRV(/r/c): 28.4%; RPV: 15.7% vs. DTG: 23.2%), 12 months (DRV(/r/c): 41.4%; RPV: 23.2% vs. DTG: 32.7%) and 24 months (DRV(/r/c): 44.0%; RPV: 33.2% vs. DTG: 42.7%) (Figure 5).

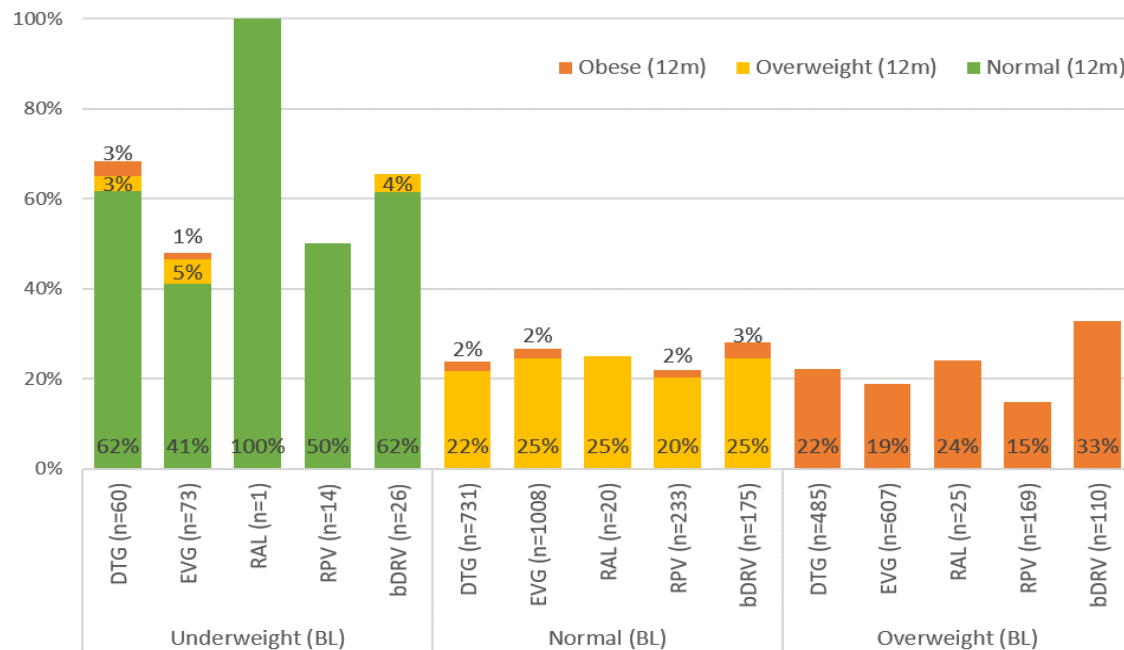
Figure 5. Comparison of pronounced weight gain definitions at 12 months following core agent initiation, by core agent (n=4606)



\*Comparison to DTG, p-value <0.05

Of underweight PLWH at baseline, the majority increased to a normal BMI at 12 months (Figure 6). Obese PLWH at baseline could not increase category, by definition. Most individuals classified as having a normal or overweight BMI at baseline remained in their baseline BMI category over follow-up.

Figure 6. Proportion of PLWH with a BMI category increase at 12 months following core agent initiation



## ART-EXPERIENCED PATIENTS

### Descriptive results

Compared to ART-experienced DTG users, RAL and RPV users were older and EVG/c were younger at baseline. DRV(/r/c) users were older and more likely to be female compared to DTG users. DRV(/r/c), RAL, and RPV users were more likely to be female compared to DTG users, while EVG/c users were more likely to be male. RAL were more likely to be on both specific concomitant medications associated with weight gain and specific medications associated with weight loss compared to DTG users, while EVG/c and RPV were less likely to be on either of these medications. Baseline weight and BMI values were higher for RAL users (median [IQR] = 79.5kg [69.9, 91.2] and 26.2 [23.3, 29.8], respectively) and RPV users (median [IQR] = 79.4kg [70.3, 90.7] and 26.2 [23.2, 29.8], respectively) compared to DTG users (median [IQR] = 78.0 [68.1, 89.8] and 25.9 [23.1, 29.3], respectively).

Median increases in weight were smaller with RAL and DRV(/r/c) than with DTG at 6 months (RAL: 0.7kg; DRV: 0.7kg vs. DTG: 1.0kg) and 12 months (RAL: 0.9kg; DRV(/r/c): 1.0kg vs. DTG: 1.5kg). Only RAL users had a smaller increase in weight than DTG users at 24 months (RAL: 0.9kg vs. DTG: 1.8kg). At 12 months following core agent initiation, only differences between DRV (/r/c) users and DTG users were significant (p-value = 0.0013). There was not a clear trend in the pattern of categorical weight changes between core agents for any of the follow-up period.



Statistical modeling of the association between core agent initiation and changes in BMI

At 6 months following core agent initiation among ART-experienced patients, after adjustment for confounding, the mean increase in BMI was lower for EVG/c, RAL, and DRV(/r/c) users compared to DTG users (EVG/c: -0.16 kg [-0.25, -0.07], RAL: -0.23 kg [-0.40, -0.05], DRV(/r/c): -0.22 kg [-0.34, -0.09]). There was however no difference in the mean increase in BMI at 6 months between RPV and DTG users (-0.05 kg [-0.16, 0.06]). These results were consistent after incorporating IPC weights (EVG/c: -0.13 kg [-0.23, -0.04], RAL: -0.20 kg [-0.38, -0.03], RPV: -0.02 kg [-0.13, 0.08], DRV(/r/c): -0.22 kg [-0.35, -0.08]). When stratifying by baseline BMI category, among those with a normal baseline BMI, EVG/c, RPV, and DRV(/r/c) users had a lower mean increase in BMI at 6 months compared to DTG users (EVG/c: -0.18 kg [-0.28, -0.07], RPV: -0.21 kg [-0.34, -0.08], DRV(/r/c): -0.16 kg [-0.31, -0.01]). There was no statistically significant difference in the mean increase in BMI between RAL (-0.20 kg [-0.41, 0.02]) and DTG users. In weighted estimates, the mean increase in BMI was lower for all core agent groups compared to DTG (EVG/c: -0.17 kg [-0.27, -0.06], RAL: -0.21 kg [-0.41, 0.00], RPV: -0.19 kg [-0.32, -0.07], DRV(/r/c): -0.20 kg [-0.36, -0.03]). EVG/c and DRV(/r/c) users who were overweight at baseline had a lower mean increase in BMI compared to DTG users (EVG/c: -0.12 kg [-0.25, 0.00], DRV(/r/c): -0.22 kg [-0.39, -0.05]). However, in weighted estimates, RAL and DRV (/r/c) users had a lower mean increase in BMI compared to DTG users (RAL: -0.24 kg [-0.47, -0.01], DRV (/r/c): -0.18 kg [-0.37, -0.01]). There were no differences in changes in BMI between core agent groups among underweight or obese ART-experienced patients at 6 months following core agent initiation.

At 12 months following core agent initiation in ART-experienced patients, the average increase in BMI was lower for RAL users compared to DTG users in adjusted estimates (-0.24 kg [0.48, 0.00]). In weighted estimates, there were no statistically significant differences in BMI increases between core agent groups. In analyses stratified by baseline BMI category, EVG/c users and DRV (/r/c) users who were a normal weight at baseline had a lower increase in BMI compared to DTG users (EVG/c: -0.23 kg [-0.37, -0.10], DRV(/r/c): -0.20 kg [-0.41, 0.00]). However, in weighted estimates, the difference in mean increase in BMI was only statistically significant for EVG/c users compared to DTG users (-0.23 kg [-0.36, -0.09]). Among patients who were obese at baseline, RAL users had a lower average increase in BMI compared to DTG users in both unweighted and weighted estimates (unweighted: -0.81 kg [-1.44, -0.18], weighted: -0.76 kg [-1.43, -0.08]). There were no differences in mean increases in BMI change between core agent groups among underweight and overweight ART-experienced patients at 12 months following core agent initiation.

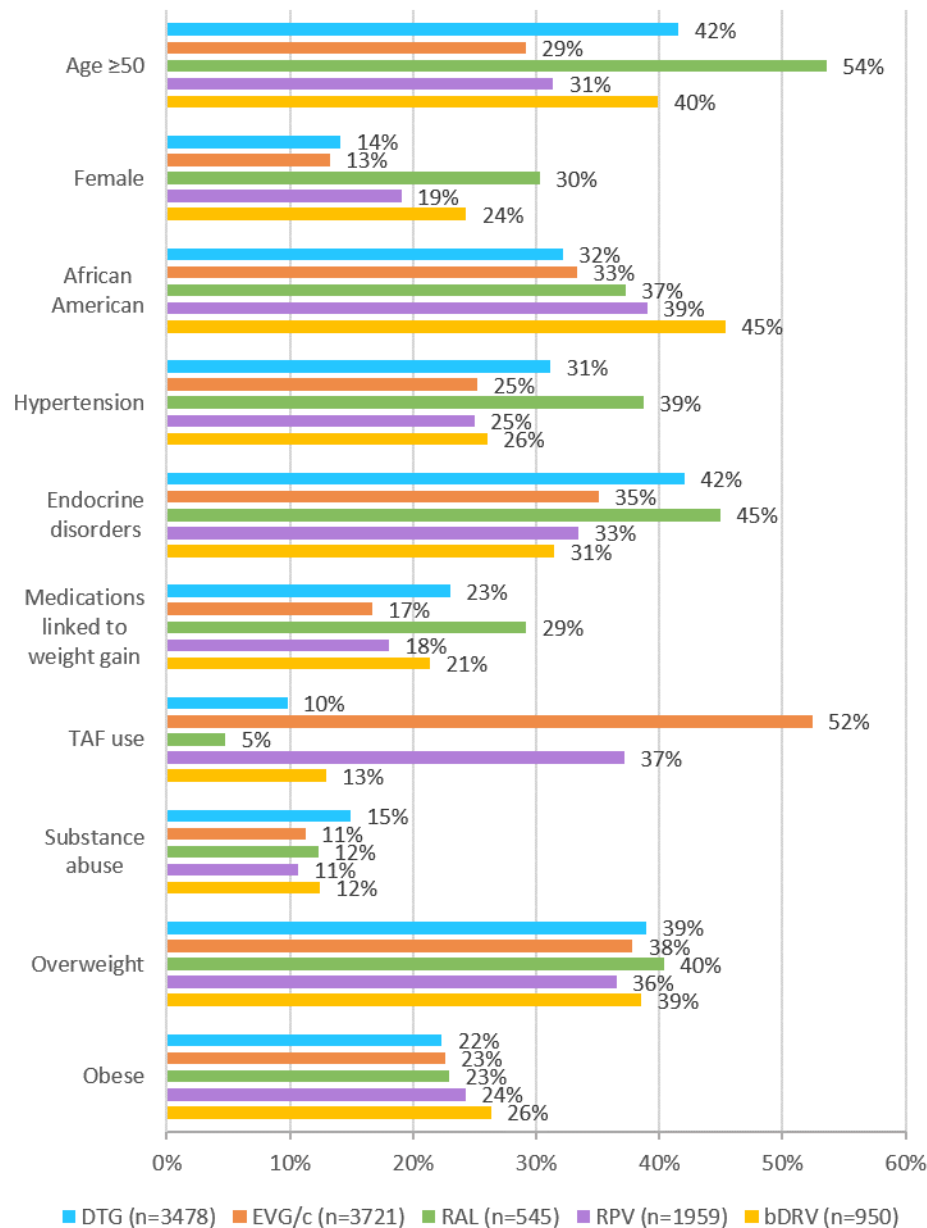
At 24 months following core agent initiation, there were no differences between core agent groups in mean increases in BMI in adjusted estimates among all ART-experienced patients. Results were also consistent in weighted estimates. In analyses stratified by baseline BMI category, EVG/c and RAL users who were a normal weight at baseline had a lower average increase in BMI compared to DTG users (EVG/c: -0.39 kg [-0.61, -0.17], RAL: -0.54 kg [-1.01, -0.07]). However, in weighted estimates, EVG/c, RAL, and RPV users had a lower mean increase in BMI compared to DTG users (EVG/c: -0.34 kg [-0.55, -0.13], RAL: -0.52 kg [-1.00, -0.04], RPV: -0.30 kg [-0.55, -0.04]). There were no differences in mean BMI increases between core agent groups among underweight, overweight, or obese ART-experienced patients at 24 months following core agent initiation.

**ART-EXPERIENCED, SUPPRESSED PATIENTS**Descriptive results

Compared to ART-experienced, suppressed DTG users, EVG/c and RPV users were younger, and RAL users were older at baseline (Figure 7). RAL and RPV users were more likely to be female compared to

DTG users. EVG/c and RPV users were less likely to be on concomitant medications associated with weight gain, while RAL users were more likely to use such medications compared to DTG users. EVG/c, DRV(r/c), and RPV users were all less likely to be on concomitant medications associated with weight loss compared to DTG users.

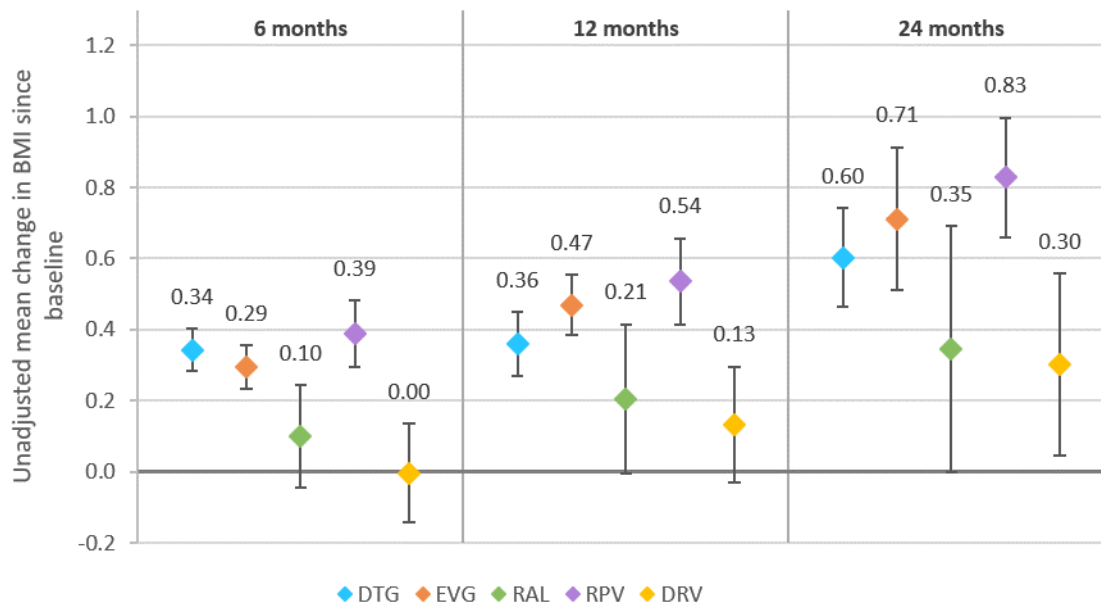
Figure 7. Baseline demographic and clinical characteristics for ART-experienced, suppressed patients (N=10,653)



DRV(/r/c) users had higher baseline weight and BMI values (median [IQR] = 80.9kg [71.2, 91.3] and 26.6 [23.9, 30.2], respectively) compared to DTG users (79.4kg [69.4, 90.7] and 26.2 [23.4, 29.5], respectively).

In the ART-experienced, suppressed subgroup, RAL and DRV(/r/c) users experienced a smaller increase in weight, but RPV users experienced a larger increase in weight than DTG users at 6 months (RAL: 0.5kg; DRV(/r/c): 0.5kg; RPV: 1.3kg vs. DTG: 0.9kg), 12 months (RAL: 0.5kg; DRV(/r/c): 0.5kg; RPV: 1.8kg vs. DTG: 1.4kg) and 24 months (RAL: 0.8kg; DRV(/r/c): 0.8kg; RPV: 2.0kg vs. DTG: 1.8kg) (Figure 8).

Figure 8. Unadjusted change in BMI ( $\text{kg}/\text{m}^2$ ) from baseline to 6,12, or 24 months after core agent initiation, by core agent



RAL and DRV(/r/c) users were less likely to have a weight increase  $\geq 5$  kg compared to DTG users at 6 months (RAL: 10.3%; DRV(/r/c): 10.8% vs. DTG: 13.2%), 12 months (RAL: 23.9%; DRV(/r/c): 21.8% vs. DTG: 26.4%), and 24 months (RAL: 23.0%; DRV(/r/c): 33.2% vs. DTG: 22.4%).

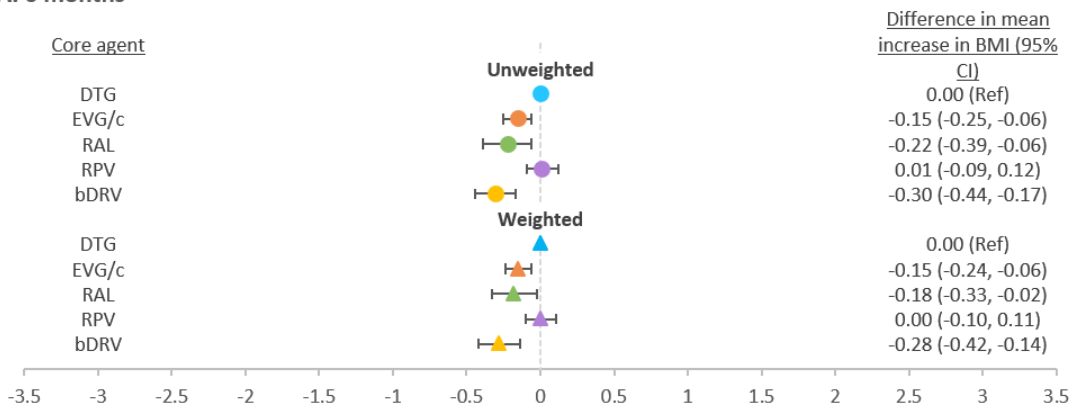
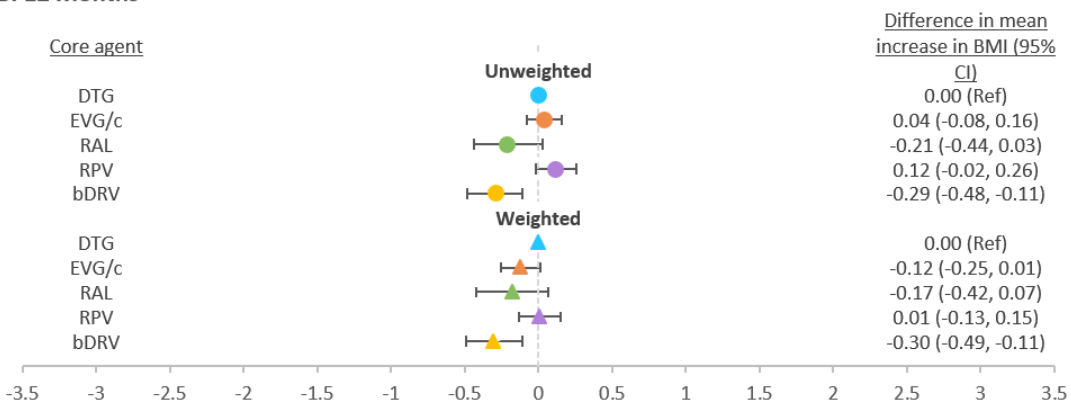
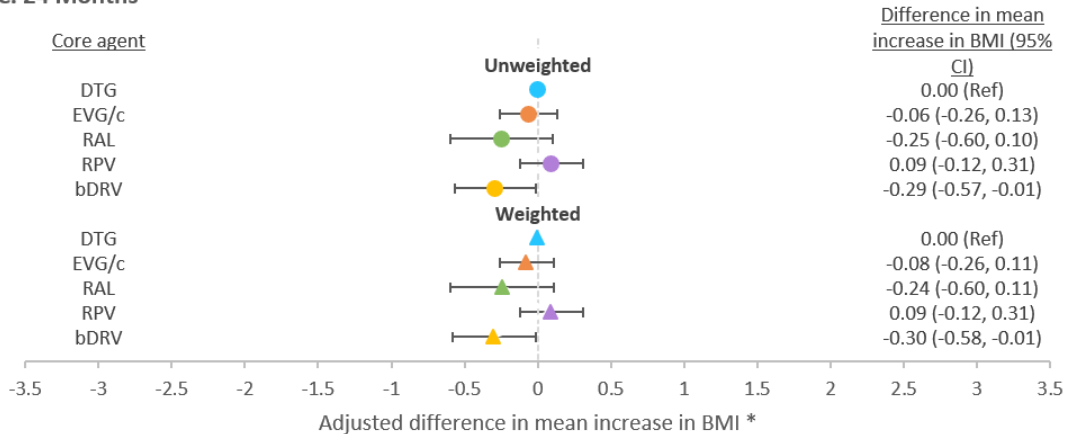
#### Statistical modeling of the association between core agent initiation and weight gain:

At **6 months** following core agent initiation among ART-experienced, suppressed patients, the average increase in BMI was lower for EVG/c, RAL, and DRV (/r/c) users compared to DTG users (EVG/c: -0.15kg [-0.25, -0.06], RAL: -0.22kg [-0.39, -0.06], DRV (/r/c): -0.30kg [-0.44, -0.17]), with similar results for inverse probability of censoring weighted estimates (Figure 9).

At **12 months** following core agent initiation in ART-experienced, suppressed patients, only DRV(/r/c) was associated with a lower increase in BMI than DTG in both unweighted (-0.31kg [-0.49, -0.12]) and weighted estimates (-0.30kg [-0.49, -0.11]).

At **24 months** following core agent initiation, ART-experienced, suppressed individuals on DRV(/r/c) had a lower average increase in BMI than those on DTG (unweighted: -0.29kg [-0.57, -0.01], weighted: -0.30kg [-0.58, -0.01]).

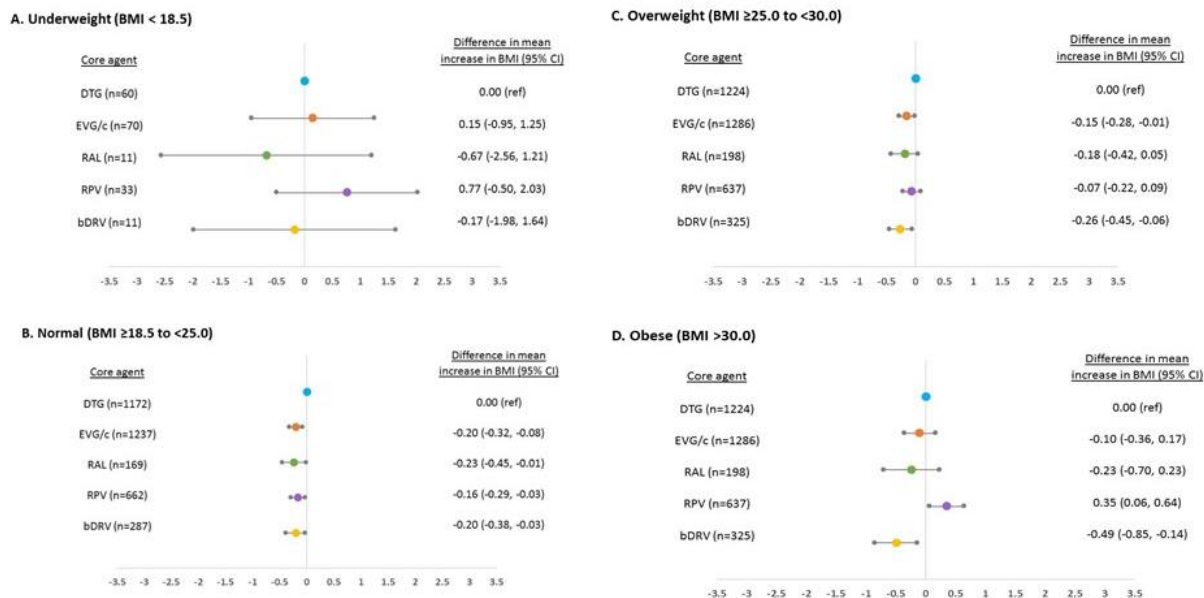
Figure 9. Adjusted difference in mean increase in BMI from baseline, stratified by time since agent initiation

**A. 6 months****B. 12 Months****C. 24 Months**

\* Adjusted for baseline BMI, age, sex, race/ethnicity, viral load, CD4 count, lipodystrophy, endocrine disorders, hypertension, use of medications associated with weight gain or with weight loss, substance abuse and TAF use

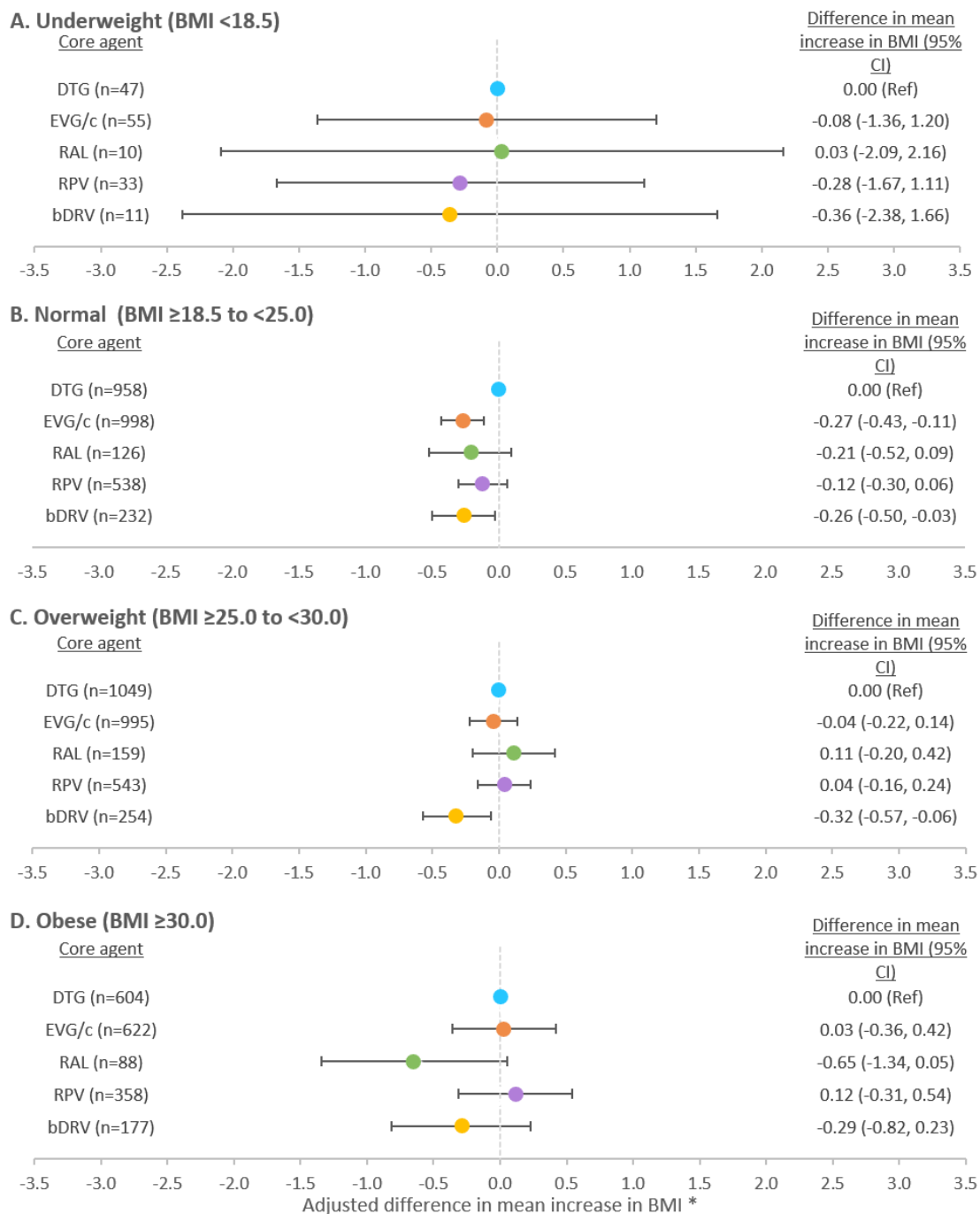
At **6 months**, in analyses stratified by baseline BMI category, among those with normal baseline BMI, all groups experienced a lower increase in BMI on average compared to DTG users (EVG/c: -0.20kg [-0.32, -0.08], RAL: -0.23kg [-0.45, -0.01], RPV: -0.16kg [-0.29, -0.03], DRV (/r/c): -0.20kg [-0.38, -0.03]), with consistent results obtained for weighted estimates (Figure 10). EVG/c and DRV (/r/c) users who were overweight at baseline had a lower mean increase in BMI compared to DTG users (EVG/c: -0.15kg [-0.28, -0.01], DRV (/r/c): -0.26kg [-0.45, -0.06]). However, in weighted estimates, the difference in mean BMI increases was only statistically significant for EVG/c users compared to DTG users (-0.15kg [-0.27, -0.01]). Among those who were obese at baseline, the mean increase in BMI was higher for RPV users and lower for DRV (/r/c) users compared to DTG users in both unweighted (RPV: 0.36kg [0.06, 0.64], DRV (/r/c): -0.49kg [-0.85, -0.14]) and weighted (RPV: 0.38kg [0.09, 0.66], DRV (/r/c): -0.44kg [-0.79, -0.08]) estimates. There were no differences in mean BMI increases between core agent groups among underweight ART-experienced patients at 6 months following core agent initiation.

Figure 10. Adjusted differences in mean increases in BMI from baseline to 6 months after core agent initiation, stratified by baseline BMI



At **24 months**, in analyses stratified by baseline BMI category, EVG/c and DRV (/r/c) users who were normal weight at baseline had a lower average increase in BMI compared to DTG users in both unweighted (EVG/c: -0.27kg [-0.43, -0.11], DRV (/r/c): -0.26kg [-0.50, -0.03]) and weighted estimates (EVG/c: -0.24kg [-0.47, 0.00], DRV (/r/c): -0.24kg [-0.47, 0.00]) (Figure 11). Among those who were overweight at baseline, the average increase in BMI was lower for DRV (/r/c) users compared to DTG users (-0.32kg [-0.57, -0.06]). IPC weighting could not be performed in this subgroup due to large weights. There were no differences in the average increase in BMI between core agent groups among underweight or obese ART-experienced patients at 12 months following core agent initiation.

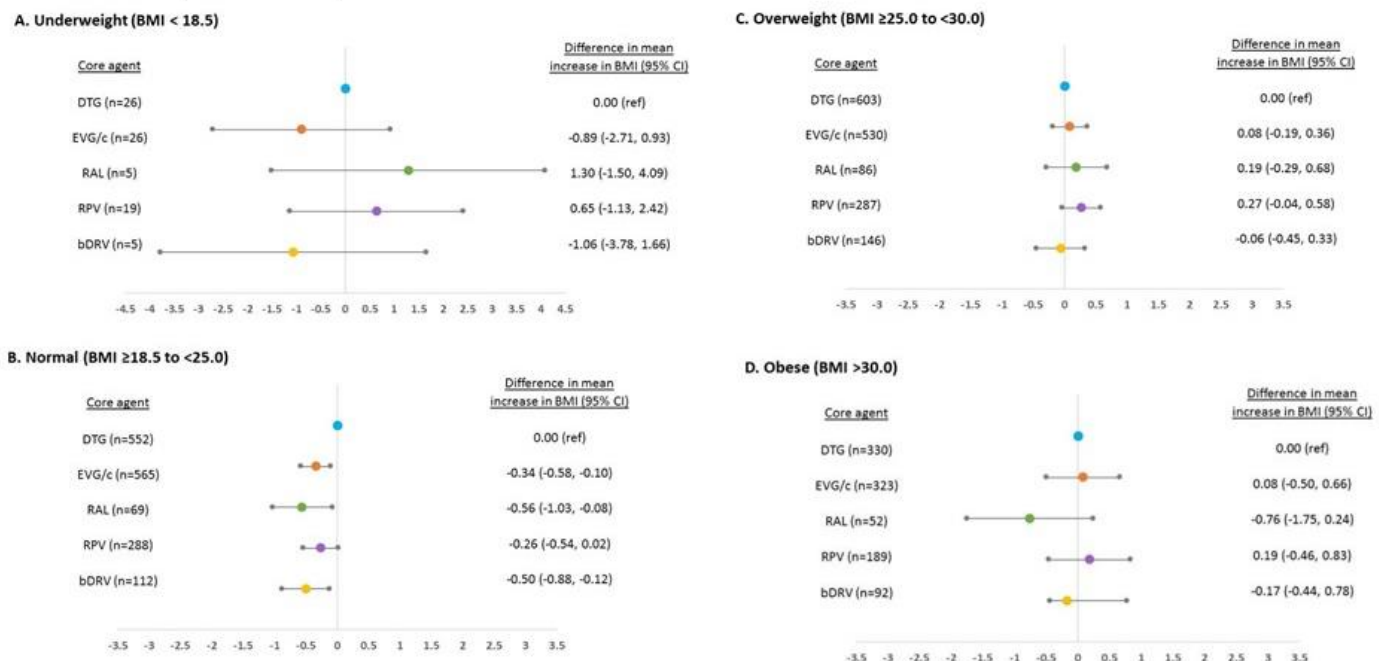
Figure 11. Adjusted differences in mean increase in BMI from baseline to 12 months after core agent initiation, stratified by baseline BMI



\* Adjusted for baseline BMI, age, sex, race/ethnicity, viral load, CD4 count, lipodystrophy, endocrine disorders, hypertension, use of medications associated with weight gain or with weight loss, substance abuse and TAF use

At **24 months**, in analyses stratified by baseline BMI category, EVG/c, RAL, and DRV (/r/c) users who were normal weight at baseline had a lower increase in BMI compared to DTG users in both unweighted (EVG/c: -0.34kg [-0.58, -0.10], RAL: -0.56kg [-1.03, -0.08], DRV(/r/c): -0.50kg [-0.88, -0.09]) and weighted (EVG/c: -0.30kg [-0.53, -0.06], RAL: -0.52kg [-1.01, -0.03], DRV(/r/c): -0.50kg [-0.89, -0.10]) estimates (Figure 12). There were no differences in the average increase in BMI between core agent groups among underweight, overweight, or obese ART-experienced patients at 24 months following core agent initiation.

Figure 12. Adjusted difference in mean increase in BMI from baseline to 24 months after core agent initiation, stratified by baseline BMI



A multivariable linear mixed model was used to assess the association between regimen and changes in BMI ( $\text{kg}/\text{m}^2$ ) over five years, with an interaction term between regimen and time (restricted cubic splines). The adjusted mean predicted BMI was reported at each year and evaluated using the referent (categorical) or average (continuous) value for each covariate.

The adjusted mean predicted BMI increased over follow-up for all regimens (Table 2). After three years, the increase in mean BMI was highest for RPV (RPV: 0.9  $\text{kg}/\text{m}^2$ ; DTG: 0.7; EVG: 0.8; RAL: 0.3; DRV: 0.5; Figure 1). BMI increases followed a similar upward trend for DTG, EVG, and RPV, with a rapid increase in the first year of use followed by slower increases beyond the first year (Figures 2-3). Slower but constant BMI increases were noted with DRV, while BMI values remained constant throughout follow-up with RAL (Figures 2-3).

Table 2. Adjusted<sup>a</sup> mean predicted BMI values by core agent at each year of follow-up after core agent initiation among ART-experienced, suppressed patients (n=10851)

	Dolutegravir (DTG)	Elvitegravir (EVG)	Raltegravir (RAL)	Darunavir (DRV)	Rilpivirine (RPV)
Baseline mean BMI, kg/m <sup>2</sup> (95% CI)	26.9 (26.8, 27.0)	26.8 (26.8, 26.9)	26.9 (26.8, 27.1)	26.9 (26.7, 27.0)	26.9 (26.7, 27.0)
Year 1 mean BMI, kg/m <sup>2</sup> (95% CI)	27.4 (27.3, 27.4)	27.3 (27.2, 27.4)	27.1 (26.9, 27.3)	27.1 (26.9, 27.2)	27.4 (27.3, 27.5)
Year 2 mean BMI, kg/m <sup>2</sup> (95% CI)	27.5 (27.4, 27.6)	27.5 (27.4, 27.6)	27.2 (27.0, 27.4)	27.2 (27.0, 27.4)	27.6 (27.5, 27.7)
Year 3 mean BMI, kg/m <sup>2</sup> (95% CI)	27.6 (27.5, 27.7)	27.6 (27.5, 27.7)	27.2 (27.0, 27.4)	27.4 (27.2, 27.6)	27.7 (27.6, 27.9)
Year 4 mean BMI, kg/m <sup>2</sup> (95% CI)	27.7 (27.5, 27.8)	27.8 (27.6, 27.9)	27.2 (26.9, 27.5)	27.6 (27.4, 27.9)	27.9 (27.7, 28.1)
Year 5 mean BMI, kg/m <sup>2</sup> (95% CI)	27.8 (27.5, 28.0)	27.9 (27.7, 28.1)	27.2 (26.8, 27.7)	27.8 (27.5, 28.2)	28.1 (27.8, 28.4)

<sup>a</sup>Evaluated at the following covariate values: male, white non-Hispanic, average baseline age (45 years), no baseline endocrine disorders, no baseline lipodystrophy, no baseline marijuana use, baseline BMI of 27 kg/m<sup>2</sup>, CD4 count of 676, no use of TAF during follow-up, no use of medications associated with weight gain during follow-up, and no use of medications associated with weight loss during follow-up



## 6. Conclusion

This study was conducted to describe weight, BMI, and lipid levels at 6, 12, and 24 months after core agent initiation among patients living with HIV in a real-world setting. This study also sought to examine the association between specific core agent initiation and changes in BMI at 6, 12, and 24 months after core agent initiation among patients who were treatment-experienced.

The total study population consisted of 21,554 patients initiating DTG, EVG/c, RAL, DRV(/r/c), or RPV, of whom 6,246 were considered treatment-naïve, 15,308 considered treatment-experienced, and 10,653 considered treatment-experienced, suppressed. The majority of patients were male. The baseline prevalence of lipodystrophy was low for all core agent groups but was higher for RAL users compared to DTG users among treatment-experienced and treatment-experienced, suppressed patients, and lower for RPV users compared to DTG users among treatment-experienced, suppressed patients.

### ART-naïve

Among treatment-naïve patients, RPV users were more likely and DRV (/r/c) users less likely to experience small changes in weight (<3 kg difference from baseline) compared to DTG users at 6, 12, and 24 months following core agent initiation. DRV(/r/c) users were more likely and RPV users were less likely to have a weight increase  $\geq 5$  kg at 6, 12, and 24 months following core agent initiation. Median increase in BMI was significantly greater among ART-naïve DTG users compared to RPV users at 6 months [0.6 (-0.3, 1.7) vs. 0.4 (-0.3, 1.2)], 12 months [0.8 (-0.3, 2.2) vs. 0.6 (-0.05, 1.6)], and 24 months [1.4 (0.0, 3.0) vs. 0.8 (0.7, 2.1)] from baseline. DRV users experienced greater median increases in BMI compared to DTG users at 6 months [0.7 (-0.2, 1.9)] and 12 months [1.1 (-0.1, 2.9)], but change in BMI was comparable by 24 months [1.1 (0.1, 3.1)].

### ART-experienced

Among ART-experienced patients, after adjustment for confounding, the mean BMI change at 6 months following core agent initiation was lower for EVG/c, RAL, and DRV(/r/c) users compared to DTG users (EVG/c: -0.16 [-0.25, -0.07], RAL: -0.23 [-0.40, -0.05], DRV(/r/c): -0.22 [-0.34, -0.09]). There was however no difference in mean BMI change at 6 months between RPV and DTG users (-0.05 [-0.16, 0.06]). These results were consistent after incorporating IPC weights. In analyses stratified by baseline BMI category, EVG/c, RPV, and DRV(/r/c) users who were normal weight at baseline had a lower increase in BMI on average compared to DTG users (EVG/c: -0.18 [-0.28, -0.07], RPV: -0.21 [-0.34, -0.08], DRV(/r/c): -0.16 [-0.31, -0.01]). The difference in mean BMI change between RAL and DTG users was not statistically significant (-0.20 [-0.41, 0.02]). In weighted estimates, the mean BMI change was lower for all core agent groups compared to DTG (EVG/c: -0.17 [-0.27, -0.06], RAL: -0.21 [-0.41, 0.00], RPV: -0.19 [-0.32, -0.07], DRV(/r/c): -0.20 [-0.36, -0.03]). EVG/c and DRV(/r/c) users who were overweight at baseline had a lower increase in BMI on average compared to DTG users (EVG/c: -0.12 [-0.25, 0.00], DRV(/r/c): -0.22 [-0.39, -0.05]). However, in weighted estimates, RAL and DRV (/r/c) users had a lower increase in BMI on average compared to DTG users (RAL: -0.24 [-0.47, -0.01], DRV (/r/c): -0.18 [-0.37, -0.01]). There were no differences in mean BMI between core agent groups among underweight or obese ART-experienced patients at 6 months following core agent initiation.

At 12 months following core agent initiation in ART-experienced patients, the mean change in BMI was lower for RAL users compared to DTG users in adjusted estimates (-0.24 [0.48, 0.00]). In weighted estimates, there were no statistically significant differences between core agent groups. In analyses stratified by baseline BMI category, EVG/c users and DRV (/r/c) users who were a normal weight at

baseline had a lower increase in BMI on average compared to DTG users (EVG/c: -0.23 [-0.37, -0.10], DRV(/r/c): -0.20 [-0.41, 0.00]). However, in weighted estimates, the difference in mean BMI change was only statistically significant for EVG/c users compared to DTG users (-0.23 [-0.36, -0.09]). Among patients who were obese at baseline, RAL users had a lower increase in BMI on average compared to DTG users in both unweighted and weighted estimates (unweighted: -0.81 [-1.44, -0.18], weighted: -0.76 [-1.43, -0.08]). There were no differences in mean BMI between core agent groups among underweight and overweight ART-experienced patients at 12 months following core agent initiation.

At 24 months following core agent initiation, there were no differences between core agent groups in mean change in BMI in adjusted estimates among all ART-experienced patients. Results were also consistent in weighted estimates. In analyses stratified by baseline BMI category, EVG/c and RAL users who were a normal weight at baseline had a lower increase in BMI on average compared to DTG users (EVG/c: -0.39 [-0.61, -0.17], RAL: -0.54 [-1.01, -0.07]). However, in weighted estimates, EVG/c, RAL, and RPV users had a lower increase in BMI on average compared to DTG users (EVG/c: -0.34 [-0.55, -0.13], RAL: -0.52 [-1.00, -0.04], RPV: -0.30 [-0.55, -0.04]). There were no differences in mean BMI between core agent groups among underweight, overweight, or obese ART-experienced patients at 24 months following core agent initiation.

#### ART-experienced, suppressed

At 6 months following core agent initiation among ART-experienced, suppressed patients, the average increase in BMI was lower for EVG/c, RAL, and DRV (/r/c) users compared to DTG users (EVG/c: -0.15kg [-0.25, -0.06], RAL: -0.22kg [-0.39, -0.06], DRV (/r/c): -0.30kg [-0.44, -0.17]), with similar results for inverse probability of censoring weighted estimates. In analyses stratified by baseline BMI category, among those with normal baseline BMI, all groups experienced a lower increase in BMI on average compared to DTG users (EVG/c: -0.20kg [-0.32, -0.08], RAL: -0.23kg [-0.45, -0.01], RPV: -0.16kg [-0.29, -0.03], DRV(/r/c): -0.20kg [-0.38, -0.03]), with consistent results obtained for weighted estimates. EVG/c and DRV (/r/c) users who were overweight at baseline had a lower mean increase in BMI compared to DTG users (EVG/c: -0.15kg [-0.28, -0.01], DRV (/r/c): -0.26kg [-0.45, -0.06]). However, in weighted estimates, the difference in mean BMI increases was only statistically significant for EVG/c users compared to DTG users (-0.15kg [-0.27, -0.01]). Among those who were obese at baseline, the mean increase in BMI was higher for RPV users and lower for DRV (/r/c) users compared to DTG users in both unweighted (RPV: 0.36kg [0.06, 0.64], DRV (/r/c): -0.49kg [-0.85, -0.14]) and weighted (RPV: 0.38kg [0.09, 0.66], DRV (/r/c): -0.44kg [-0.79, -0.08]) estimates. There were no differences in mean BMI increases between core agent groups among underweight ART-experienced patients at 6 months following core agent initiation.

At 12 months following core agent initiation in ART-experienced, suppressed patients, only DRV(/r/c) was associated with a lower increase in BMI than DTG in both unweighted (-0.31kg [-0.49, -0.12]) and weighted estimates (-0.30kg [-0.49, -0.11]). In analyses stratified by baseline BMI category, EVG/c and DRV(/r/c) users who were normal weight at baseline had a lower average increase in BMI compared to DTG users in both unweighted (EVG/c: -0.27kg [-0.43, -0.11], DRV(/r/c): -0.26kg [-0.50, -0.03]) and weighted estimates (EVG/c: -0.24kg [-0.47, 0.00], DRV(/r/c): -0.24kg [-0.47, 0.00]). Among those who were overweight at baseline, the average increase in BMI was lower for DRV (/r/c) users compared to DTG users (-0.32kg [-0.57, -0.06]). IPC weighting could not be performed in this subgroup due to large weights. There were no differences in the average increase in BMI between core agent groups among underweight or obese ART-experienced patients at 12 months following core agent initiation.

At 24 months following core agent initiation, ART-experienced, suppressed individuals on DRV(/r/c) had a lower average increase in BMI than those on DTG (unweighted: -0.29kg [-0.57, -0.01], weighted: -0.30kg [-0.58, -0.01]). In analyses stratified by baseline BMI category, EVG/c, RAL, and DRV (/r/c) users who were normal weight at baseline had a lower increase in BMI compared to DTG users in both unweighted (EVG/c: -0.34kg [-0.58, -0.10], RAL: -0.56kg [-1.03, -0.08], DRV(/r/c): -0.50kg [-0.88, -0.09]) and weighted (EVG/c: -0.30kg [-0.53, -0.06], RAL: -0.52kg [-1.01, -0.03], DRV(/r/c): -0.50kg [-0.89, -0.10]) estimates. There were no differences in the average increase in BMI between core agent groups among underweight, overweight, or obese ART-experienced patients at 24 months following core agent initiation.

Among treatment-experienced, suppressed patients, RAL and DRV (/r/c) users were less likely to have a weight increase  $\geq 5$  kg at 6, 12, and 24 months following core agent initiation.

Incident lipodystrophy was rare among all treatment groups regardless of treatment history at 6, 12, and 24 months following core agent initiation.

The OPERA cohort follows a large number of patients receiving clinical care across the U.S. An important strength of this study is the extremely large sample size, with a total of 21,559 patients included in the overall study population. Despite such a large sample size, underweight patients represented a relatively small subset of the population. As a result, inferences in this group were somewhat limited. Another strength of this study included the use of IPC weights, which assume that the data are missing at random, to account for selection bias induced by censoring due to lost to follow-up, deaths, pregnancies, or unavailability of a BMI measurement during the time windows of interest.

It must also be noted that different patients were included in the analyses of each time point, based on the availability of a BMI measurement at 6-, 12- or 24-months following core agent initiation. Inverse probability of censoring weighting attempted to control for potential biases arising from this study design. In addition, a strong assumption of linearity was made by assessing changes in BMI at 3 subsequent time points in different models. Linear models assume that the slope of change in BMI is constant over the entire follow-up time. If this assumption held, estimates would be consistent across models between each time points. However, this cannot be assessed easily due to the use of different populations for each set of models. Further, an extensive list of conditions and medications known to increase and decrease weight were evaluated and controlled for in this analysis, but recreational marijuana use was not assessed.

In conclusion, weight gains at 6, 12, and 24 months following initiation were relatively small for all core agent groups even after two years of follow up. Among all ART-experienced patients, EVG/c, RAL and DRV(/r/c) users had lower increases in mean BMI than DTG users at 6 months following initiation. Only RAL users had a lower increase in mean BMI than DTG users at 12 months following initiation. There were no differences in mean BMI at 24 months following initiation for EVG/c, RAL, RPV, and DRV (/r/c) users compared to DTG users.

## 7. Acknowledgements

This research would not be possible without the patients of the OPERA Observational Database and the healthcare providers who care for them.

## 8. References

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## **Supplemental Materials: Tables**

### **An Evaluation of Weight Gain in Patients Treated with Dolutegravir vs. Other Core Agents**

Study Report: July 20, 2019

OPERA Build: January 9, 2019

## Table of Contents

1.	Appendix: Tables for all results.....	7
1.1.	Description of the study population .....	7
1.1.1.	Identification of the study population .....	7
1.1.2.	Baseline characteristics (stratified by ART experience) .....	10
1.1.2.1.	Treatment-naïve patients .....	10
1.1.2.2.	Treatment-experienced patients .....	24
1.1.2.3.	Treatment-experienced, suppressed patients.....	40
1.2.	Description of baseline BMI categories, weight, lipid levels, and lipodystrophy (stratified by ART experience) .....	55
1.2.1.	Treatment-naïve patients .....	55
1.2.2.	Treatment-experienced patients .....	59
1.2.3.	Treatment-experienced, suppressed patients.....	63
1.3.	Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 6-months of follow-up (stratified by ART experience) .....	67
1.3.1.	Identification of the study population (subset of patients with a weight measurement between >3 and ≤9 months after core agent initiation).....	67
1.3.2.	Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 6-months of follow-up (stratified by ART experience) .....	69
1.3.2.1.	Treatment-naïve patients .....	69
1.3.2.2.	Treatment-experienced patients .....	84
1.3.2.3.	Treatment-experienced, suppressed patients.....	99
1.4.	Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 12-months of follow-up (stratified by ART experience) .....	115
1.4.1.	Identification of the study population (subset of patients with a weight measurement between >9 and ≤15 months after core agent initiation).....	115
1.4.2.	Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 12-months of follow-up (stratified by ART experience).....	117
1.4.2.1.	Treatment-naïve patients .....	117
1.4.2.2.	Treatment-experienced patients .....	132
1.4.2.3.	Treatment-experienced, suppressed patients.....	147
1.5.	Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 24-months of follow-up (stratified by ART experience) .....	162
1.5.1.	Identification of the study population (subset of patients with a weight measurement between >21 and ≤27 months after core agent initiation).....	162
1.5.2.	Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 24-months of follow-up (stratified by ART experience).....	164

1.5.2.1.	Treatment-naïve patients .....	164
1.5.2.2.	Treatment-experienced patients .....	178
1.5.2.3.	Treatment-experienced, suppressed patients .....	193
1.6.	Association between core agent group and changes in BMI (among treatment-experienced patients only) .....	209
1.6.1.	Differences in mean BMI at 6-months .....	209
1.6.1.1.	Overall: Unadjusted and adjusted differences in mean BMI at 6 months (with and without TAF use) .....	209
1.6.1.2.	Overall: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights) .....	210
1.6.1.3.	Underweight: Unadjusted and adjusted differences in mean BMI at 6 months .....	211
1.6.1.4.	Underweight: Unadjusted and adjusted differences in means BMI at 6-months (with IPC weights) .....	213
1.6.1.5.	Normal weight: Unadjusted and adjusted differences in mean BMI at 6 months .....	213
1.6.1.6.	Normal weight: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights) .....	214
1.6.1.7.	Overweight: Unadjusted and adjusted differences in mean BMI at 6 months .....	215
1.6.1.8.	Overweight: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights) .....	217
1.6.1.9.	Obese: Unadjusted and adjusted differences in mean BMI at 6 months .....	218
1.6.1.10.	Obese: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights) .....	219
1.6.2.	Differences in mean BMI at 12-months .....	221
1.6.2.1.	Overall: Unadjusted and adjusted differences in mean BMI at 12 months (with and without TAF use) .....	221
1.6.2.2.	Overall: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights) .....	222
1.6.2.3.	Underweight: Unadjusted and adjusted differences in mean BMI at 12 months ....	223
1.6.2.4.	Underweight: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights) .....	225
1.6.2.5.	Normal weight: Unadjusted and adjusted differences in mean BMI at 12 months .....	226
1.6.2.6.	Normal weight: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights) .....	227
1.6.2.7.	Overweight: Unadjusted and adjusted differences in mean BMI at 12 months .....	228
1.6.2.8.	Overweight: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights) .....	230
1.6.2.9.	Obese: Unadjusted and adjusted differences in mean BMI at 12 months .....	231



1.6.2.10.	Obese: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights)	232
1.6.3.	Differences in mean BMI at 24-months	234
1.6.3.1.	Overall: Unadjusted and adjusted differences in mean BMI at 24-months (with and without TAF use)	234
1.6.3.2.	Overall: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)	235
1.6.3.3.	Underweight: Unadjusted and adjusted differences in mean BMI at 24 months	236
1.6.3.4.	Underweight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)	238
1.6.3.5.	Normal weight: Unadjusted and adjusted differences in mean BMI at 24 months	239
1.6.3.6.	Normal weight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)	240
1.6.3.7.	Overweight: Unadjusted and adjusted differences in mean BMI at 24 months	242
1.6.3.8.	Overweight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)	243
1.6.3.9.	Obese: Unadjusted and adjusted differences in mean BMI at 24 months	244
1.6.3.10.	Obese: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)	246
1.7.	Association between core agent group and changes in BMI (among treatment-experienced, suppressed patients only)	247
1.7.1.	Differences in mean BMI at 6-months	249
1.7.1.1.	Overall: Unadjusted and adjusted differences in mean BMI at 6 months (with and without TAF use)	249
1.7.1.2.	Overall: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)	250
1.7.1.3.	Underweight: Unadjusted and adjusted differences in mean BMI at 6 months	251
1.7.1.4.	Underweight: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)	253
1.7.1.5.	Normal weight: Unadjusted and adjusted differences in mean BMI at 6 months	253
1.7.1.6.	Normal weight: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)	254
1.7.1.7.	Overweight: Unadjusted and adjusted differences in mean BMI at 6 months	255
1.7.1.8.	Overweight: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)	257
1.7.1.9.	Obese: Unadjusted and adjusted differences in mean BMI at 6 months	258
1.7.1.10.	Obese: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)	259
1.7.2.	Differences in mean BMI at 12-months	261

1.7.2.1.	Overall: Unadjusted and adjusted differences in mean BMI at 12 months (with and without TAF use) .....	261
1.7.2.2.	Overall: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights) .....	262
1.7.2.3.	Underweight: Unadjusted and adjusted differences in mean BMI at 12 months ....	263
1.7.2.4.	Underweight: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights).....	265
1.7.2.5.	Normal weight: Unadjusted and adjusted differences in mean BMI at 12 months .	266
1.7.2.6.	Normal weight: Unadjusted and adjusted differences in means BMI at 12-months (with IPC weights) .....	267
1.7.2.7.	Overweight: Unadjusted and adjusted differences in mean BMI at 12 months .....	269
1.7.2.8.	Overweight: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights).....	270
1.7.2.9.	Obese: Unadjusted and adjusted differences in mean BMI at 12 months .....	270
1.7.2.10.	Obese: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights) .....	271
1.7.3.	Differences in mean BMI at 24-months .....	273
1.7.3.1.	Overall: Unadjusted and adjusted differences in mean BMI at 24 months (with and without TAF use) .....	273
1.7.3.2.	Overall: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights) .....	274
1.7.3.3.	Underweight: Unadjusted and adjusted differences in mean BMI at 24 months ....	276
1.7.3.4.	Underweight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights).....	277
1.7.3.5.	Normal weight: Unadjusted and adjusted differences in mean BMI at 24 months .	278
1.7.3.6.	Normal weight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights) .....	279
1.7.3.7.	Overweight: Unadjusted and adjusted differences in mean BMI at 24 months .....	281
1.7.3.8.	Overweight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights).....	282
1.7.3.9.	Obese: Unadjusted and adjusted differences in mean BMI at 24 months .....	283
1.7.3.10.	Obese: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights) .....	285



## 1. Appendix: Tables for all results

### 1.1. Description of the study population

#### 1.1.1. Identification of the study population

Table 3. Identification of the study population

		Patients Included	%	Patients Excluded	%
1	Patients who are HIV+	94,852	.	0	.
2	Patients ever prescribed ART after first OPERA visit	83,671	88.2	11,181	11.8
3	Patients ever prescribed DTG, EVG/c, RAL, RPV, BIC, DRV/r, or DRV/c	64,942	77.6	18,729	22.4
4	Patients prescribed DTG, EVG/c, RAL, RPV, BIC, DRV/r, or DRV/c between August 1, 2013 and December 31, 2017 on or after their first OPERA visit	48,186	74.2	16,756	25.8
5	Patients were prescribed DTG, EVG/c, RAL, RPV, BIC, DRV/r, or DRV/c for the first time of the period of subject inclusion*	36,403	89.0	4,506	11.0
6	Patients aged 18 years and older at regimen initiation	36,329	99.8	74	0.2
7	Patients whose first regimen of interest did not include two or more of the core agents of interest	34,073	93.8	2,256	6.2
8	Patients with at least one viral load available prior to or at initiation of the regimen of interest	29,301	86.0	4,772	14.0
9	Patients with at least one measurement for weight available within 3 months before or at core agent initiation	27,510	93.9	1,791	6.1
10	Patients with at least one measurement for weight available within 3 months before or at core agent initiation AND with a value for BMI that is between $\geq 10$ and $\leq 50$	27,205	98.9	305	1.1
11	Patients with at least one follow-up measurement for weight available between $>3$ and $\leq 15$ months OR $>21$ and $\leq 27$ months after core agent initiation where weight is $<500$ kg and change in weight from baseline is $<450$ kg	21,559	79.2	5,646	20.8

\* Prior exposure to DTG, EVG, RAL, RPV, BIC, or DRV was not allowed regardless of boosting agent use

Table 4. Study population by core agent of interest and ART experience

Core Agent	N (%)	ART experience	N (%)
DTG	7,179 (33.3%)	ART-naïve	2,118 (29.5%)
		ART-experienced	5,061 (70.5%)
		ART-experienced, suppressed	3,478 (48.4%)
EVG/c	8,244 (38.2%)	ART-naïve	2,665 (32.3%)
		ART-experienced	5,579 (67.7%)
		ART-experienced, suppressed	3,721 (45.1%)
RAL	790 ( 3.7%)	ART-naïve	116 (14.7%)
		ART-experienced	674 (85.3%)
		ART-experienced, suppressed	545 (69.0%)
RPV	3,244 (15.0%)	ART-naïve	757 (23.3%)
		ART-experienced	2,487 (76.7%)
		ART-experienced, suppressed	1,959 (60.4%)
BIC	5 ( 0.0%)	ART-naïve	1 (20.0%)
		ART-experienced	4 (80.0%)
		ART-experienced, suppressed	3 (60.0%)
DRV/r or DRV/c	2,097 ( 9.7%)	ART-naïve	590 (28.1%)
		ART-experienced	1,507 (71.9%)
		ART-experienced, suppressed	950 (45.3%)

Table 5. Study population by core agent of interest and ART experience (excluding patients with BIC)

Core Agent	N (%)	ART experience	N (%)
DTG	7,179 (33.3%)	ART-naïve	2,118 (29.5%)
		ART-experienced	5,061 (70.5%)
		ART-experienced, suppressed	3,478 (48.4%)
EVG/c	8,244 (38.2%)	ART-naïve	2,665 (32.3%)
		ART-experienced	5,579 (67.7%)
		ART-experienced, suppressed	3,721 (45.1%)
RAL	790 ( 3.7%)	ART-naïve	116 (14.7%)
		ART-experienced	674 (85.3%)
		ART-experienced, suppressed	545 (69.0%)
RPV	3,244 (15.1%)	ART-naïve	757 (23.3%)
		ART-experienced	2,487 (76.7%)
		ART-experienced, suppressed	1,959 (60.4%)
DRV/r or DRV/c	2,097 ( 9.7%)	ART-naïve	590 (28.1%)
		ART-experienced	1,507 (71.9%)
		ART-experienced, suppressed	950 (45.3%)

### 1.1.2. Baseline characteristics (stratified by ART experience)

#### 1.1.2.1. Treatment-naïve patients

Table 6. Baseline demographic characteristics by core agent group among ART-naïve patients

		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
Age	Median (IQR)	31.0 (25.5, 41.0)	30.8 (25.6, 41.3)	0.7095	44.3 (32.7, 52.9)	<.0001	36.5 (27.8, 46.1)	<.0001	30.9 (25.5, 39.7)	0.2222
	18-25	591 (27.9%)	736 (27.6%)	0.8514	10 (8.6%)	<.0001	109 (18.5%)	<.0001	212 (28.0%)	0.0146
	26-49	1290 (60.9%)	1642 (61.6%)	.	66 (56.9%)	.	400 (67.8%)	.	488 (64.5%)	.
	50+	237 (11.2%)	287 (10.8%)	.	40 (34.5%)	.	81 (13.7%)	.	57 (7.5%)	.
Sex	Male	1870 (88.3%)	2379 (89.3%)	0.3083	80 (69.0%)	<.0001	491 (83.2%)	0.0025	625 (82.6%)	0.0002
	Female	245 (11.6%)	285 (10.7%)	.	36 (31.0%)	.	99 (16.8%)	.	131 (17.3%)	.
	Unknown	3 (0.1%)	1 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (0.1%)	.
Race/Ethnicity	Black non-Hispanic	881 (41.6%)	1225 (46.0%)	0.0010	60 (51.7%)	0.0248	321 (54.4%)	<.0001	406 (53.6%)	<.0001
	White non-Hispanic	480 (22.7%)	624 (23.4%)	.	32 (27.6%)	.	122 (20.7%)	.	145 (19.2%)	.
	Other non-Hispanic	91 (4.3%)	77 (2.9%)	.	2 (1.7%)	.	16 (2.7%)	.	21 (2.8%)	.

		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
	Hispanic	611 (28.8%)	688 (25.8%)	.	20 (17.2%)	.	123 (20.8%)	.	173 (22.9%)	.
	Missing	55 (2.6%)	51 (1.9%)	.	2 (1.7%)	.	8 (1.4%)	.	12 (1.6%)	.
Marital Status	Single	1601 (75.6%)	1948 (73.1%)	0.0769	77 (66.4%)	0.0751	429 (72.7%)	0.0636	569 (75.2%)	0.1374
	Married	91 (4.3%)	134 (5.0%)	.	11 (9.5%)	.	44 (7.5%)	.	45 (5.9%)	.
	Domestic partnership	21 (1.0%)	22 (0.8%)	.	2 (1.7%)	.	6 (1.0%)	.	10 (1.3%)	.
	Widowed	12 (0.6%)	6 (0.2%)	.	0 (0.0%)	.	5 (0.8%)	.	0 (0.0%)	.
	Separated/divorced	50 (2.4%)	62 (2.3%)	.	4 (3.4%)	.	13 (2.2%)	.	17 (2.2%)	.
	Unknown	343 (16.2%)	493 (18.5%)	.	22 (19.0%)	.	93 (15.8%)	.	116 (15.3%)	.
Men who have sex with men	Yes	1462 (69.0%)	1817 (68.2%)	0.5307	55 (47.4%)	<.0001	341 (57.8%)	<.0001	519 (68.6%)	0.8116
History of injection drug use	Yes	96 (4.5%)	117 (4.4%)	0.8126	7 (6.0%)	0.4526	32 (5.4%)	0.3670	36 (4.8%)	0.8013
Region	Northeast	128 (6.0%)	143 (5.4%)	<.0001	11 (9.5%)	0.0035	41 (6.9%)	<.0001	61 (8.1%)	<.0001
	South	1201 (56.7%)	1809 (67.9%)	.	80 (69.0%)	.	389 (65.9%)	.	520 (68.7%)	.
	Midwest	64 (3.0%)	118 (4.4%)	.	4 (3.4%)	.	10 (1.7%)	.	43 (5.7%)	.
	West	725 (34.2%)	595 (22.3%)	.	21 (18.1%)	.	150 (25.4%)	.	133 (17.6%)	.



		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
Medicaid	Yes	356 (16.8%)	342 (12.8%)	0.0001	22 (19.0%)	0.5463	116 (19.7%)	0.1062	102 (13.5%)	0.0314
Medicare	Yes	108 (5.1%)	70 (2.6%)	<.0001	18 (15.5%)	<.0001	52 (8.8%)	0.0007	20 (2.6%)	0.0049
Commercial Insurance	Yes	795 (37.5%)	988 (37.1%)	0.7426	43 (37.1%)	0.9195	172 (29.2%)	0.0002	272 (35.9%)	0.4330
Cash	Yes	1106 (52.2%)	1379 (51.7%)	0.7444	66 (56.9%)	0.3260	302 (51.2%)	0.6570	438 (57.9%)	0.0075
ADAP/Ryan White	Yes	866 (40.9%)	1031 (38.7%)	0.1222	38 (32.8%)	0.0824	242 (41.0%)	0.9549	307 (40.6%)	0.8729
Other	Yes	7 (0.3%)	22 (0.8%)	0.0375	2 (1.7%)	0.0758	0 (0.0%)	0.3585	5 (0.7%)	0.3205
No Payer info	Yes	242 (11.4%)	383 (14.4%)	0.0027	18 (15.5%)	0.1809	75 (12.7%)	0.3902	110 (14.5%)	0.0253

Table 7. Baseline HIV-infection characteristics by core agent group among ART-naïve patients

		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
Months from first OPERA visit to baseline	Median (IQR)	0.7 (0.2, 1.5)	0.7 (0.2, 1.6)	0.4842	0.3 (0.0, 1.1)	<.0001	0.3 (0.0, 1.0)	<.0001	0.9 (0.5, 1.8)	<.0001
	0	454 (21.4%)	577 (21.7%)	0.3083	51 (44.0%)	<.0001	246 (41.7%)	<.0001	135 (17.8%)	0.1309
	>0 to 6	1405 (66.3%)	1725 (64.7%)	.	54 (46.6%)	.	294 (49.8%)	.	539 (71.2%)	.
	>6 to 12	66 (3.1%)	87 (3.3%)	.	3 (2.6%)	.	11 (1.9%)	.	18 (2.4%)	.
	>12 to 24	60 (2.8%)	105 (3.9%)	.	5 (4.3%)	.	15 (2.5%)	.	23 (3.0%)	.
	>24	133 (6.3%)	171 (6.4%)	.	3 (2.6%)	.	24 (4.1%)	.	42 (5.5%)	.
Duration of follow-up, months	Median (IQR)	23.3 (15.8, 33.2)	23.9 (16.7, 36.2)	0.0007	18.2 (8.9, 29.7)	<.0001	19.2 (12.3, 28.7)	<.0001	27.5 (18.6, 45.5)	<.0001
	>0 to 6	54 (2.5%)	74 (2.8%)	0.8070	15 (12.9%)	<.0001	52 (8.8%)	<.0001	25 (3.3%)	<.0001
	>6 to 12	172 (8.1%)	209 (7.8%)	.	25 (21.6%)	.	81 (13.7%)	.	61 (8.1%)	.
	>12 to 24	869 (41.0%)	1065 (40.0%)	.	40 (34.5%)	.	255 (43.2%)	.	221 (29.2%)	.
	>24	1023 (48.3%)	1317 (49.4%)	.	36 (31.0%)	.	202 (34.2%)	.	450 (59.4%)	.
Year of study inclusion	Median (IQR)	2016.0 (2015.0, 2017.0)	2016.0 (2014.0, 2017.0)	<.0001	2014.0 (2014.0, 2015.5)	<.0001	2015.0 (2014.0, 2017.0)	<.0001	2014.0 (2014.0, 2016.0)	<.0001
	2013	63 (3.0%)	243 (9.1%)	<.0001	25 (21.6%)	<.0001	68 (11.5%)	<.0001	136 (18.0%)	<.0001
	2014	295 (13.9%)	506 (19.0%)	.	38 (32.8%)	.	135 (22.9%)	.	267 (35.3%)	.

		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
	2015	497 (23.5%)	504 (18.9%)	.	24 (20.7%)	.	108 (18.3%)	.	141 (18.6%)	.
	2016	583 (27.5%)	641 (24.1%)	.	10 (8.6%)	.	106 (18.0%)	.	126 (16.6%)	.
	2017	680 (32.1%)	771 (28.9%)	.	19 (16.4%)	.	173 (29.3%)	.	87 (11.5%)	.
History of AIDS-defining Illnesses	Yes	345 (16.3%)	384 (14.4%)	0.0724	32 (27.6%)	0.0016	190 (32.2%)	<.0001	58 (7.7%)	<.0001
HIV viral load (copies/ml)	Median (IQR)	49805.0 (16330.0, 136980.0)	46770.0 (13920.0, 134312.0)	0.1798	42485.0 (14580.0, 85615.0)	0.0746	61650.0 (16730.0, 237970.0)	0.0078	22170.0 (8060.0, 46110.0)	<.0001
	>= 1,000 to < 10,000	357 (16.9%)	514 (19.3%)	0.0936	25 (21.6%)	0.0378	111 (18.8%)	<.0001	223 (29.5%)	<.0001
	>= 10,000 to < 100,000	1069 (50.5%)	1298 (48.7%)	.	66 (56.9%)	.	240 (40.7%)	.	498 (65.8%)	.
	>= 100,000	692 (32.7%)	853 (32.0%)	.	25 (21.6%)	.	239 (40.5%)	.	36 (4.8%)	.
Log10 HIV viral load	Median (IQR)	4.7 (4.2, 5.1)	4.7 (4.1, 5.1)	0.1798	4.6 (4.2, 4.9)	0.0746	4.8 (4.2, 5.4)	0.0078	4.3 (3.9, 4.7)	<.0001
	>= 3 to < 4	357 (16.9%)	514 (19.3%)	0.0936	25 (21.6%)	0.0378	111 (18.8%)	<.0001	223 (29.5%)	<.0001
	>= 4 to < 5	1069 (50.5%)	1298 (48.7%)	.	66 (56.9%)	.	240 (40.7%)	.	498 (65.8%)	.
	>= 5	692 (32.7%)	853 (32.0%)	.	25 (21.6%)	.	239 (40.5%)	.	36 (4.8%)	.
CD4 cell count (cell/μl)	Median (IQR)	371.0 (224.0, 533.5)	375.0 (219.0, 537.0)	0.8582	328.5 (141.5, 486.0)	0.0242	230.0 (78.0, 441.0)	<.0001	482.0 (341.0, 625.5)	<.0001
	>500	624 (29.5%)	777 (29.2%)	0.9538	27 (23.3%)	0.0178	104 (17.6%)	<.0001	336 (44.4%)	<.0001

		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
	>350 to <= 500	499 (23.6%)	650 (24.4%)	.	29 (25.0%)	.	89 (15.1%)	.	210 (27.7%)	.
	>200 to <= 350	502 (23.7%)	616 (23.1%)	.	23 (19.8%)	.	132 (22.4%)	.	145 (19.2%)	.
	>50 to <= 200	296 (14.0%)	381 (14.3%)	.	19 (16.4%)	.	135 (22.9%)	.	44 (5.8%)	.
	<= 50	159 (7.5%)	200 (7.5%)	.	18 (15.5%)	.	115 (19.5%)	.	9 (1.2%)	.
	Missing	38 (1.8%)	41 (1.5%)	.	0 (0.0%)	.	15 (2.5%)	.	13 (1.7%)	.

*Table 8. Baseline clinical characteristics by core agent group among ART-naïve patients*

		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
Hemoglobin, g/dL	Median (IQR)	14.2 (13.0, 15.2)	14.2 (13.0, 15.1)	0.4431	13.5 (11.9, 14.8)	0.0011	13.6 (12.0, 14.6)	<.0001	14.4 (13.3, 15.3)	0.0155
	Normal	1943 (91.7%)	2483 (93.2%)	0.1618	95 (81.9%)	0.0005	499 (84.6%)	<.0001	701 (92.6%)	<.0001
	DAIDS Grade 1 (mild)	71 (3.4%)	71 (2.7%)	.	7 (6.0%)	.	33 (5.6%)	.	12 (1.6%)	.
	DAIDS Grade 2 (moderate)	40 (1.9%)	30 (1.1%)	.	2 (1.7%)	.	22 (3.7%)	.	6 (0.8%)	.
	DAIDS Grade 3 (Severe)	23 (1.1%)	23 (0.9%)	.	4 (3.4%)	.	14 (2.4%)	.	3 (0.4%)	.

		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
	DAIDS Grade 4 (potentially life- threatening)	2 (0.1%)	2 (0.1%)	.	0 (0.0%)	.	1 (0.2%)	.	0 (0.0%)	.
	Missing	39 (1.8%)	56 (2.1%)	.	8 (6.9%)	.	21 (3.6%)	.	35 (4.6%)	.
Hematocrit, %	Median (IQR)	42.5 (39.2, 45.2)	42.5 (39.4, 44.9)	0.9336	40.6 (36.7, 43.3)	0.0001	40.7 (36.5, 43.6)	<.0001	43.1 (40.0, 45.5)	0.0025
	Low	390 (18.4%)	465 (17.4%)	0.6124	29 (25.0%)	0.0003	178 (30.2%)	<.0001	77 (10.2%)	<.0001
	Normal	1641 (77.5%)	2086 (78.3%)	.	78 (67.2%)	.	380 (64.4%)	.	625 (82.6%)	.
	High	49 (2.3%)	56 (2.1%)	.	1 (0.9%)	.	11 (1.9%)	.	19 (2.5%)	.
	Missing	38 (1.8%)	58 (2.2%)	.	8 (6.9%)	.	21 (3.6%)	.	36 (4.8%)	.
Systolic blood pressure, mmHg	Median (IQR)	125.0 (115.0, 135.0)	124.0 (115.0, 135.0)	0.7713	128.0 (116.0, 138.0)	0.3277	123.0 (114.0, 133.5)	0.0376	125.0 (117.0, 136.0)	0.7557
	Low	6 (0.3%)	9 (0.3%)	0.6319	0 (0.0%)	0.5531	4 (0.7%)	0.6751	3 (0.4%)	0.5300
	Normal	1692 (79.9%)	2124 (79.7%)	.	87 (75.0%)	.	477 (80.8%)	.	599 (79.1%)	.
	DAIDS Grade 1 hypertension (mild)	279 (13.2%)	370 (13.9%)	.	22 (19.0%)	.	68 (11.5%)	.	115 (15.2%)	.
	DAIDS Grade 2 hypertension (moderate)	48 (2.3%)	43 (1.6%)	.	3 (2.6%)	.	15 (2.5%)	.	11 (1.5%)	.

		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
	DAIDS Grade 3 hypertension (severe)	13 (0.6%)	14 (0.5%)	.	1 (0.9%)	.	4 (0.7%)	.	4 (0.5%)	.
	Missing	80 (3.8%)	105 (3.9%)	.	3 (2.6%)	.	22 (3.7%)	.	25 (3.3%)	.
Diastolic blood pressure, mmHg	Median (IQR)	78.0 (71.0, 85.0)	78.0 (72.0, 85.0)	0.0645	79.0 (72.0, 89.0)	0.0526	79.0 (72.0, 86.0)	0.0331	79.0 (72.0, 86.0)	0.0052
	Low	66 (3.1%)	47 (1.8%)	0.0540	1 (0.9%)	0.2518	14 (2.4%)	0.7138	15 (2.0%)	0.3391
	Normal	1675 (79.1%)	2154 (80.8%)	.	88 (75.9%)	.	457 (77.5%)	.	593 (78.3%)	.
	DAIDS Grade 1 hypertension (mild)	223 (10.5%)	280 (10.5%)	.	18 (15.5%)	.	73 (12.4%)	.	95 (12.5%)	.
	DAIDS Grade 2 hypertension (moderate)	51 (2.4%)	52 (2.0%)	.	5 (4.3%)	.	17 (2.9%)	.	22 (2.9%)	.
	DAIDS Grade 3 hypertension (severe)	23 (1.1%)	27 (1.0%)	.	1 (0.9%)	.	7 (1.2%)	.	7 (0.9%)	.
	Missing	80 (3.8%)	105 (3.9%)	.	3 (2.6%)	.	22 (3.7%)	.	25 (3.3%)	.
VACS mortality index	Median (IQR)	20.0 (13.0, 34.0)	20.0 (13.0, 31.0)	0.5058	35.0 (20.0, 52.0)	<.0001	30.0 (17.0, 53.0)	<.0001	13.0 (12.0, 23.0)	<.0001
	0 to <15	722 (34.1%)	897 (33.7%)	0.3595	18 (15.5%)	<.0001	104 (17.6%)	<.0001	342 (45.2%)	<.0001
	>=15 to <30	578 (27.3%)	759 (28.5%)	.	24 (20.7%)	.	145 (24.6%)	.	219 (28.9%)	.

		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
	>=30 to <45	299 (14.1%)	340 (12.8%)	.	22 (19.0%)	.	97 (16.4%)	.	59 (7.8%)	.
	>= 45	297 (14.0%)	356 (13.4%)	.	34 (29.3%)	.	170 (28.8%)	.	30 (4.0%)	.
	Missing	222 (10.5%)	313 (11.7%)	.	18 (15.5%)	.	74 (12.5%)	.	107 (14.1%)	.
Specific concomitant non-ART medications associated with weight gain - Any	Yes	228 (10.8%)	245 (9.2%)	0.0705	26 (22.4%)	0.0001	87 (14.7%)	0.0076	90 (11.9%)	0.3973
Antipsychotics and mood stabilizer	Yes	36 (1.7%)	33 (1.2%)	0.2219	4 (3.4%)	0.1507	20 (3.4%)	0.0141	13 (1.7%)	1.0000
Antidepressants	Yes	46 (2.2%)	60 (2.3%)	0.9213	5 (4.3%)	0.1857	19 (3.2%)	0.1694	28 (3.7%)	0.0314
Antihyperglycemics	Yes	28 (1.3%)	22 (0.8%)	0.1148	4 (3.4%)	0.0809	8 (1.4%)	1.0000	12 (1.6%)	0.5898
Antihypertensives	Yes	25 (1.2%)	27 (1.0%)	0.5783	5 (4.3%)	0.0174	10 (1.7%)	0.3084	8 (1.1%)	1.0000
Corticosteroids	Yes	58 (2.7%)	72 (2.7%)	0.9381	7 (6.0%)	0.0397	17 (2.9%)	0.8516	21 (2.8%)	0.9589
Hormones	Yes	6 (0.3%)	5 (0.2%)	0.5527	0 (0.0%)	1.0000	2 (0.3%)	0.6878	2 (0.3%)	1.0000
Anticonvulsants	Yes	57 (2.7%)	47 (1.8%)	0.0289	6 (5.2%)	0.1160	23 (3.9%)	0.1257	19 (2.5%)	0.7895
Antihistamines	Yes	9 (0.4%)	19 (0.7%)	0.2525	2 (1.7%)	0.1083	6 (1.0%)	0.1112	2 (0.3%)	0.7382
Number of specific concomitant non- ART medications	0	1890 (89.2%)	2420 (90.8%)	0.1687	90 (77.6%)	0.0006	503 (85.3%)	0.0123	667 (88.1%)	0.3565

		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
associated with weight gain listed above										
	1-2	219 (10.3%)	237 (8.9%)	.	24 (20.7%)	.	81 (13.7%)	.	84 (11.1%)	.
	3-4	9 (0.4%)	8 (0.3%)	.	2 (1.7%)	.	6 (1.0%)	.	6 (0.8%)	.
Specific concomitant non-ART medications associated with weight loss - Any	Yes	168 (7.9%)	160 (6.0%)	0.0088	12 (10.3%)	0.3526	61 (10.3%)	0.0631	59 (7.8%)	0.9038
Anti-infectives	Yes	39 (1.8%)	37 (1.4%)	0.2133	7 (6.0%)	0.0020	24 (4.1%)	0.0015	10 (1.3%)	0.3424
Antineoplastics	Yes	0 (0.0%)	1 (0.0%)	1.0000	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
Bronchodilators	Yes	85 (4.0%)	73 (2.7%)	0.0179	4 (3.4%)	1.0000	26 (4.4%)	0.6402	37 (4.9%)	0.2956
Cardiovascular drugs	Yes	1 (0.0%)	1 (0.0%)	1.0000	0 (0.0%)	1.0000	3 (0.5%)	0.0345	0 (0.0%)	1.0000
Stimulants	Yes	2 (0.1%)	1 (0.0%)	0.5875	0 (0.0%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	1.0000
Anti-depressants	Yes	44 (2.1%)	44 (1.7%)	0.2808	2 (1.7%)	1.0000	10 (1.7%)	0.6214	13 (1.7%)	0.6491
Anti-convulsants	Yes	3 (0.1%)	6 (0.2%)	0.7396	0 (0.0%)	1.0000	2 (0.3%)	0.2996	5 (0.7%)	0.0337
Anti-hyperglycemics	Yes	1 (0.0%)	2 (0.1%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	1.0000
Anti-inflammatories		0	0	.	0	.	0	.	0	.
Weight loss drugs	Yes	1 (0.0%)	2 (0.1%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	1.0000



		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
Dementia treatment		0	0	.	0	.	0	.	0	.
Number of specific concomitant non- ART medications associated with weight loss listed above	0	1950 (92.1%)	2505 (94.0%)	0.0094	104 (89.7%)	0.4093	529 (89.7%)	0.1192	698 (92.2%)	0.6183
	1-2	167 (7.9%)	160 (6.0%)	.	12 (10.3%)	.	61 (10.3%)	.	58 (7.7%)	.
	3-4	1 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (0.1%)	.

Table 9. Baseline comorbidities by core agent group among ART-naïve patients

	DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
Any Comorbidity at baseline	1017 (48.0%)	1191 (44.7%)	0.0219	77 (66.4%)	0.0001	287 (48.6%)	0.7875	377 (49.8%)	0.3990
Any Cardiovascular Disease Conditions - Any	47 (2.2%)	49 (1.8%)	0.3514	6 (5.2%)	0.0418	23 (3.9%)	0.0230	9 (1.2%)	0.0783
Arrhythmia	17 (0.8%)	17 (0.6%)	0.6039	2 (1.7%)	0.2590	6 (1.0%)	0.6134	4 (0.5%)	0.6201
Myocardial Infarction	2 (0.1%)	3 (0.1%)	1.0000	1 (0.9%)	0.1479	2 (0.3%)	0.2087	1 (0.1%)	1.0000
Angina	0 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	1 (0.2%)	0.2179	0 (0.0%)	.
Other/Unspecified CHD	19 (0.9%)	24 (0.9%)	1.0000	4 (3.4%)	0.0284	11 (1.9%)	0.0711	2 (0.3%)	0.0859
Occlusion/stenosis of precerebral arteries	0	0	.	0	.	0	.	0	.
Stroke	8 (0.4%)	7 (0.3%)	0.6045	0 (0.0%)	1.0000	4 (0.7%)	0.3066	3 (0.4%)	1.0000
Transient Ischemic Attack	2 (0.1%)	1 (0.0%)	0.5875	0 (0.0%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	1.0000
Other CBV	10 (0.5%)	8 (0.3%)	0.3518	0 (0.0%)	1.0000	6 (1.0%)	0.1332	4 (0.5%)	0.7691
Peripheral Arterial Disease	1 (0.0%)	1 (0.0%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	1.0000
Abdominal Aortic Aneurysm	0	0	.	0	.	0	.	0	.
Invasive Cancer	31 (1.5%)	35 (1.3%)	0.7087	2 (1.7%)	0.6883	19 (3.2%)	0.0086	6 (0.8%)	0.1905

	DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
Endocrine Disorders	239 (11.3%)	258 (9.7%)	0.0711	22 (19.0%)	0.0122	44 (7.5%)	0.0072	92 (12.2%)	0.5203
Type 1 Diabetes Mellitus (diagnosis)	7 (0.3%)	8 (0.3%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	0.3585	2 (0.3%)	1.0000
Type 2 Diabetes Mellitus (labs/meds or diagnosis)	95 (4.5%)	83 (3.1%)	0.0128	9 (7.8%)	0.1032	23 (3.9%)	0.5367	27 (3.6%)	0.2818
Hyperlipidemia	162 (7.6%)	189 (7.1%)	0.4633	12 (10.3%)	0.2914	27 (4.6%)	0.0096	64 (8.5%)	0.4796
Hyperthyroidism	1 (0.0%)	4 (0.2%)	0.3910	1 (0.9%)	0.1012	0 (0.0%)	1.0000	0 (0.0%)	1.0000
Hypothyroidism	12 (0.6%)	24 (0.9%)	0.2382	4 (3.4%)	0.0077	2 (0.3%)	0.7471	8 (1.1%)	0.2002
Thyroiditis	0 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (0.1%)	0.2633
Mental Health Conditions - Any	306 (14.4%)	399 (15.0%)	0.6114	26 (22.4%)	0.0188	84 (14.2%)	0.8976	109 (14.4%)	0.9739
Anxiety Disorders	186 (8.8%)	283 (10.6%)	0.0338	16 (13.8%)	0.0669	51 (8.6%)	0.9166	71 (9.4%)	0.6211
Bipolar or Manic Disorders	64 (3.0%)	66 (2.5%)	0.2827	5 (4.3%)	0.4034	23 (3.9%)	0.2914	28 (3.7%)	0.3994
Major Depressive Disorder	70 (3.3%)	66 (2.5%)	0.0868	9 (7.8%)	0.0114	15 (2.5%)	0.3474	19 (2.5%)	0.2783
Schizophrenic Disorder	22 (1.0%)	18 (0.7%)	0.2012	0 (0.0%)	0.6256	9 (1.5%)	0.3793	5 (0.7%)	0.5098
Dementia	2 (0.1%)	3 (0.1%)	1.0000	0 (0.0%)	1.0000	1 (0.2%)	0.5217	1 (0.1%)	1.0000
Suicidality	5 (0.2%)	2 (0.1%)	0.2528	0 (0.0%)	1.0000	0 (0.0%)	0.5920	0 (0.0%)	0.3346
Liver Diseases - Any	153 (7.2%)	174 (6.5%)	0.3443	18 (15.5%)	0.0011	59 (10.0%)	0.0264	49 (6.5%)	0.4878

	DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
Hepatitis B	65 (3.1%)	92 (3.5%)	0.5135	4 (3.4%)	0.7802	34 (5.8%)	0.0040	23 (3.0%)	1.0000
Hepatitis C	82 (3.9%)	84 (3.2%)	0.1768	11 (9.5%)	0.0032	26 (4.4%)	0.5568	26 (3.4%)	0.5873
Other chronic liver disease	15 (0.7%)	12 (0.5%)	0.2496	5 (4.3%)	0.0029	3 (0.5%)	0.7782	4 (0.5%)	0.7952
Bone Diseases	1 (0.0%)	1 (0.0%)	1.0000	0 (0.0%)	1.0000	1 (0.2%)	0.3883	3 (0.4%)	0.0585
Peripheral Neuropathy	33 (1.6%)	28 (1.1%)	0.1530	4 (3.4%)	0.1222	18 (3.1%)	0.0250	12 (1.6%)	1.0000
Renal Disease - Any	290 (13.7%)	323 (12.1%)	0.1062	28 (24.1%)	0.0017	96 (16.3%)	0.1130	83 (11.0%)	0.0552
Renal Impairment	290 (13.7%)	323 (12.1%)	0.1062	28 (24.1%)	0.0017	96 (16.3%)	0.1130	83 (11.0%)	0.0552
Moderate/Severe CKD	8 (0.4%)	1 (0.0%)	0.0132	0 (0.0%)	1.0000	1 (0.2%)	0.6935	0 (0.0%)	0.1202
End Stage Renal Disease	0	0	.	0	.	0	.	0	.
Hypertension	240 (11.3%)	300 (11.3%)	0.9356	28 (24.1%)	<.0001	82 (13.9%)	0.0885	115 (15.2%)	0.0056
Rheumatoid Arthritis	0 (0.0%)	3 (0.1%)	0.2597	0 (0.0%)	.	0 (0.0%)	.	4 (0.5%)	0.0048
Substance Abuse - Any	247 (11.7%)	254 (9.5%)	0.0168	12 (10.3%)	0.6661	62 (10.5%)	0.4358	87 (11.5%)	0.9008
Alcohol Dependence	49 (2.3%)	54 (2.0%)	0.5476	4 (3.4%)	0.3523	12 (2.0%)	0.7561	14 (1.8%)	0.5629
Drug Abuse	238 (11.2%)	244 (9.2%)	0.0175	12 (10.3%)	0.7666	60 (10.2%)	0.4637	84 (11.1%)	0.9162

## 1.1.2.2. Treatment-experienced patients

Table 10. Baseline demographic characteristics by core agent group among ART-experienced patients

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
Age	Median (IQR)	44.9 (33.2, 53.2)	39.9 (30.4, 49.8)	<.0001	49.7 (41.9, 55.6)	<.0001	45.5 (35.0, 52.6)	0.0611	41.2 (30.6, 51.0)	<.0001
	18-25	459 (9.1%)	710 (12.7%)	<.0001	15 (2.2%)	<.0001	94 (6.2%)	0.0014	269 (10.8%)	<.0001
	26-49	2841 (56.1%)	3493 (62.6%)	.	330 (49.0%)	.	893 (59.3%)	.	1529 (61.5%)	.
	50+	1761 (34.8%)	1376 (24.7%)	.	329 (48.8%)	.	520 (34.5%)	.	689 (27.7%)	.
Sex	Male	4319 (85.3%)	4841 (86.8%)	0.0246	554 (82.2%)	0.0293	1187 (78.8%)	<.0001	2008 (80.7%)	<.0001
	Female	741 (14.6%)	733 (13.1%)	.	119 (17.7%)	.	320 (21.2%)	.	478 (19.2%)	.
	Unknown	1 (0.0%)	5 (0.1%)	.	1 (0.1%)	.	0 (0.0%)	.	1 (0.0%)	.
Race/Ethnicity	Black non-Hispanic	1849 (36.5%)	2128 (38.1%)	0.0607	232 (34.4%)	<.0001	690 (45.8%)	<.0001	1076 (43.3%)	<.0001
	White non-Hispanic	1600 (31.6%)	1650 (29.6%)	.	288 (42.7%)	.	426 (28.3%)	.	716 (28.8%)	.
	Other non-Hispanic	137 (2.7%)	159 (2.8%)	.	17 (2.5%)	.	33 (2.2%)	.	69 (2.8%)	.
	Hispanic	1370 (27.1%)	1496 (26.8%)	.	119 (17.7%)	.	339 (22.5%)	.	568 (22.8%)	.

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
	Missing	105 (2.1%)	146 (2.6%)	.	18 (2.7%)	.	19 (1.3%)	.	58 (2.3%)	.
Marital Status	Single	3667 (72.5%)	3965 (71.1%)	0.0581	445 (66.0%)	<.0001	1053 (69.9%)	0.0001	1694 (68.1%)	<.0001
	Married	332 (6.6%)	454 (8.1%)	.	72 (10.7%)	.	153 (10.2%)	.	232 (9.3%)	.
	Domestic partnership	62 (1.2%)	78 (1.4%)	.	11 (1.6%)	.	15 (1.0%)	.	26 (1.0%)	.
	Widowed	42 (0.8%)	41 (0.7%)	.	7 (1.0%)	.	13 (0.9%)	.	28 (1.1%)	.
	Separated/divorced	139 (2.7%)	149 (2.7%)	.	39 (5.8%)	.	51 (3.4%)	.	86 (3.5%)	.
	Unknown	819 (16.2%)	892 (16.0%)	.	100 (14.8%)	.	222 (14.7%)	.	421 (16.9%)	.
Men who have sex with men	Yes	3344 (66.1%)	3743 (67.1%)	0.2666	376 (55.8%)	<.0001	835 (55.4%)	<.0001	1531 (61.6%)	0.0001
History of injection drug use	Yes	390 (7.7%)	275 (4.9%)	<.0001	56 (8.3%)	0.5832	117 (7.8%)	0.9412	133 (5.3%)	0.0001
Region	Northeast	392 (7.7%)	394 (7.1%)	<.0001	58 (8.6%)	<.0001	80 (5.3%)	<.0001	288 (11.6%)	<.0001
	South	2560 (50.6%)	3415 (61.2%)	.	413 (61.3%)	.	947 (62.8%)	.	1499 (60.3%)	.
	Midwest	173 (3.4%)	212 (3.8%)	.	31 (4.6%)	.	32 (2.1%)	.	105 (4.2%)	.
	West	1936 (38.3%)	1558 (27.9%)	.	172 (25.5%)	.	448 (29.7%)	.	595 (23.9%)	.
Medicaid	Yes	1174 (23.2%)	1018 (18.2%)	<.0001	183 (27.2%)	0.0233	380 (25.2%)	0.1055	416 (16.7%)	<.0001

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
Medicare	Yes	710 (14.0%)	474 (8.5%)	<.0001	137 (20.3%)	<.0001	241 (16.0%)	0.0573	218 (8.8%)	<.0001
Commercial Insurance	Yes	1922 (38.0%)	2303 (41.3%)	0.0005	294 (43.6%)	0.0047	509 (33.8%)	0.0030	1057 (42.5%)	0.0002
Cash	Yes	2960 (58.5%)	3129 (56.1%)	0.0124	427 (63.4%)	0.0158	923 (61.2%)	0.0556	1447 (58.2%)	0.8012
ADAP/Ryan White	Yes	1611 (31.8%)	1849 (33.1%)	0.1496	144 (21.4%)	<.0001	478 (31.7%)	0.9341	765 (30.8%)	0.3460
Other	Yes	12 (0.2%)	27 (0.5%)	0.0373	2 (0.3%)	0.6760	8 (0.5%)	0.1040	13 (0.5%)	0.0539
No Payer info	Yes	446 (8.8%)	606 (10.9%)	0.0004	90 (13.4%)	0.0001	148 (9.8%)	0.2309	300 (12.1%)	<.0001

Table 11. Baseline HIV-infection characteristics by core agent group among ART-experienced patients

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
Months from first OPERA visit to baseline	Median (IQR)	11.2 (0.7, 61.6)	4.1 (0.5, 42.6)	<.0001	0.9 (0.0, 20.7)	<.0001	1.5 (0.0, 41.2)	<.0001	3.6 (0.1, 37.0)	<.0001
	0	741 (14.6%)	1077 (19.3%)	<.0001	247 (36.6%)	<.0001	436 (28.9%)	<.0001	609 (24.5%)	<.0001
	>0 to 6	1565 (30.9%)	1862 (33.4%)	.	193 (28.6%)	.	445 (29.5%)	.	722 (29.0%)	.
	>6 to 12	262 (5.2%)	278 (5.0%)	.	37 (5.5%)	.	68 (4.5%)	.	146 (5.9%)	.
	>12 to 24	382 (7.5%)	410 (7.3%)	.	33 (4.9%)	.	83 (5.5%)	.	196 (7.9%)	.
	>24	2111 (41.7%)	1952 (35.0%)	.	164 (24.3%)	.	475 (31.5%)	.	814 (32.7%)	.
Duration of follow-up, months	Median (IQR)	24.4 (16.7, 34.9)	23.4 (15.9, 33.0)	0.0002	22.1 (12.3, 36.5)	0.0009	22.4 (14.4, 34.0)	<.0001	23.5 (16.2, 33.3)	0.0533
	>0 to 6	145 (2.9%)	156 (2.8%)	0.0084	39 (5.8%)	<.0001	81 (5.4%)	<.0001	107 (4.3%)	0.0068
	>6 to 12	434 (8.6%)	566 (10.1%)	.	123 (18.2%)	.	190 (12.6%)	.	220 (8.8%)	.
	>12 to 24	1900 (37.5%)	2159 (38.7%)	.	201 (29.8%)	.	545 (36.2%)	.	946 (38.0%)	.
	>24	2582 (51.0%)	2698 (48.4%)	.	311 (46.1%)	.	691 (45.9%)	.	1214 (48.8%)	.
Year of study inclusion	Median (IQR)	2016.0 (2015.0, 2017.0)	2016.0 (2015.0, 2017.0)	0.0362	2014.0 (2014.0, 2015.0)	<.0001	2015.0 (2014.0, 2016.0)	<.0001	2016.0 (2014.0, 2016.0)	<.0001



		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
	2013	148 (2.9%)	283 (5.1%)	<.0001	123 (18.2%)	<.0001	218 (14.5%)	<.0001	172 (6.9%)	<.0001
	2014	841 (16.6%)	867 (15.5%)	.	253 (37.5%)	.	406 (26.9%)	.	567 (22.8%)	.
	2015	1276 (25.2%)	1015 (18.2%)	.	142 (21.1%)	.	329 (21.8%)	.	442 (17.8%)	.
	2016	1419 (28.0%)	1899 (34.0%)	.	91 (13.5%)	.	292 (19.4%)	.	685 (27.5%)	.
	2017	1377 (27.2%)	1515 (27.2%)	.	65 (9.6%)	.	262 (17.4%)	.	621 (25.0%)	.
Number of classes of core agents experienced prior to baseline	1	2469 (48.8%)	2259 (40.5%)	<.0001	171 (25.4%)	<.0001	481 (31.9%)	<.0001	1072 (43.1%)	<.0001
	2	342 (6.8%)	212 (3.8%)	.	34 (5.0%)	.	114 (7.6%)	.	74 (3.0%)	.
	3	1 (0.0%)	1 (0.0%)	.	1 (0.1%)	.	0 (0.0%)	.	0 (0.0%)	.
	Missing	2249 (44.4%)	3107 (55.7%)	.	468 (69.4%)	.	912 (60.5%)	.	1341 (53.9%)	.
Duration of the previous ART regimen, months	Median (IQR)	34.1 (11.9, 71.2)	32.4 (12.0, 61.4)	0.0061	18.1 (5.9, 54.7)	<.0001	28.2 (6.9, 62.3)	0.0002	26.2 (10.1, 52.3)	<.0001
History of AIDS-defining Illnesses	Yes	1510 (29.8%)	1152 (20.6%)	<.0001	210 (31.2%)	0.4819	522 (34.6%)	0.0004	450 (18.1%)	<.0001
HIV viral load (copies/ml)	Median (IQR)	19.0 (19.0, 1486.5)	19.0 (19.0, 4400.0)	0.3704	19.0 (19.0, 90.0)	<.0001	40.0 (19.0, 4700.0)	<.0001	19.0 (19.0, 90.0)	<.0001

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
	< 50	3020 (59.7%)	3262 (58.5%)	0.1812	468 (69.4%)	<.0001	789 (52.4%)	<.0001	1760 (70.8%)	<.0001
	>= 50 to < 200	457 (9.0%)	459 (8.2%)	.	77 (11.4%)	.	161 (10.7%)	.	199 (8.0%)	.
	>= 200 to < 1,000	283 (5.6%)	304 (5.4%)	.	51 (7.6%)	.	120 (8.0%)	.	147 (5.9%)	.
	>= 1,000 to < 10,000	266 (5.3%)	321 (5.8%)	.	17 (2.5%)	.	95 (6.3%)	.	133 (5.3%)	.
	>= 10,000 to < 100,000	665 (13.1%)	808 (14.5%)	.	37 (5.5%)	.	197 (13.1%)	.	225 (9.0%)	.
	>= 100,000	369 (7.3%)	425 (7.6%)	.	24 (3.6%)	.	145 (9.6%)	.	23 (0.9%)	.
	Missing	1 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
Log10 HIV viral load	Median (IQR)	1.3 (1.3, 3.2)	1.3 (1.3, 3.6)	0.3294	1.3 (1.3, 2.0)	<.0001	1.6 (1.3, 3.7)	<.0001	1.3 (1.3, 2.0)	<.0001
	< 1.7	3085 (61.0%)	3322 (59.5%)	0.2124	474 (70.3%)	<.0001	805 (53.4%)	<.0001	1787 (71.9%)	<.0001
	>= 1.7 to < 2.3	392 (7.7%)	399 (7.2%)	.	71 (10.5%)	.	145 (9.6%)	.	172 (6.9%)	.
	>= 2.3 to < 3	283 (5.6%)	304 (5.4%)	.	51 (7.6%)	.	120 (8.0%)	.	147 (5.9%)	.
	>= 3 to < 4	266 (5.3%)	321 (5.8%)	.	17 (2.5%)	.	95 (6.3%)	.	133 (5.3%)	.
	>= 4 to < 5	665 (13.1%)	808 (14.5%)	.	37 (5.5%)	.	197 (13.1%)	.	225 (9.0%)	.
	>= 5	369 (7.3%)	425 (7.6%)	.	24 (3.6%)	.	145 (9.6%)	.	23 (0.9%)	.

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
	Missing	1 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
CD4 cell count (cell/ $\mu$ l)	Median (IQR)	565.0 (369.0, 777.0)	565.0 (389.0, 776.0)	0.1895	564.0 (355.0, 776.0)	0.9428	494.0 (288.0, 704.0)	<.0001	638.0 (475.0, 836.0)	<.0001
	>500	2920 (57.7%)	3309 (59.3%)	0.0128	376 (55.8%)	0.4882	721 (47.8%)	<.0001	1753 (70.5%)	<.0001
	>350 to <= 500	937 (18.5%)	1071 (19.2%)	.	125 (18.5%)	.	281 (18.6%)	.	446 (17.9%)	.
	>200 to <= 350	631 (12.5%)	687 (12.3%)	.	92 (13.6%)	.	236 (15.7%)	.	209 (8.4%)	.
	>50 to <= 200	390 (7.7%)	339 (6.1%)	.	54 (8.0%)	.	162 (10.7%)	.	57 (2.3%)	.
	<= 50	131 (2.6%)	120 (2.2%)	.	15 (2.2%)	.	82 (5.4%)	.	2 (0.1%)	.
	Missing	52 (1.0%)	53 (0.9%)	.	12 (1.8%)	.	25 (1.7%)	.	20 (0.8%)	.

Table 12. Baseline clinical characteristics by core agent group among ART-experienced patients

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
Hemoglobin, g/dL	Median (IQR)	14.4 (13.3, 15.4)	14.5 (13.4, 15.4)	0.0223	14.4 (13.0, 15.4)	0.1316	14.0 (12.7, 15.1)	<.0001	14.5 (13.4, 15.5)	0.0130
	Normal	4837 (95.6%)	5334 (95.6%)	0.0792	616 (91.4%)	<.0001	1391 (92.3%)	<.0001	2390 (96.1%)	0.0024
	DAIDS Grade 1 (mild)	99 (2.0%)	88 (1.6%)	.	16 (2.4%)	.	40 (2.7%)	.	25 (1.0%)	.
	DAIDS Grade 2 (moderate)	40 (0.8%)	32 (0.6%)	.	15 (2.2%)	.	31 (2.1%)	.	13 (0.5%)	.
	DAIDS Grade 3 (Severe)	27 (0.5%)	32 (0.6%)	.	2 (0.3%)	.	19 (1.3%)	.	11 (0.4%)	.
	DAIDS Grade 4 (potentially life- threatening)	1 (0.0%)	4 (0.1%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (0.0%)	.
	Missing	57 (1.1%)	89 (1.6%)	.	25 (3.7%)	.	26 (1.7%)	.	47 (1.9%)	.
Hematocrit, %	Median (IQR)	42.8 (39.8, 45.3)	43.1 (40.2, 45.6)	<.0001	42.6 (38.9, 45.4)	0.1669	41.7 (38.5, 44.7)	<.0001	43.1 (40.2, 45.5)	0.0003
	Low	699 (13.8%)	632 (11.3%)	0.0002	116 (17.2%)	<.0001	277 (18.4%)	<.0001	228 (9.2%)	<.0001
	Normal	4148 (82.0%)	4667 (83.7%)	.	499 (74.0%)	.	1161 (77.0%)	.	2112 (84.9%)	.
	High	155 (3.1%)	186 (3.3%)	.	32 (4.7%)	.	42 (2.8%)	.	94 (3.8%)	.

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
	Missing	59 (1.2%)	94 (1.7%)	.	27 (4.0%)	.	27 (1.8%)	.	53 (2.1%)	.
Systolic blood pressure, mmHg	Median (IQR)	125.0 (115.0, 135.0)	124.0 (115.0, 133.0)	0.0073	124.0 (117.0, 135.0)	0.8685	124.0 (114.0, 134.0)	0.0062	124.0 (115.0, 134.0)	0.1735
	Low	24 (0.5%)	16 (0.3%)	<.0001	0 (0.0%)	0.0008	4 (0.3%)	<.0001	4 (0.2%)	0.0004
	Normal	4089 (80.8%)	4590 (82.3%)	.	531 (78.8%)	.	1217 (80.8%)	.	2042 (82.1%)	.
	DAIDS Grade 1 hypertension (mild)	721 (14.2%)	691 (12.4%)	.	92 (13.6%)	.	187 (12.4%)	.	321 (12.9%)	.
	DAIDS Grade 2 hypertension (moderate)	119 (2.4%)	85 (1.5%)	.	20 (3.0%)	.	27 (1.8%)	.	39 (1.6%)	.
	DAIDS Grade 3 hypertension (severe)	22 (0.4%)	16 (0.3%)	.	4 (0.6%)	.	9 (0.6%)	.	10 (0.4%)	.
	Missing	86 (1.7%)	181 (3.2%)	.	27 (4.0%)	.	63 (4.2%)	.	71 (2.9%)	.
Diastolic blood pressure, mmHg	Median (IQR)	78.0 (72.0, 85.0)	78.0 (72.0, 85.0)	0.5527	80.0 (73.0, 86.0)	0.0232	78.0 (72.0, 85.0)	0.9675	79.0 (72.0, 85.0)	0.3175
	Low	93 (1.8%)	84 (1.5%)	<.0001	7 (1.0%)	0.0015	23 (1.5%)	<.0001	39 (1.6%)	0.0114
	Normal	4198 (82.9%)	4606 (82.6%)	.	535 (79.4%)	.	1236 (82.0%)	.	2057 (82.7%)	.
	DAIDS Grade 1 hypertension (mild)	529 (10.5%)	561 (10.1%)	.	81 (12.0%)	.	141 (9.4%)	.	267 (10.7%)	.

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
	DAIDS Grade 2 hypertension (moderate)	118 (2.3%)	110 (2.0%)	.	19 (2.8%)	.	32 (2.1%)	.	39 (1.6%)	.
	DAIDS Grade 3 hypertension (severe)	33 (0.7%)	31 (0.6%)	.	5 (0.7%)	.	11 (0.7%)	.	14 (0.6%)	.
	Missing	90 (1.8%)	187 (3.4%)	.	27 (4.0%)	.	64 (4.2%)	.	71 (2.9%)	.
VACS mortality index	Median (IQR)	15.0 (6.0, 28.0)	12.0 (6.0, 22.0)	<.0001	18.0 (10.0, 33.0)	<.0001	18.0 (10.0, 33.0)	<.0001	10.0 (0.0, 22.0)	<.0001
	0 to <15	2373 (46.9%)	2996 (53.7%)	<.0001	214 (31.8%)	<.0001	540 (35.8%)	<.0001	1382 (55.6%)	<.0001
	>=15 to <30	1381 (27.3%)	1304 (23.4%)	.	203 (30.1%)	.	460 (30.5%)	.	618 (24.8%)	.
	>=30 to <45	537 (10.6%)	434 (7.8%)	.	85 (12.6%)	.	176 (11.7%)	.	167 (6.7%)	.
	>= 45	458 (9.0%)	348 (6.2%)	.	75 (11.1%)	.	195 (12.9%)	.	69 (2.8%)	.
	Missing	312 (6.2%)	497 (8.9%)	.	97 (14.4%)	.	136 (9.0%)	.	251 (10.1%)	.
Specific concomitant non-ART medications associated with weight gain - Any	Yes	1064 (21.0%)	870 (15.6%)	<.0001	202 (30.0%)	<.0001	316 (21.0%)	0.9635	420 (16.9%)	<.0001
Antipsychotics and mood stabilizer	Yes	178 (3.5%)	133 (2.4%)	0.0005	39 (5.8%)	0.0037	64 (4.2%)	0.1868	81 (3.3%)	0.5595

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
Antidepressants	Yes	332 (6.6%)	251 (4.5%)	<.0001	56 (8.3%)	0.0895	87 (5.8%)	0.2725	115 (4.6%)	0.0008
Antihyperglycemics	Yes	139 (2.7%)	89 (1.6%)	<.0001	45 (6.7%)	<.0001	37 (2.5%)	0.5388	47 (1.9%)	0.0240
Antihypertensives	Yes	169 (3.3%)	137 (2.5%)	0.0065	56 (8.3%)	<.0001	55 (3.6%)	0.5601	84 (3.4%)	0.9308
Corticosteroids	Yes	199 (3.9%)	172 (3.1%)	0.0171	22 (3.3%)	0.3974	46 (3.1%)	0.1137	70 (2.8%)	0.0138
Hormones	Yes	10 (0.2%)	17 (0.3%)	0.3360	2 (0.3%)	0.6433	3 (0.2%)	1.0000	9 (0.4%)	0.2211
Anticonvulsants	Yes	313 (6.2%)	235 (4.2%)	<.0001	62 (9.2%)	0.0029	110 (7.3%)	0.1217	106 (4.3%)	0.0006
Antihistamines	Yes	31 (0.6%)	38 (0.7%)	0.7174	4 (0.6%)	1.0000	11 (0.7%)	0.5840	8 (0.3%)	0.1234
Number of specific concomitant non- ART medications associated with weight gain listed above	0	3997 (79.0%)	4709 (84.4%)	<.0001	472 (70.0%)	<.0001	1191 (79.0%)	0.4695	2067 (83.1%)	0.0001
	1-2	984 (19.4%)	819 (14.7%)	.	171 (25.4%)	.	285 (18.9%)	.	392 (15.8%)	.
	3-4	78 (1.5%)	49 (0.9%)	.	29 (4.3%)	.	31 (2.1%)	.	28 (1.1%)	.
	5+	2 (0.0%)	2 (0.0%)	.	2 (0.3%)	.	0 (0.0%)	.	0 (0.0%)	.
Specific concomitant non-ART medications	Yes	708 (14.0%)	594 (10.6%)	<.0001	126 (18.7%)	0.0011	197 (13.1%)	0.3646	288 (11.6%)	0.0037

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
associated with weight loss - Any										
Anti-infectives	Yes	98 (1.9%)	70 (1.3%)	0.0048	12 (1.8%)	0.7815	40 (2.7%)	0.0881	21 (0.8%)	0.0003
Antineoplastics	Yes	5 (0.1%)	2 (0.0%)	0.2685	1 (0.1%)	0.5279	0 (0.0%)	0.5954	3 (0.1%)	0.7237
Bronchodilators	Yes	339 (6.7%)	280 (5.0%)	0.0002	70 (10.4%)	0.0005	92 (6.1%)	0.4141	158 (6.4%)	0.5697
Cardiovascular drugs	Yes	19 (0.4%)	12 (0.2%)	0.1500	8 (1.2%)	0.0101	6 (0.4%)	0.8157	1 (0.0%)	0.0069
Stimulants	Yes	18 (0.4%)	18 (0.3%)	0.8676	4 (0.6%)	0.3180	2 (0.1%)	0.2832	9 (0.4%)	1.0000
Anti-depressants	Yes	278 (5.5%)	224 (4.0%)	0.0003	36 (5.3%)	0.8708	70 (4.6%)	0.1970	108 (4.3%)	0.0330
Anti-convulsants	Yes	21 (0.4%)	24 (0.4%)	1.0000	8 (1.2%)	0.0158	3 (0.2%)	0.3297	8 (0.3%)	0.6928
Anti-hyperglycemics	Yes	2 (0.0%)	4 (0.1%)	0.6896	2 (0.3%)	0.0704	0 (0.0%)	1.0000	3 (0.1%)	0.3396
Anti-inflammatories	Yes	1 (0.0%)	2 (0.0%)	1.0000	0 (0.0%)	1.0000	1 (0.1%)	0.4063	0 (0.0%)	1.0000
Weight loss drugs	Yes	6 (0.1%)	4 (0.1%)	0.5332	2 (0.3%)	0.2403	0 (0.0%)	0.3474	4 (0.2%)	0.7383
Dementia treatment	Yes	0 (0.0%)	1 (0.0%)	1.0000	1 (0.1%)	0.1175	0 (0.0%)	.	0 (0.0%)	.
Number of specific concomitant non- ART medications associated with weight loss listed above	0	4353 (86.0%)	4985 (89.4%)	<.0001	548 (81.3%)	0.0036	1310 (86.9%)	0.5481	2199 (88.4%)	0.0111



		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
	1-2	700 (13.8%)	588 (10.5%)	.	124 (18.4%)	.	196 (13.0%)	.	286 (11.5%)	.
	3-4	8 (0.2%)	6 (0.1%)	.	2 (0.3%)	.	1 (0.1%)	.	2 (0.1%)	.

Table 13. Baseline comorbidities by core agent group among ART-experienced patients

	DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
Any Comorbidity at baseline	3835 (75.8%)	3709 (66.5%)	<.0001	576 (85.5%)	<.0001	1140 (75.6%)	0.9186	1741 (70.0%)	<.0001
Any Cardiovascular Disease Conditions - Any	438 (8.7%)	332 (6.0%)	<.0001	84 (12.5%)	0.0012	103 (6.8%)	0.0241	130 (5.2%)	<.0001
Arrhythmia	154 (3.0%)	109 (2.0%)	0.0003	15 (2.2%)	0.2385	31 (2.1%)	0.0423	47 (1.9%)	0.0034
Myocardial Infarction	40 (0.8%)	23 (0.4%)	0.0111	10 (1.5%)	0.0689	13 (0.9%)	0.7831	16 (0.6%)	0.4842
Angina	23 (0.5%)	11 (0.2%)	0.0242	3 (0.4%)	1.0000	8 (0.5%)	0.6714	6 (0.2%)	0.2337
Other/Unspecified CHD	215 (4.2%)	147 (2.6%)	<.0001	48 (7.1%)	0.0008	60 (4.0%)	0.6499	62 (2.5%)	0.0001
Occlusion/stenosis of precerebral arteries	9 (0.2%)	2 (0.0%)	0.0315	3 (0.4%)	0.1592	2 (0.1%)	1.0000	3 (0.1%)	0.7615

	DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
Stroke	60 (1.2%)	46 (0.8%)	0.0611	13 (1.9%)	0.1059	12 (0.8%)	0.2027	16 (0.6%)	0.0266
Transient Ischemic Attack	12 (0.2%)	13 (0.2%)	1.0000	3 (0.4%)	0.4078	2 (0.1%)	0.7497	6 (0.2%)	1.0000
Other CBV	96 (1.9%)	76 (1.4%)	0.0290	26 (3.9%)	0.0009	21 (1.4%)	0.1947	30 (1.2%)	0.0277
Peripheral Arterial Disease	39 (0.8%)	24 (0.4%)	0.0223	6 (0.9%)	0.7409	8 (0.5%)	0.3324	9 (0.4%)	0.0358
Abdominal Aortic Aneurysm	1 (0.0%)	3 (0.1%)	0.6267	0 (0.0%)	1.0000	0 (0.0%)	1.0000	1 (0.0%)	0.5504
Invasive Cancer	318 (6.3%)	240 (4.3%)	<.0001	53 (7.9%)	0.1172	113 (7.5%)	0.0945	116 (4.7%)	0.0045
Endocrine Disorders	1777 (35.1%)	1592 (28.5%)	<.0001	280 (41.5%)	0.0011	425 (28.2%)	<.0001	732 (29.4%)	<.0001
Type 1 Diabetes Mellitus (diagnosis)	20 (0.4%)	19 (0.3%)	0.7485	6 (0.9%)	0.1147	4 (0.3%)	0.6282	15 (0.6%)	0.2118
Type 2 Diabetes Mellitus (labs/meds or diagnosis)	441 (8.7%)	371 (6.6%)	<.0001	114 (16.9%)	<.0001	124 (8.2%)	0.5552	180 (7.2%)	0.0283
Hyperlipidemia	1528 (30.2%)	1363 (24.4%)	<.0001	210 (31.2%)	0.6084	354 (23.5%)	<.0001	616 (24.8%)	<.0001
Hyperthyroidism	30 (0.6%)	20 (0.4%)	0.0886	5 (0.7%)	0.5975	6 (0.4%)	0.4327	6 (0.2%)	0.0487
Hypothyroidism	141 (2.8%)	102 (1.8%)	0.0010	35 (5.2%)	0.0007	27 (1.8%)	0.0318	51 (2.1%)	0.0565
Thyroiditis	6 (0.1%)	1 (0.0%)	0.0588	0 (0.0%)	1.0000	0 (0.0%)	0.3474	1 (0.0%)	0.4377
Mental Health Conditions - Any	1457 (28.8%)	1306 (23.4%)	<.0001	195 (28.9%)	0.9386	381 (25.3%)	0.0078	568 (22.8%)	<.0001
Anxiety Disorders	895 (17.7%)	887 (15.9%)	0.0138	104 (15.4%)	0.1472	214 (14.2%)	0.0015	353 (14.2%)	0.0001

	DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
Bipolar or Manic Disorders	236 (4.7%)	223 (4.0%)	0.0913	40 (5.9%)	0.1473	79 (5.2%)	0.3557	97 (3.9%)	0.1293
Major Depressive Disorder	588 (11.6%)	391 (7.0%)	<.0001	66 (9.8%)	0.1612	141 (9.4%)	0.0141	162 (6.5%)	<.0001
Schizophrenic Disorder	90 (1.8%)	62 (1.1%)	0.0038	12 (1.8%)	0.9969	22 (1.5%)	0.4019	24 (1.0%)	0.0065
Dementia	14 (0.3%)	12 (0.2%)	0.5598	3 (0.4%)	0.4413	3 (0.2%)	0.7770	6 (0.2%)	1.0000
Suicidality	24 (0.5%)	14 (0.3%)	0.0722	2 (0.3%)	0.7615	4 (0.3%)	0.3691	7 (0.3%)	0.2546
Liver Diseases - Any	897 (17.7%)	707 (12.7%)	<.0001	158 (23.4%)	0.0003	275 (18.2%)	0.6407	333 (13.4%)	<.0001
Hepatitis B	306 (6.0%)	298 (5.3%)	0.1167	50 (7.4%)	0.1655	112 (7.4%)	0.0531	123 (4.9%)	0.0523
Hepatitis C	558 (11.0%)	337 (6.0%)	<.0001	102 (15.1%)	0.0017	154 (10.2%)	0.3767	187 (7.5%)	<.0001
Other chronic liver disease	195 (3.9%)	145 (2.6%)	0.0002	26 (3.9%)	0.9954	47 (3.1%)	0.1841	66 (2.7%)	0.0074
Bone Diseases	144 (2.8%)	84 (1.5%)	<.0001	14 (2.1%)	0.2524	21 (1.4%)	0.0016	30 (1.2%)	<.0001
Peripheral Neuropathy	400 (7.9%)	297 (5.3%)	<.0001	63 (9.3%)	0.1962	129 (8.6%)	0.4110	123 (4.9%)	<.0001
Renal Disease - Any	1805 (35.7%)	1555 (27.9%)	<.0001	284 (42.1%)	0.0010	531 (35.2%)	0.7599	702 (28.2%)	<.0001
Renal Impairment	1805 (35.7%)	1555 (27.9%)	<.0001	284 (42.1%)	0.0010	531 (35.2%)	0.7599	702 (28.2%)	<.0001
Moderate/Severe CKD	138 (2.7%)	58 (1.0%)	<.0001	32 (4.7%)	0.0037	22 (1.5%)	0.0051	25 (1.0%)	<.0001
End Stage Renal Disease	7 (0.1%)	0 (0.0%)	0.0055	4 (0.6%)	0.0317	2 (0.1%)	1.0000	1 (0.0%)	0.2853

	DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
Hypertension	1392 (27.5%)	1232 (22.1%)	<.0001	257 (38.1%)	<.0001	385 (25.5%)	0.1333	595 (23.9%)	0.0009
Rheumatoid Arthritis	25 (0.5%)	20 (0.4%)	0.2983	2 (0.3%)	0.7632	7 (0.5%)	1.0000	8 (0.3%)	0.3550
Substance Abuse - Any	831 (16.4%)	687 (12.3%)	<.0001	85 (12.6%)	0.0112	241 (16.0%)	0.6933	289 (11.6%)	<.0001
Alcohol Dependence	226 (4.5%)	171 (3.1%)	0.0001	22 (3.3%)	0.1497	68 (4.5%)	0.9386	70 (2.8%)	0.0005
Drug Abuse	798 (15.8%)	664 (11.9%)	<.0001	82 (12.2%)	0.0148	232 (15.4%)	0.7268	281 (11.3%)	<.0001

### 1.1.2.3. Treatment-experienced, suppressed patients

Table 14. Baseline demographic characteristics by core agent group among ART-experienced, suppressed patients

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
Age	Median (IQR)	47.5 (36.7, 54.8)	43.2 (32.6, 51.5)	<.0001	50.8 (42.9, 56.7)	<.0001	47.5 (38.0, 53.7)	0.4908	43.1 (32.4, 52.4)	<.0001
	18-25	206 (5.9%)	332 (8.9%)	<.0001	9 (1.7%)	<.0001	45 (4.7%)	0.1722	152 (7.8%)	<.0001
	26-49	1826 (52.5%)	2305 (61.9%)	.	244 (44.8%)	.	526 (55.4%)	.	1192 (60.8%)	.
	50+	1446 (41.6%)	1084 (29.1%)	.	292 (53.6%)	.	379 (39.9%)	.	615 (31.4%)	.
Sex	Male	2987 (85.9%)	3226 (86.7%)	0.2248	457 (83.9%)	0.0576	748 (78.7%)	<.0001	1586 (81.0%)	<.0001
	Female	491 (14.1%)	493 (13.2%)	.	87 (16.0%)	.	202 (21.3%)	.	373 (19.0%)	.
	Unknown	0 (0.0%)	2 (0.1%)	.	1 (0.2%)	.	0 (0.0%)	.	0 (0.0%)	.
Race/Ethnicity	Black non-Hispanic	1118 (32.1%)	1240 (33.3%)	0.2273	165 (30.3%)	<.0001	398 (41.9%)	<.0001	764 (39.0%)	<.0001
	White non-Hispanic	1218 (35.0%)	1206 (32.4%)	.	253 (46.4%)	.	302 (31.8%)	.	611 (31.2%)	.
	Other non-Hispanic	100 (2.9%)	109 (2.9%)	.	11 (2.0%)	.	20 (2.1%)	.	54 (2.8%)	.
	Hispanic	956 (27.5%)	1065 (28.6%)	.	99 (18.2%)	.	216 (22.7%)	.	480 (24.5%)	.
	Missing	86 (2.5%)	101 (2.7%)	.	17 (3.1%)	.	14 (1.5%)	.	50 (2.6%)	.

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
Marital Status	Single	2467 (70.9%)	2603 (70.0%)	0.0664	349 (64.0%)	<.0001	643 (67.7%)	0.0019	1295 (66.1%)	0.0003
	Married	257 (7.4%)	347 (9.3%)	.	65 (11.9%)	.	108 (11.4%)	.	194 (9.9%)	.
	Domestic partnership	44 (1.3%)	54 (1.5%)	.	10 (1.8%)	.	12 (1.3%)	.	20 (1.0%)	.
	Widowed	26 (0.7%)	31 (0.8%)	.	6 (1.1%)	.	9 (0.9%)	.	26 (1.3%)	.
	Separated/divorced	99 (2.8%)	99 (2.7%)	.	33 (6.1%)	.	35 (3.7%)	.	74 (3.8%)	.
	Unknown	585 (16.8%)	587 (15.8%)	.	82 (15.0%)	.	143 (15.1%)	.	350 (17.9%)	.
Men who have sex with men	Yes	2324 (66.8%)	2477 (66.6%)	0.8207	308 (56.5%)	<.0001	540 (56.8%)	<.0001	1181 (60.3%)	<.0001
History of injection drug use	Yes	272 (7.8%)	177 (4.8%)	<.0001	43 (7.9%)	0.9553	68 (7.2%)	0.4966	99 (5.1%)	0.0001
Region	Northeast	297 (8.5%)	252 (6.8%)	<.0001	54 (9.9%)	<.0001	49 (5.2%)	<.0001	255 (13.0%)	<.0001
	South	1669 (48.0%)	2217 (59.6%)	.	332 (60.9%)	.	614 (64.6%)	.	1140 (58.2%)	.
	Midwest	102 (2.9%)	109 (2.9%)	.	24 (4.4%)	.	25 (2.6%)	.	82 (4.2%)	.
	West	1410 (40.5%)	1143 (30.7%)	.	135 (24.8%)	.	262 (27.6%)	.	482 (24.6%)	.
Medicaid	Yes	756 (21.7%)	650 (17.5%)	<.0001	131 (24.0%)	0.2285	225 (23.7%)	0.2002	317 (16.2%)	<.0001

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
Medicare	Yes	528 (15.2%)	336 (9.0%)	<.0001	112 (20.6%)	0.0014	170 (17.9%)	0.0419	189 (9.6%)	<.0001
Commercial Insurance	Yes	1401 (40.3%)	1663 (44.7%)	0.0002	255 (46.8%)	0.0041	352 (37.1%)	0.0713	868 (44.3%)	0.0038
Cash	Yes	2042 (58.7%)	2067 (55.5%)	0.0068	345 (63.3%)	0.0425	578 (60.8%)	0.2365	1133 (57.8%)	0.5291
ADAP/Ryan White	Yes	1019 (29.3%)	1076 (28.9%)	0.7218	101 (18.5%)	<.0001	282 (29.7%)	0.8171	553 (28.2%)	0.4035
Other	Yes	7 (0.2%)	16 (0.4%)	0.0969	2 (0.4%)	0.3498	4 (0.4%)	0.2645	8 (0.4%)	0.1828
No Payer info	Yes	353 (10.1%)	457 (12.3%)	0.0042	76 (13.9%)	0.0076	93 (9.8%)	0.7438	267 (13.6%)	0.0001

*Table 15. Baseline HIV-infection characteristics by core agent group among ART-experienced, suppressed patients*

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
Months from first OPERA visit to baseline	Median (IQR)	20.6 (0.6, 73.1)	7.7 (0.0, 51.3)	<.0001	0.7 (0.0, 20.0)	<.0001	0.7 (0.0, 34.4)	<.0001	6.6 (0.0, 42.6)	<.0001
	0	686 (19.7%)	1010 (27.1%)	<.0001	224 (41.1%)	<.0001	390 (41.1%)	<.0001	573 (29.2%)	<.0001
	>0 to 6	656 (18.9%)	785 (21.1%)	.	138 (25.3%)	.	209 (22.0%)	.	394 (20.1%)	.
	>6 to 12	176 (5.1%)	196 (5.3%)	.	28 (5.1%)	.	38 (4.0%)	.	119 (6.1%)	.
	>12 to 24	298 (8.6%)	262 (7.0%)	.	23 (4.2%)	.	41 (4.3%)	.	159 (8.1%)	.

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
	>24	1662 (47.8%)	1468 (39.5%)	.	132 (24.2%)	.	272 (28.6%)	.	714 (36.4%)	.
Duration of follow-up, months	Median (IQR)	24.5 (16.2, 35.2)	23.2 (15.6, 31.9)	<.0001	23.2 (13.1, 37.2)	0.0588	22.7 (14.5, 36.1)	0.0286	23.4 (16.3, 32.2)	0.0351
	>0 to 6	101 (2.9%)	101 (2.7%)	0.0049	29 (5.3%)	<.0001	53 (5.6%)	<.0001	81 (4.1%)	0.0334
	>6 to 12	314 (9.0%)	406 (10.9%)	.	92 (16.9%)	.	114 (12.0%)	.	173 (8.8%)	.
	>12 to 24	1281 (36.8%)	1440 (38.7%)	.	161 (29.5%)	.	335 (35.3%)	.	756 (38.6%)	.
	>24	1782 (51.2%)	1774 (47.7%)	.	263 (48.3%)	.	448 (47.2%)	.	949 (48.4%)	.
Year of study inclusion	Median (IQR)	2016.0 (2015.0, 2017.0)	2016.0 (2015.0, 2017.0)	<.0001	2014.0 (2014.0, 2015.0)	<.0001	2015.0 (2014.0, 2016.0)	<.0001	2016.0 (2014.0, 2017.0)	0.0621
	2013	107 (3.1%)	165 (4.4%)	<.0001	85 (15.6%)	<.0001	118 (12.4%)	<.0001	114 (5.8%)	<.0001
	2014	620 (17.8%)	485 (13.0%)	.	209 (38.3%)	.	252 (26.5%)	.	412 (21.0%)	.
	2015	833 (24.0%)	606 (16.3%)	.	118 (21.7%)	.	216 (22.7%)	.	335 (17.1%)	.
	2016	979 (28.1%)	1412 (37.9%)	.	79 (14.5%)	.	189 (19.9%)	.	582 (29.7%)	.
	2017	939 (27.0%)	1053 (28.3%)	.	54 (9.9%)	.	175 (18.4%)	.	516 (26.3%)	.
Number of classes of core agents	1	2029 (58.3%)	1776 (47.7%)	<.0001	128 (23.5%)	<.0001	253 (26.6%)	<.0001	962 (49.1%)	<.0001



		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
experienced prior to baseline										
	2	268 (7.7%)	159 (4.3%)	.	25 (4.6%)	.	73 (7.7%)	.	62 (3.2%)	.
	3	1 (0.0%)	1 (0.0%)	.	1 (0.2%)	.	0 (0.0%)	.	0 (0.0%)	.
	Missing	1180 (33.9%)	1785 (48.0%)	.	391 (71.7%)	.	624 (65.7%)	.	935 (47.7%)	.
Duration of the previous ART regimen, months	Median (IQR)	35.4 (12.0, 72.8)	34.9 (12.6, 65.3)	0.1358	22.8 (8.4, 63.3)	0.0035	29.9 (8.7, 71.2)	0.0479	28.3 (11.0, 54.7)	<.0001
History of AIDS-defining Illnesses	Yes	1051 (30.2%)	800 (21.5%)	<.0001	152 (27.9%)	0.2696	292 (30.7%)	0.7581	394 (20.1%)	<.0001
HIV viral load (copies/ml)	Median (IQR)	19.0 (19.0, 20.0)	19.0 (19.0, 19.0)	0.0098	19.0 (19.0, 20.0)	0.8799	19.0 (19.0, 30.0)	0.0006	19.0 (19.0, 19.0)	<.0001
	< 50	3020 (86.8%)	3262 (87.7%)	0.3453	468 (85.9%)	0.7581	789 (83.1%)	0.0097	1760 (89.8%)	0.0039
	>= 50 to < 200	457 (13.1%)	459 (12.3%)	.	77 (14.1%)	.	161 (16.9%)	.	199 (10.2%)	.
	Missing	1 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
Log10 HIV viral load	Median (IQR)	1.3 (1.3, 1.3)	1.3 (1.3, 1.3)	0.0134	1.3 (1.3, 1.3)	0.6577	1.3 (1.3, 1.5)	0.0005	1.3 (1.3, 1.3)	<.0001
	< 1.7	3085 (88.7%)	3322 (89.3%)	0.4430	474 (87.0%)	0.4541	805 (84.7%)	0.0033	1787 (91.2%)	0.0114

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
	>= 1.7 to < 2.3	392 (11.3%)	399 (10.7%)	.	71 (13.0%)	.	145 (15.3%)	.	172 (8.8%)	.
	Missing	1 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
CD4 cell count (cell/μl)	Median (IQR)	647.0 (466.0, 837.0)	644.0 (482.0, 852.0)	0.2056	613.0 (419.0, 814.0)	0.0223	580.0 (412.0, 788.0)	<.0001	673.0 (515.0, 874.0)	<.0001
	>500	2408 (69.2%)	2665 (71.6%)	0.0121	337 (61.8%)	0.0038	564 (59.4%)	<.0001	1491 (76.1%)	<.0001
	>350 to <= 500	603 (17.3%)	626 (16.8%)	.	108 (19.8%)	.	196 (20.6%)	.	302 (15.4%)	.
	>200 to <= 350	297 (8.5%)	294 (7.9%)	.	62 (11.4%)	.	112 (11.8%)	.	129 (6.6%)	.
	>50 to <= 200	122 (3.5%)	83 (2.2%)	.	26 (4.8%)	.	49 (5.2%)	.	21 (1.1%)	.
	<= 50	4 (0.1%)	9 (0.2%)	.	3 (0.6%)	.	6 (0.6%)	.	0 (0.0%)	.
	Missing	44 (1.3%)	44 (1.2%)	.	9 (1.7%)	.	23 (2.4%)	.	16 (0.8%)	.

Table 16. Baseline clinical characteristics by core agent group among ART-experienced, suppressed patients

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
Hemoglobin, g/dL	Median (IQR)	14.6 (13.6, 15.5)	14.7 (13.6, 15.6)	0.0495	14.5 (13.2, 15.5)	0.0600	14.2 (13.1, 15.3)	<.0001	14.6 (13.5, 15.5)	0.9955
	Normal	3370 (96.9%)	3593 (96.6%)	0.0774	506 (92.8%)	<.0001	905 (95.3%)	0.0165	1889 (96.4%)	0.0626
	DAIDS Grade 1 (mild)	45 (1.3%)	35 (0.9%)	.	10 (1.8%)	.	13 (1.4%)	.	15 (0.8%)	.
	DAIDS Grade 2 (moderate)	12 (0.3%)	9 (0.2%)	.	8 (1.5%)	.	10 (1.1%)	.	10 (0.5%)	.
	DAIDS Grade 3 (Severe)	9 (0.3%)	13 (0.3%)	.	1 (0.2%)	.	6 (0.6%)	.	8 (0.4%)	.
	DAIDS Grade 4 (potentially life- threatening)	0 (0.0%)	2 (0.1%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
	Missing	42 (1.2%)	69 (1.9%)	.	20 (3.7%)	.	16 (1.7%)	.	37 (1.9%)	.
Hematocrit, %	Median (IQR)	43.1 (40.4, 45.6)	43.5 (40.8, 46.0)	<.0001	43.0 (39.5, 45.6)	0.0990	42.3 (39.3, 45.1)	<.0001	43.3 (40.4, 45.6)	0.3088
	Low	354 (10.2%)	283 (7.6%)	0.0002	84 (15.4%)	<.0001	120 (12.6%)	0.0816	152 (7.8%)	0.0025
	Normal	2951 (84.8%)	3219 (86.5%)	.	411 (75.4%)	.	777 (81.8%)	.	1688 (86.2%)	.
	High	130 (3.7%)	147 (4.0%)	.	28 (5.1%)	.	36 (3.8%)	.	78 (4.0%)	.

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
	Missing	43 (1.2%)	72 (1.9%)	.	22 (4.0%)	.	17 (1.8%)	.	41 (2.1%)	.
Systolic blood pressure, mmHg	Median (IQR)	125.0 (115.0, 135.0)	124.0 (115.0, 133.0)	0.0004	125.0 (118.0, 135.0)	0.5099	124.0 (115.0, 134.0)	0.0186	124.0 (115.0, 133.0)	0.0103
	Low	13 (0.4%)	10 (0.3%)	<.0001	0 (0.0%)	0.0131	2 (0.2%)	<.0001	4 (0.2%)	0.0001
	Normal	2801 (80.5%)	3077 (82.7%)	.	428 (78.5%)	.	770 (81.1%)	.	1620 (82.7%)	.
	DAIDS Grade 1 hypertension (mild)	487 (14.0%)	429 (11.5%)	.	76 (13.9%)	.	113 (11.9%)	.	245 (12.5%)	.
	DAIDS Grade 2 hypertension (moderate)	98 (2.8%)	54 (1.5%)	.	15 (2.8%)	.	18 (1.9%)	.	24 (1.2%)	.
	DAIDS Grade 3 hypertension (severe)	14 (0.4%)	10 (0.3%)	.	3 (0.6%)	.	5 (0.5%)	.	7 (0.4%)	.
	Missing	65 (1.9%)	141 (3.8%)	.	23 (4.2%)	.	42 (4.4%)	.	59 (3.0%)	.
Diastolic blood pressure, mmHg	Median (IQR)	78.0 (72.0, 84.0)	78.0 (72.0, 85.0)	0.8737	80.0 (73.0, 86.0)	0.0300	78.0 (72.0, 85.0)	0.6006	78.0 (72.0, 84.0)	0.9398
	Low	66 (1.9%)	56 (1.5%)	<.0001	3 (0.6%)	0.0037	16 (1.7%)	0.0005	31 (1.6%)	0.0203
	Normal	2905 (83.5%)	3086 (82.9%)	.	440 (80.7%)	.	788 (82.9%)	.	1642 (83.8%)	.
	DAIDS Grade 1 hypertension (mild)	339 (9.7%)	345 (9.3%)	.	62 (11.4%)	.	85 (8.9%)	.	193 (9.9%)	.

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
	DAIDS Grade 2 hypertension (moderate)	81 (2.3%)	71 (1.9%)	.	14 (2.6%)	.	13 (1.4%)	.	27 (1.4%)	.
	DAIDS Grade 3 hypertension (severe)	19 (0.5%)	18 (0.5%)	.	3 (0.6%)	.	6 (0.6%)	.	7 (0.4%)	.
	Missing	68 (2.0%)	145 (3.9%)	.	23 (4.2%)	.	42 (4.4%)	.	59 (3.0%)	.
VACS mortality index	Median (IQR)	12.0 (0.0, 22.0)	10.0 (0.0, 18.0)	<.0001	18.0 (10.0, 28.0)	<.0001	16.0 (6.0, 24.0)	<.0001	10.0 (0.0, 18.0)	<.0001
	0 to <15	1884 (54.2%)	2339 (62.9%)	<.0001	187 (34.3%)	<.0001	428 (45.1%)	<.0001	1163 (59.4%)	<.0001
	>=15 to <30	943 (27.1%)	770 (20.7%)	.	169 (31.0%)	.	303 (31.9%)	.	441 (22.5%)	.
	>=30 to <45	301 (8.7%)	203 (5.5%)	.	61 (11.2%)	.	88 (9.3%)	.	118 (6.0%)	.
	>= 45	154 (4.4%)	88 (2.4%)	.	46 (8.4%)	.	47 (4.9%)	.	43 (2.2%)	.
	Missing	196 (5.6%)	321 (8.6%)	.	82 (15.0%)	.	84 (8.8%)	.	194 (9.9%)	.
Specific concomitant non-ART medications associated with weight gain - Any	Yes	800 (23.0%)	621 (16.7%)	<.0001	159 (29.2%)	0.0017	203 (21.4%)	0.2865	354 (18.1%)	<.0001
Antipsychotics and mood stabilizer	Yes	123 (3.5%)	88 (2.4%)	0.0032	30 (5.5%)	0.0255	48 (5.1%)	0.0316	64 (3.3%)	0.6006

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
Antidepressants	Yes	252 (7.2%)	188 (5.1%)	0.0001	43 (7.9%)	0.5916	57 (6.0%)	0.1817	102 (5.2%)	0.0034
Antihyperglycemics	Yes	108 (3.1%)	68 (1.8%)	0.0005	40 (7.3%)	<.0001	23 (2.4%)	0.2700	40 (2.0%)	0.0207
Antihypertensives	Yes	141 (4.1%)	106 (2.8%)	0.0050	47 (8.6%)	<.0001	35 (3.7%)	0.6051	74 (3.8%)	0.6153
Corticosteroids	Yes	140 (4.0%)	113 (3.0%)	0.0228	16 (2.9%)	0.2206	25 (2.6%)	0.0444	56 (2.9%)	0.0267
Hormones	Yes	10 (0.3%)	10 (0.3%)	1.0000	1 (0.2%)	1.0000	2 (0.2%)	1.0000	5 (0.3%)	1.0000
Anticonvulsants	Yes	244 (7.0%)	175 (4.7%)	<.0001	47 (8.6%)	0.1778	76 (8.0%)	0.2990	95 (4.8%)	0.0015
Antihistamines	Yes	15 (0.4%)	23 (0.6%)	0.3295	3 (0.6%)	0.7261	3 (0.3%)	0.7790	5 (0.3%)	0.3585
Number of specific concomitant non- ART medications associated with weight gain listed above	0	2678 (77.0%)	3100 (83.3%)	<.0001	386 (70.8%)	<.0001	747 (78.6%)	0.1715	1605 (81.9%)	0.0001
	1-2	740 (21.3%)	583 (15.7%)	.	134 (24.6%)	.	180 (18.9%)	.	327 (16.7%)	.
	3-4	58 (1.7%)	37 (1.0%)	.	23 (4.2%)	.	23 (2.4%)	.	27 (1.4%)	.
	5+	2 (0.1%)	1 (0.0%)	.	2 (0.4%)	.	0 (0.0%)	.	0 (0.0%)	.
Specific concomitant non-ART medications	Yes	532 (15.3%)	417 (11.2%)	<.0001	98 (18.0%)	0.1087	116 (12.2%)	0.0171	238 (12.1%)	0.0014

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
associated with weight loss - Any										
Anti-infectives	Yes	51 (1.5%)	40 (1.1%)	0.1409	5 (0.9%)	0.4301	18 (1.9%)	0.3743	13 (0.7%)	0.0084
Antineoplastics	Yes	4 (0.1%)	2 (0.1%)	0.4385	1 (0.2%)	0.5172	0 (0.0%)	0.5839	2 (0.1%)	1.0000
Bronchodilators	Yes	251 (7.2%)	184 (4.9%)	<.0001	53 (9.7%)	0.0394	54 (5.7%)	0.0983	132 (6.7%)	0.5079
Cardiovascular drugs	Yes	15 (0.4%)	8 (0.2%)	0.1423	7 (1.3%)	0.0219	4 (0.4%)	1.0000	1 (0.1%)	0.0157
Stimulants	Yes	18 (0.5%)	13 (0.3%)	0.2864	4 (0.7%)	0.5276	1 (0.1%)	0.0968	8 (0.4%)	0.6845
Anti-depressants	Yes	236 (6.8%)	177 (4.8%)	0.0002	32 (5.9%)	0.4263	50 (5.3%)	0.0907	90 (4.6%)	0.0011
Anti-convulsants	Yes	15 (0.4%)	19 (0.5%)	0.7315	7 (1.3%)	0.0219	1 (0.1%)	0.2198	8 (0.4%)	1.0000
Anti-hyperglycemics	Yes	1 (0.0%)	4 (0.1%)	0.3763	2 (0.4%)	0.0500	0 (0.0%)	1.0000	3 (0.2%)	0.1365
Anti-inflammatories	Yes	1 (0.0%)	1 (0.0%)	1.0000	0 (0.0%)	1.0000	1 (0.1%)	0.3831	0 (0.0%)	1.0000
Weight loss drugs	Yes	5 (0.1%)	3 (0.1%)	0.4946	2 (0.4%)	0.2430	0 (0.0%)	0.5915	4 (0.2%)	0.7306
Dementia treatment	Yes	0 (0.0%)	1 (0.0%)	1.0000	1 (0.2%)	0.1355	0 (0.0%)	.	0 (0.0%)	.
Number of specific concomitant non- ART medications associated with weight loss listed above	0	2946 (84.7%)	3304 (88.8%)	<.0001	447 (82.0%)	0.1577	834 (87.8%)	0.0496	1721 (87.9%)	0.0042

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
	1-2	525 (15.1%)	413 (11.1%)	.	96 (17.6%)	.	115 (12.1%)	.	236 (12.0%)	.
	3-4	7 (0.2%)	4 (0.1%)	.	2 (0.4%)	.	1 (0.1%)	.	2 (0.1%)	.

*Table 17. Baseline comorbidities by core agent group among ART-experienced, suppressed patients*

	DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
Any Comorbidity at baseline	2851 (82.0%)	2692 (72.3%)	<.0001	476 (87.3%)	0.0021	738 (77.7%)	0.0028	1442 (73.6%)	<.0001
Any Cardiovascular Disease Conditions - Any	358 (10.3%)	257 (6.9%)	<.0001	72 (13.2%)	0.0404	68 (7.2%)	0.0037	111 (5.7%)	<.0001
Arrhythmia	121 (3.5%)	81 (2.2%)	0.0008	15 (2.8%)	0.3828	16 (1.7%)	0.0046	38 (1.9%)	0.0012
Myocardial Infarction	31 (0.9%)	16 (0.4%)	0.0152	8 (1.5%)	0.2015	10 (1.1%)	0.6455	14 (0.7%)	0.4900
Angina	18 (0.5%)	11 (0.3%)	0.1916	3 (0.6%)	0.7572	5 (0.5%)	1.0000	5 (0.3%)	0.1931
Other/Unspecified CHD	185 (5.3%)	119 (3.2%)	<.0001	41 (7.5%)	0.0378	44 (4.6%)	0.3964	55 (2.8%)	<.0001



	DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
Occlusion/stenosis of precerebral arteries	9 (0.3%)	1 (0.0%)	0.0094	3 (0.6%)	0.2152	1 (0.1%)	0.6996	3 (0.2%)	0.5548
Stroke	47 (1.4%)	30 (0.8%)	0.0246	10 (1.8%)	0.3745	8 (0.8%)	0.2091	15 (0.8%)	0.0509
Transient Ischemic Attack	9 (0.3%)	13 (0.3%)	0.5281	3 (0.6%)	0.2152	2 (0.2%)	1.0000	5 (0.3%)	1.0000
Other CBV	79 (2.3%)	55 (1.5%)	0.0128	22 (4.0%)	0.0143	13 (1.4%)	0.0837	25 (1.3%)	0.0101
Peripheral Arterial Disease	32 (0.9%)	21 (0.6%)	0.0971	4 (0.7%)	0.8105	7 (0.7%)	0.6981	7 (0.4%)	0.0185
Abdominal Aortic Aneurysm	1 (0.0%)	3 (0.1%)	0.6258	0 (0.0%)	1.0000	0 (0.0%)	1.0000	1 (0.1%)	1.0000
Invasive Cancer	264 (7.6%)	193 (5.2%)	<.0001	47 (8.6%)	0.4010	86 (9.1%)	0.1388	102 (5.2%)	0.0008
Endocrine Disorders	1462 (42.0%)	1305 (35.1%)	<.0001	245 (45.0%)	0.1999	299 (31.5%)	<.0001	655 (33.4%)	<.0001
Type 1 Diabetes Mellitus (diagnosis)	16 (0.5%)	11 (0.3%)	0.3349	6 (1.1%)	0.1069	1 (0.1%)	0.1453	10 (0.5%)	0.8388
Type 2 Diabetes Mellitus (labs/meds or diagnosis)	346 (9.9%)	287 (7.7%)	0.0008	102 (18.7%)	<.0001	79 (8.3%)	0.1301	151 (7.7%)	0.0059
Hyperlipidemia	1299 (37.3%)	1137 (30.6%)	<.0001	183 (33.6%)	0.0897	257 (27.1%)	<.0001	566 (28.9%)	<.0001
Hyperthyroidism	26 (0.7%)	17 (0.5%)	0.1262	4 (0.7%)	1.0000	6 (0.6%)	0.8312	5 (0.3%)	0.0231
Hypothyroidism	112 (3.2%)	85 (2.3%)	0.0150	32 (5.9%)	0.0019	21 (2.2%)	0.1061	44 (2.2%)	0.0388
Thyroiditis	5 (0.1%)	1 (0.0%)	0.1133	0 (0.0%)	1.0000	0 (0.0%)	0.5915	1 (0.1%)	0.4288

	DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
Mental Health Conditions - Any	1088 (31.3%)	934 (25.1%)	<.0001	158 (29.0%)	0.2820	240 (25.3%)	0.0003	476 (24.3%)	<.0001
Anxiety Disorders	700 (20.1%)	649 (17.4%)	0.0035	88 (16.1%)	0.0295	129 (13.6%)	<.0001	309 (15.8%)	<.0001
Bipolar or Manic Disorders	148 (4.3%)	140 (3.8%)	0.2862	31 (5.7%)	0.1315	52 (5.5%)	0.1090	75 (3.8%)	0.4461
Major Depressive Disorder	450 (12.9%)	289 (7.8%)	<.0001	54 (9.9%)	0.0469	89 (9.4%)	0.0029	134 (6.8%)	<.0001
Schizophrenic Disorder	53 (1.5%)	40 (1.1%)	0.0919	8 (1.5%)	0.9208	15 (1.6%)	0.9026	17 (0.9%)	0.0394
Dementia	12 (0.3%)	9 (0.2%)	0.5136	1 (0.2%)	1.0000	1 (0.1%)	0.3224	6 (0.3%)	1.0000
Suicidality	18 (0.5%)	9 (0.2%)	0.0806	2 (0.4%)	1.0000	2 (0.2%)	0.2810	6 (0.3%)	0.2944
Liver Diseases - Any	674 (19.4%)	490 (13.2%)	<.0001	136 (25.0%)	0.0025	163 (17.2%)	0.1212	274 (14.0%)	<.0001
Hepatitis B	226 (6.5%)	195 (5.2%)	0.0231	39 (7.2%)	0.5648	68 (7.2%)	0.4690	96 (4.9%)	0.0166
Hepatitis C	415 (11.9%)	233 (6.3%)	<.0001	91 (16.7%)	0.0018	86 (9.1%)	0.0130	156 (8.0%)	<.0001
Other chronic liver disease	158 (4.5%)	115 (3.1%)	0.0013	24 (4.4%)	0.8844	36 (3.8%)	0.3147	54 (2.8%)	0.0011
Bone Diseases	131 (3.8%)	71 (1.9%)	<.0001	14 (2.6%)	0.1631	17 (1.8%)	0.0027	29 (1.5%)	<.0001
Peripheral Neuropathy	329 (9.5%)	221 (5.9%)	<.0001	56 (10.3%)	0.5472	82 (8.6%)	0.4358	110 (5.6%)	<.0001
Renal Disease - Any	1491 (42.9%)	1256 (33.8%)	<.0001	245 (45.0%)	0.3609	393 (41.4%)	0.4069	626 (32.0%)	<.0001
Renal Impairment	1491 (42.9%)	1256 (33.8%)	<.0001	245 (45.0%)	0.3609	393 (41.4%)	0.4069	626 (32.0%)	<.0001

	DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
Moderate/Severe CKD	128 (3.7%)	50 (1.3%)	<.0001	27 (5.0%)	0.1508	13 (1.4%)	0.0003	25 (1.3%)	<.0001
End Stage Renal Disease	7 (0.2%)	0 (0.0%)	0.0061	3 (0.6%)	0.1433	2 (0.2%)	1.0000	1 (0.1%)	0.2724
Hypertension	1084 (31.2%)	938 (25.2%)	<.0001	211 (38.7%)	0.0005	247 (26.0%)	0.0021	489 (25.0%)	<.0001
Rheumatoid Arthritis	23 (0.7%)	13 (0.3%)	0.0668	1 (0.2%)	0.2392	3 (0.3%)	0.3356	6 (0.3%)	0.1190
Substance Abuse - Any	520 (15.0%)	419 (11.3%)	<.0001	67 (12.3%)	0.1022	118 (12.4%)	0.0491	209 (10.7%)	<.0001
Alcohol Dependence	152 (4.4%)	109 (2.9%)	0.0011	17 (3.1%)	0.1758	40 (4.2%)	0.8303	51 (2.6%)	0.0010
Drug Abuse	495 (14.2%)	400 (10.7%)	<.0001	65 (11.9%)	0.1482	112 (11.8%)	0.0524	204 (10.4%)	<.0001

## 1.2. Description of baseline BMI categories, weight, lipid levels, and lipodystrophy (stratified by ART experience)

### 1.2.1. Treatment-naïve patients

Table 18. Baseline weight, BMI, and lipodystrophy in ART-naïve patients

		DTG N= 2,118	EVG/c N= 2,665	DTG vs. EVG/c p-value	RAL N= 116	DTG vs. RAL p-value	DRV(/r/c) N= 590	DTG vs. DRV(/r/c) p-value	RPV N= 757	DTG vs. RPV p-value
Weight, kg	Median (IQR)	73.9 (65.3, 85.7)	74.8 (66.0, 86.2)	0.0632	76.9 (65.5, 90.2)	0.0828	74.4 (64.0, 85.1)	0.6600	77.1 (68.0, 90.7)	<.0001
BMI	Median (IQR)	24.8 (22.0, 28.3)	24.6 (22.0, 27.8)	0.1904	25.9 (23.0, 29.6)	0.0218	24.6 (21.8, 28.3)	0.2507	25.9 (22.6, 30.3)	<.0001
	Underweight (BMI: <18.5)	88 (4.2%)	93 (3.5%)	0.0497	5 (4.3%)	0.2373	36 (6.1%)	0.2128	20 (2.6%)	<.0001
	Normal (BMI: 18.5 – 24.9)	1003 (47.4%)	1355 (50.8%)	.	44 (37.9%)	.	283 (48.0%)	.	322 (42.5%)	.
	Overweight (BMI: 25.0-29.9)	640 (30.2%)	789 (29.6%)	.	40 (34.5%)	.	168 (28.5%)	.	219 (28.9%)	.
	Obese (BMI: ≥30)	387 (18.3%)	428 (16.1%)	.	27 (23.3%)	.	103 (17.5%)	.	196 (25.9%)	.
Prevalent lipodystrophy (within 12 months before/on baseline)	Yes	1 (0.0%)	2 (0.1%)	1.0000	0 (0.0%)	1.0000	1 (0.2%)	0.3883	0 (0.0%)	1.0000
	% (95% CI)	0.05 (0.00, 0.26)	0.08 (0.01, 0.27)	.		.	0.17 (0.00, 0.94)	.		.

Table 19. Baseline weight, BMI, and lipodystrophy in ART-naïve patients with at least one lipid test available

		DTG N= 1,613	EVG/c N= 1,821	DTG vs. EVG/c p-value	RAL N= 87	DTG vs. RAL p-value	DRV(/r/c) N= 431	DTG vs. DRV(/r/c) p-value	RPV N= 544	DTG vs. RPV p-value
Weight, kg	Median (IQR)	73.9 (65.3, 85.7)	74.8 (66.2, 86.2)	0.0957	77.1 (65.3, 89.8)	0.1028	74.8 (64.0, 85.3)	0.9848	78.0 (68.0, 91.0)	<.0001
BMI	Median (IQR)	24.8 (22.0, 28.3)	24.6 (22.1, 27.9)	0.2960	25.9 (23.2, 29.6)	0.0546	24.6 (21.8, 28.6)	0.2873	25.9 (22.6, 30.5)	<.0001
	Underweight (BMI: <18.5)	58 (3.6%)	65 (3.6%)	0.3861	3 (3.4%)	0.3494	28 (6.5%)	0.0607	17 (3.1%)	0.0003
	Normal (BMI: 18.5 – 24.9)	766 (47.5%)	914 (50.2%)	.	33 (37.9%)	.	202 (46.9%)	.	231 (42.5%)	.
	Overweight (BMI: 25.0-29.9)	496 (30.8%)	543 (29.8%)	.	31 (35.6%)	.	123 (28.5%)	.	150 (27.6%)	.
	Obese (BMI: ≥30)	293 (18.2%)	299 (16.4%)	.	20 (23.0%)	.	78 (18.1%)	.	146 (26.8%)	.
Prevalent lipodystrophy (within 12 months before/on baseline)	Yes	1 (0.1%)	2 (0.1%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	1.0000
	% (95% CI)	0.06 (0.00, 0.34)	0.11 (0.01, 0.40)	.		.		.		.
Total Cholesterol, mg/dL	Normal (<200 mg/dl)	1410 (87.4%)	1619 (88.9%)	0.1137	71 (81.6%)	0.3343	378 (87.7%)	0.6079	469 (86.2%)	0.9253

		DTG N= 1,613	EVG/c N= 1,821	DTG vs. EVG/c p-value	RAL N= 87	DTG vs. RAL p-value	DRV(/r/c) N= 431	DTG vs. DRV(/r/c) p-value	RPV N= 544	DTG vs. RPV p-value
	Borderline Abnormal (>=200 to <240 mg/dl)	161 (10.0%)	156 (8.6%)	.	13 (14.9%)	.	43 (10.0%)	.	62 (11.4%)	.
	Dyslipidemia (>=240 to <280 mg/dl)	31 (1.9%)	25 (1.4%)	.	3 (3.4%)	.	6 (1.4%)	.	10 (1.8%)	.
	Severe Dyslipidemia (>=280 mg/dl)	7 (0.4%)	8 (0.4%)	.	0 (0.0%)	.	1 (0.2%)	.	2 (0.4%)	.
	Missing	4 (0.2%)	13 (0.7%)	.	0 (0.0%)	.	3 (0.7%)	.	1 (0.2%)	.
LDL, mg/dL	Normal (<100 mg/dl)	1051 (65.2%)	1218 (66.9%)	0.7614	50 (57.5%)	0.0502	300 (69.6%)	0.2587	313 (57.5%)	0.0122
	Borderline Abnormal (>=100 to <130 mg/dl)	389 (24.1%)	413 (22.7%)	.	22 (25.3%)	.	88 (20.4%)	.	163 (30.0%)	.
	Dyslipidemia (>=130 to <160 mg/dl)	108 (6.7%)	118 (6.5%)	.	11 (12.6%)	.	27 (6.3%)	.	49 (9.0%)	.
	Severe Dyslipidemia (>=160 to <190 mg/dl)	15 (0.9%)	23 (1.3%)	.	3 (3.4%)	.	6 (1.4%)	.	7 (1.3%)	.
	Very Severe Dyslipidemia (>=190 mg/dl)	10 (0.6%)	9 (0.5%)	.	0 (0.0%)	.	0 (0.0%)	.	4 (0.7%)	.
	Missing	40 (2.5%)	40 (2.2%)	.	1 (1.1%)	.	10 (2.3%)	.	8 (1.5%)	.

		DTG N= 1,613	EVG/c N= 1,821	DTG vs. EVG/c p-value	RAL N= 87	DTG vs. RAL p-value	DRV(/r/c) N= 431	DTG vs. DRV(/r/c) p-value	RPV N= 544	DTG vs. RPV p-value
HDL, mg/dL	Normal ( $\geq 60$ mg/dl)	189 (11.7%)	197 (10.8%)	0.1081	9 (10.3%)	0.9755	52 (12.1%)	0.2707	75 (13.8%)	0.0007
	Borderline Abnormal ( $\geq 40$ to $< 60$ mg/dl)	685 (42.5%)	722 (39.6%)	.	38 (43.7%)	.	162 (37.6%)	.	274 (50.4%)	.
	Dyslipidemia ( $< 40$ mg/dl)	731 (45.3%)	886 (48.7%)	.	40 (46.0%)	.	214 (49.7%)	.	193 (35.5%)	.
	Missing	8 (0.5%)	16 (0.9%)	.	0 (0.0%)	.	3 (0.7%)	.	2 (0.4%)	.
Triglycerides, mg/dL	Normal ( $< 150$ mg/dl)	1145 (71.0%)	1321 (72.5%)	0.4267	59 (67.8%)	0.7348	279 (64.7%)	0.0873	407 (74.8%)	0.0338
	Borderline Abnormal ( $\geq 150$ to $< 200$ mg/dl)	199 (12.3%)	237 (13.0%)	.	14 (16.1%)	.	70 (16.2%)	.	75 (13.8%)	.
	Dyslipidemia ( $\geq 200$ to $< 500$ mg/dl)	247 (15.3%)	240 (13.2%)	.	13 (14.9%)	.	77 (17.9%)	.	60 (11.0%)	.
	Severe Dyslipidemia ( $\geq 500$ mg/dl)	18 (1.1%)	17 (0.9%)	.	1 (1.1%)	.	5 (1.2%)	.	2 (0.4%)	.
	Missing	4 (0.2%)	6 (0.3%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.

### 1.2.2. Treatment-experienced patients

Table 20. Baseline weight, BMI, and lipodystrophy in ART-experienced patients

		DTG N= 5,061	EVG/c N= 5,579	DTG vs. EVG/c p-value	RAL N= 674	DTG vs. RAL p-value	DRV(/r/c) N= 1,507	DTG vs. DRV(/r/c) p-value	RPV N= 2,487	DTG vs. RPV p-value
Weight, kg	Median (IQR)	78.0 (68.1, 89.8)	78.5 (68.9, 89.4)	0.2431	79.5 (69.9, 91.2)	0.0310	78.5 (68.5, 89.4)	0.6669	79.4 (70.3, 90.7)	0.0004
BMI	Median (IQR)	25.9 (23.1, 29.3)	25.8 (23.0, 29.3)	0.5387	26.2 (23.3, 29.8)	0.0723	26.2 (23.1, 29.4)	0.0983	26.2 (23.2, 29.8)	0.0008
	Underweight (BMI: <18.5)	134 (2.6%)	144 (2.6%)	0.9408	16 (2.4%)	0.2285	36 (2.4%)	0.3457	52 (2.1%)	0.0234
	Normal (BMI: 18.5 – 24.9)	2016 (39.8%)	2255 (40.4%)	.	242 (35.9%)	.	571 (37.9%)	.	934 (37.6%)	.
	Overweight (BMI: 25.0-29.9)	1827 (36.1%)	1997 (35.8%)	.	260 (38.6%)	.	549 (36.4%)	.	903 (36.3%)	.
	Obese (BMI: ≥30)	1084 (21.4%)	1183 (21.2%)	.	156 (23.1%)	.	351 (23.3%)	.	598 (24.0%)	.
Prevalent lipodystrophy (within 12 months before/on baseline)	Yes	54 (1.1%)	43 (0.8%)	0.1084	20 (3.0%)	<.0001	12 (0.8%)	0.3550	17 (0.7%)	0.1048
	% (95% CI)	1.07 (0.80, 1.39)	0.77 (0.56, 1.04)	.	2.97 (1.82, 4.55)	.	0.80 (0.41, 1.39)	.	0.68 (0.40, 1.09)	.



Table 21. Baseline weight, BMI, and lipodystrophy in ART-experienced patients with at least one lipid test available

		DTG N= 3,287	EVG/c N= 3,651	DTG vs. EVG/c p-value	RAL N= 462	DTG vs. RAL p-value	DRV(/r/c) N= 987	DTG vs. DRV(/r/c) p-value	RPV N= 1,648	DTG vs. RPV p-value
Weight, kg	Median (IQR)	78.7 (68.5, 90.3)	78.9 (69.4, 90.0)	0.2297	79.8 (69.9, 91.5)	0.0805	79.4 (68.6, 89.8)	0.8333	79.8 (70.3, 91.5)	0.0042
BMI	Median (IQR)	26.0 (23.1, 29.5)	25.8 (23.1, 29.4)	0.6432	26.4 (23.5, 29.8)	0.0869	26.2 (23.2, 29.4)	0.4205	26.2 (23.2, 30.0)	0.0240
	Underweight (BMI: <18.5)	82 (2.5%)	87 (2.4%)	0.8896	12 (2.6%)	0.0864	16 (1.6%)	0.3243	34 (2.1%)	0.1942
	Normal (BMI: 18.5 – 24.9)	1278 (38.9%)	1441 (39.5%)	.	152 (32.9%)	.	371 (37.6%)	.	610 (37.0%)	.
	Overweight (BMI: 25.0-29.9)	1186 (36.1%)	1325 (36.3%)	.	189 (40.9%)	.	371 (37.6%)	.	592 (35.9%)	.
	Obese (BMI: ≥30)	741 (22.5%)	798 (21.9%)	.	109 (23.6%)	.	229 (23.2%)	.	412 (25.0%)	.
Prevalent lipodystrophy (within 12 months before/on baseline)	Yes	38 (1.2%)	30 (0.8%)	0.1581	9 (1.9%)	0.1520	11 (1.1%)	0.9143	12 (0.7%)	0.1569
	% (95% CI)	1.16 (0.82, 1.58)	0.82 (0.56, 1.17)	.	1.95 (0.89, 3.67)	.	1.11 (0.56, 1.99)	.	0.73 (0.38, 1.27)	.
Total Cholesterol, mg/dL	Normal (<200 mg/dl)	2403 (73.1%)	2708 (74.2%)	0.0348	328 (71.0%)	0.5612	714 (72.3%)	0.0006	1213 (73.6%)	0.4179
	Borderline Abnormal	634 (19.3%)	713 (19.5%)	.	91 (19.7%)	.	211 (21.4%)	.	315 (19.1%)	.

		DTG N= 3,287	EVG/c N= 3,651	DTG vs. EVG/c p-value	RAL N= 462	DTG vs. RAL p-value	DRV(/r/c) N= 987	DTG vs. DRV(/r/c) p-value	RPV N= 1,648	DTG vs. RPV p-value
	(>=200 to <240 mg/dl)									
	Dyslipidemia (>=240 to <280 mg/dl)	194 (5.9%)	171 (4.7%)	.	36 (7.8%)	.	43 (4.4%)	.	87 (5.3%)	.
	Severe Dyslipidemia (>=280 mg/dl)	52 (1.6%)	46 (1.3%)	.	7 (1.5%)	.	10 (1.0%)	.	27 (1.6%)	.
	Missing	4 (0.1%)	13 (0.4%)	.	0 (0.0%)	.	9 (0.9%)	.	6 (0.4%)	.
LDL, mg/dL	Normal (<100 mg/dl)	1767 (53.8%)	1889 (51.7%)	0.0039	245 (53.0%)	0.5469	514 (52.1%)	0.1358	860 (52.2%)	0.2961
	Borderline Abnormal (>=100 to <130 mg/dl)	847 (25.8%)	1082 (29.6%)	.	116 (25.1%)	.	293 (29.7%)	.	469 (28.5%)	.
	Dyslipidemia (>=130 to <160 mg/dl)	412 (12.5%)	407 (11.1%)	.	63 (13.6%)	.	106 (10.7%)	.	191 (11.6%)	.
	Severe Dyslipidemia (>=160 to <190 mg/dl)	103 (3.1%)	94 (2.6%)	.	14 (3.0%)	.	31 (3.1%)	.	58 (3.5%)	.
	Very Severe Dyslipidemia (>=190 mg/dl)	39 (1.2%)	33 (0.9%)	.	2 (0.4%)	.	7 (0.7%)	.	14 (0.8%)	.
	Missing	119 (3.6%)	146 (4.0%)	.	22 (4.8%)	.	36 (3.6%)	.	56 (3.4%)	.

		DTG N= 3,287	EVG/c N= 3,651	DTG vs. EVG/c p-value	RAL N= 462	DTG vs. RAL p-value	DRV(/r/c) N= 987	DTG vs. DRV(/r/c) p-value	RPV N= 1,648	DTG vs. RPV p-value
HDL, mg/dL	Normal ( $\geq 60$ mg/dl)	691 (21.0%)	704 (19.3%)	0.0041	89 (19.3%)	0.3336	180 (18.2%)	0.0264	335 (20.3%)	0.0093
	Borderline Abnormal ( $\geq 40$ to $< 60$ mg/dl)	1501 (45.7%)	1785 (48.9%)	.	205 (44.4%)	.	469 (47.5%)	.	814 (49.4%)	.
	Dyslipidemia ( $< 40$ mg/dl)	1083 (32.9%)	1134 (31.1%)	.	168 (36.4%)	.	328 (33.2%)	.	486 (29.5%)	.
	Missing	12 (0.4%)	28 (0.8%)	.	0 (0.0%)	.	10 (1.0%)	.	13 (0.8%)	.
Triglycerides, mg/dL	Normal ( $< 150$ mg/dl)	1978 (60.2%)	2288 (62.7%)	0.2145	282 (61.0%)	0.5349	598 (60.6%)	0.2117	1127 (68.4%)	$< .0001$
	Borderline Abnormal ( $\geq 150$ to $< 200$ mg/dl)	569 (17.3%)	595 (16.3%)	.	73 (15.8%)	.	160 (16.2%)	.	221 (13.4%)	.
	Dyslipidemia ( $\geq 200$ to $< 500$ mg/dl)	677 (20.6%)	692 (19.0%)	.	94 (20.3%)	.	209 (21.2%)	.	265 (16.1%)	.
	Severe Dyslipidemia ( $\geq 500$ mg/dl)	59 (1.8%)	69 (1.9%)	.	13 (2.8%)	.	15 (1.5%)	.	34 (2.1%)	.
	Missing	4 (0.1%)	7 (0.2%)	.	0 (0.0%)	.	5 (0.5%)	.	1 (0.1%)	.

### 1.2.3. Treatment-experienced, suppressed patients

Table 22. Baseline weight, BMI, and lipodystrophy in ART-experienced, suppressed patients

		DTG N= 3,478	EVG/c N= 3,721	DTG vs. EVG/c p-value	RAL N= 545	DTG vs. RAL p-value	DRV(/r/c) N= 950	DTG vs. DRV(/r/c) p-value	RPV N= 1,959	DTG vs. RPV p-value
Weight, kg	Median (IQR)	79.4 (69.4, 90.7)	79.4 (70.3, 90.7)	0.2611	79.8 (70.3, 91.2)	0.2640	80.9 (71.2, 91.3)	0.0194	79.8 (70.8, 90.7)	0.2942
BMI	Median (IQR)	26.2 (23.4, 29.5)	26.1 (23.4, 29.6)	0.9233	26.3 (23.5, 29.8)	0.5976	26.6 (23.9, 30.2)	0.0011	26.2 (23.4, 29.8)	0.3841
	Underweight (BMI: <18.5)	66 (1.9%)	77 (2.1%)	0.7781	12 (2.2%)	0.7405	12 (1.3%)	0.0351	40 (2.0%)	0.2499
	Normal (BMI: 18.5 – 24.9)	1281 (36.8%)	1396 (37.5%)	.	188 (34.5%)	.	322 (33.9%)	.	729 (37.2%)	.
	Overweight (BMI: 25.0-29.9)	1354 (38.9%)	1408 (37.8%)	.	220 (40.4%)	.	366 (38.5%)	.	715 (36.5%)	.
	Obese (BMI: ≥30)	777 (22.3%)	840 (22.6%)	.	125 (22.9%)	.	250 (26.3%)	.	475 (24.2%)	.
Prevalent lipodystrophy (within 12 months before/on baseline)	Yes	50 (1.4%)	40 (1.1%)	0.1664	20 (3.7%)	0.0002	11 (1.2%)	0.5121	16 (0.8%)	0.0447
	% (95% CI)	1.44 (1.07, 1.89)	1.07 (0.77, 1.46)	.	3.67 (2.26, 5.61)	.	1.16 (0.58, 2.06)	.	0.82 (0.47, 1.32)	.

Table 23. Baseline weight, BMI, and lipodystrophy in ART-experienced, suppressed patients with at least one lipid test available

		DTG N= 2,268	EVG/c N= 2,463	DTG vs. EVG/c p-value	RAL N= 377	DTG vs. RAL p-value	DRV(/r/c) N= 634	DTG vs. DRV(/r/c) p-value	RPV N= 1,314	DTG vs. RPV p-value
Weight, kg	Median (IQR)	79.8 (69.9, 91.2)	79.8 (70.8, 91.2)	0.4807	80.3 (70.8, 91.6)	0.4754	81.2 (70.8, 90.9)	0.2756	79.8 (70.3, 90.7)	0.8979
BMI	Median (IQR)	26.4 (23.5, 29.8)	26.2 (23.6, 29.7)	0.6326	26.5 (23.5, 29.7)	0.7980	26.6 (23.9, 30.1)	0.1130	26.2 (23.3, 29.9)	0.7928
	Underweight (BMI: <18.5)	39 (1.7%)	50 (2.0%)	0.8184	9 (2.4%)	0.3711	5 (0.8%)	0.1938	26 (2.0%)	0.4843
	Normal (BMI: 18.5 – 24.9)	811 (35.8%)	897 (36.4%)	.	121 (32.1%)	.	211 (33.3%)	.	487 (37.1%)	.
	Overweight (BMI: 25.0-29.9)	881 (38.8%)	943 (38.3%)	.	160 (42.4%)	.	256 (40.4%)	.	477 (36.3%)	.
	Obese (BMI: ≥30)	537 (23.7%)	573 (23.3%)	.	87 (23.1%)	.	162 (25.6%)	.	324 (24.7%)	.
Prevalent lipodystrophy (within 12 months before/on baseline)	Yes	34 (1.5%)	28 (1.1%)	0.2737	9 (2.4%)	0.2067	10 (1.6%)	0.8868	11 (0.8%)	0.0865
	% (95% CI)	1.50 (1.04, 2.09)	1.14 (0.76, 1.64)	.	2.39 (1.10, 4.48)	.	1.58 (0.76, 2.88)	.	0.84 (0.42, 1.49)	.

		DTG N= 2,268	EVG/c N= 2,463	DTG vs. EVG/c p-value	RAL N= 377	DTG vs. RAL p-value	DRV(/r/c) N= 634	DTG vs. DRV(/r/c) p-value	RPV N= 1,314	DTG vs. RPV p-value
Total Cholesterol, mg/dL	Normal (<200 mg/dl)	1530 (67.5%)	1687 (68.5%)	0.0243	261 (69.2%)	0.6019	423 (66.7%)	0.0358	931 (70.9%)	0.0050
	Borderline Abnormal (>=200 to <240 mg/dl)	524 (23.1%)	584 (23.7%)	.	79 (21.0%)	.	168 (26.5%)	.	278 (21.2%)	.
	Dyslipidemia (>=240 to <280 mg/dl)	169 (7.5%)	146 (5.9%)	.	32 (8.5%)	.	34 (5.4%)	.	76 (5.8%)	.
	Severe Dyslipidemia (>=280 mg/dl)	45 (2.0%)	40 (1.6%)	.	5 (1.3%)	.	8 (1.3%)	.	24 (1.8%)	.
	Missing	0 (0.0%)	6 (0.2%)	.	0 (0.0%)	.	1 (0.2%)	.	5 (0.4%)	.
LDL, mg/dL	Normal (<100 mg/dl)	1109 (48.9%)	1128 (45.8%)	0.0014	193 (51.2%)	0.5258	277 (43.7%)	0.0098	650 (49.5%)	0.1210
	Borderline Abnormal (>=100 to <130 mg/dl)	606 (26.7%)	791 (32.1%)	.	98 (26.0%)	.	218 (34.4%)	.	389 (29.6%)	.
	Dyslipidemia (>=130 to <160 mg/dl)	339 (14.9%)	316 (12.8%)	.	55 (14.6%)	.	81 (12.8%)	.	164 (12.5%)	.
	Severe Dyslipidemia (>=160 to <190 mg/dl)	84 (3.7%)	78 (3.2%)	.	11 (2.9%)	.	24 (3.8%)	.	51 (3.9%)	.

		DTG N= 2,268	EVG/c N= 2,463	DTG vs. EVG/c p-value	RAL N= 377	DTG vs. RAL p-value	DRV(/r/c) N= 634	DTG vs. DRV(/r/c) p-value	RPV N= 1,314	DTG vs. RPV p-value
	Very Severe Dyslipidemia (≥190 mg/dl)	29 (1.3%)	28 (1.1%)	.	1 (0.3%)	.	6 (0.9%)	.	11 (0.8%)	.
	Missing	101 (4.5%)	122 (5.0%)	.	19 (5.0%)	.	28 (4.4%)	.	49 (3.7%)	.
HDL, mg/dL	Normal (≥60 mg/dl)	540 (23.8%)	544 (22.1%)	0.0022	72 (19.1%)	0.0140	128 (20.2%)	0.0867	293 (22.3%)	0.1189
	Borderline Abnormal (≥40 to <60 mg/dl)	1074 (47.4%)	1274 (51.7%)	.	169 (44.8%)	.	333 (52.5%)	.	642 (48.9%)	.
	Dyslipidemia (<40 mg/dl)	646 (28.5%)	625 (25.4%)	.	136 (36.1%)	.	170 (26.8%)	.	367 (27.9%)	.
	Missing	8 (0.4%)	20 (0.8%)	.	0 (0.0%)	.	3 (0.5%)	.	12 (0.9%)	.
Triglycerides, mg/dL	Normal (<150 mg/dl)	1270 (56.0%)	1461 (59.3%)	0.1324	230 (61.0%)	0.2188	363 (57.3%)	0.4559	882 (67.1%)	<.0001
	Borderline Abnormal (≥150 to <200 mg/dl)	412 (18.2%)	420 (17.1%)	.	57 (15.1%)	.	107 (16.9%)	.	175 (13.3%)	.
	Dyslipidemia (≥200 to <500 mg/dl)	532 (23.5%)	518 (21.0%)	.	78 (20.7%)	.	149 (23.5%)	.	227 (17.3%)	.
	Severe Dyslipidemia (≥500 mg/dl)	51 (2.2%)	58 (2.4%)	.	12 (3.2%)	.	12 (1.9%)	.	29 (2.2%)	.
	Missing	3 (0.1%)	6 (0.2%)	.	0 (0.0%)	.	3 (0.5%)	.	1 (0.1%)	.

### 1.3. Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 6-months of follow-up (stratified by ART experience)

#### 1.3.1. Identification of the study population (subset of patients with a weight measurement between >3 and ≤9 months after core agent initiation)

Table 24. Identification of the study population

		Patients Included	%	Patients Excluded	%
1	Patients in Population 1b	21,554	.	0	.
2	Patients with follow-up measurement for weight available between >3 and ≤9 months after core agent initiation where the follow-up value for weight is <500 kg and the value for change in weight from baseline is <450 kg	19,959	92.6	1,595	7.4

Table 25. Study population by core agent of interest and ART experience

Core Agent	N (%)	ART experience	N (%)
DTG	6,700 (33.6%)	ART-naïve	1,968 (29.4%)
		ART-experienced	4,732 (70.6%)
		ART-experienced, suppressed	3,273 (48.9%)
EVG/c	7,598 (38.1%)	ART-naïve	2,432 (32.0%)
		ART-experienced	5,166 (68.0%)
		ART-experienced, suppressed	3,484 (45.9%)
RAL	737 ( 3.7%)	ART-naïve	112 (15.2%)
		ART-experienced	625 (84.8%)
		ART-experienced, suppressed	513 (69.6%)
RPV	2,996 (15.0%)	ART-naïve	690 (23.0%)
		ART-experienced	2,306 (77.0%)
		ART-experienced, suppressed	1,830 (61.1%)
DRV/r or DRV/c	1,928 ( 9.7%)	ART-naïve	549 (28.5%)
		ART-experienced	1,379 (71.5%)



Core Agent	N (%)	ART experience	N (%)
		ART-experienced, suppressed	880 (45.6%)

### 1.3.2. Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 6-months of follow-up (stratified by ART experience)

#### 1.3.2.1. Treatment-naïve patients

Table 26. Weight, BMI, and incident lipodystrophy at 6-months follow-up in ART-naïve patients

		Overall N= 5,751	DTG N= 1,968	EVG/c N= 2,432	DTG vs. EVG p-value	RAL N= 112	DTG vs. RAL p-value	DRV(/r/c) N= 549	DTG vs. DRV(/r/c) p-value	RPV N= 690	DTG vs. RPV p-value
Weight, kg	Median (IQR)	77.0 (68.0, 89.4)	76.2 (67.1, 88.5)	77.1 (68.3, 88.9)	0.0351	78.7 (67.8, 90.4)	0.4281	76.7 (67.0, 88.9)	0.5582	78.0 (68.9, 91.6)	0.0008
Change in weight from baseline, kg	Median (IQR)	1.7 (-0.9, 4.5)	1.8 (-0.9, 5.0)	1.8 (-0.9, 4.5)	0.6230	0.9 (-1.8, 4.3)	0.1211	2.1 (-0.7, 5.9)	0.0476	1.4 (-0.9, 3.6)	0.0034
	Mean (SD)	2.3 (6.3)	2.4 (6.2)	2.3 (6.2)	.	1.3 (4.7)	.	2.7 (8.7)	.	1.5 (4.8)	.
	No change ( $\pm$ <3 kg)	2967 (51.6%)	1016 (51.6%)	1253 (51.5%)	0.2223	55 (49.1%)	0.4134	240 (43.7%)	0.0079	403 (58.4%)	0.0007
	Weight increase 3 to <5 kg	864 (15.0%)	274 (13.9%)	391 (16.1%)	.	16 (14.3%)	.	80 (14.6%)	.	103 (14.9%)	.
	Weight increase $\geq$ 5 kg	1293 (22.5%)	457 (23.2%)	550 (22.6%)	.	22 (19.6%)	.	156 (28.4%)	.	108 (15.7%)	.
	Weight decrease 3 to <5 kg	347 (6.0%)	126 (6.4%)	137 (5.6%)	.	10 (8.9%)	.	35 (6.4%)	.	39 (5.7%)	.
	Weight decrease $\geq$ 5 kg	280 (4.9%)	95 (4.8%)	101 (4.2%)	.	9 (8.0%)	.	38 (6.9%)	.	37 (5.4%)	.

		Overall N= 5,751	DTG N= 1,968	EVG/c N= 2,432	DTG vs. EVG p-value	RAL N= 112	DTG vs. RAL p-value	DRV(/r/c) N= 549	DTG vs. DRV(/r/c) p-value	RPV N= 690	DTG vs. RPV p-value
Change in weight from baseline, %	Median (IQR)	2.1 (-1.1, 6.1)	2.2 (-1.2, 6.2)	2.2 (-1.0, 6.2)	0.8049	1.6 (-2.0, 5.2)	0.0953	2.8 (-0.8, 8.2)	0.0320	1.5 (-1.1, 4.6)	0.0011
	Mean (SD)	3.3 (8.9)	3.5 (9.0)	3.4 (9.0)	.	1.8 (6.4)	.	4.0 (10.6)	.	2.0 (6.3)	.
	No change (± <5%)	3576 (62.2%)	1230 (62.5%)	1505 (61.9%)	0.9020	68 (60.7%)	0.0811	290 (52.8%)	0.0002	483 (70.0%)	0.0005
	Weight increase ≥5%	1753 (30.5%)	601 (30.5%)	758 (31.2%)	.	30 (26.8%)	.	207 (37.7%)	.	157 (22.8%)	.
	Weight decrease ≥5%	422 (7.3%)	137 (7.0%)	169 (6.9%)	.	14 (12.5%)	.	52 (9.5%)	.	50 (7.2%)	.
BMI	Median (IQR)	25.6 (22.7, 29.3)	25.5 (22.6, 29.3)	25.5 (22.7, 28.8)	0.5231	26.0 (22.8, 30.3)	0.2670	25.5 (22.8, 29.7)	0.7859	26.3 (22.9, 30.6)	0.0029
Change in BMI from baseline	Median (IQR)	0.5 (-0.3, 1.6)	0.6 (-0.3, 1.7)	0.5 (-0.3, 1.5)	0.5435	0.4 (-0.7, 1.4)	0.1779	0.7 (-0.2, 1.9)	0.0213	0.4 (-0.3, 1.2)	0.0029
	Mean (SD)	0.8 (2.2)	0.8 (2.2)	0.8 (2.2)	.	0.4 (1.6)	.	0.9 (2.9)	.	0.5 (1.8)	.
Number of patients without lipodystrophy at baseline	Yes	5747 (99.9%)	1967 (99.9%)	2430 (99.9%)	1.0000	112 (100.0%)	1.0000	548 (99.8%)	0.3887	690 (100.0%)	1.0000
Number of incident cases of lipodystrophy	Yes	6 (0.1%)	3 (0.2%)	2 (0.1%)	0.6620	0 (0.0%)	1.0000	1 (0.2%)	1.0000	0 (0.0%)	0.5728

		Overall N= 5,751	DTG N= 1,968	EVG/c N= 2,432	DTG vs. EVG p-value	RAL N= 112	DTG vs. RAL p-value	DRV(/r/c) N= 549	DTG vs. DRV(/r/c) p-value	RPV N= 690	DTG vs. RPV p-value
Incident lipodystrophy	% (95% CI)	0.10 (0.04, 0.23)	0.15 (0.03, 0.45)	0.08 (0.01, 0.30)	.		.	0.18 (0.00, 1.01)	.		.

*Table 27. Changes in BMI category at 6-months follow-up in ART-naïve patients*

		Overall N= 5,751	DTG N= 1,968	EVG/c N= 2,432	DTG vs. EVG p-value	RAL N= 112	DTG vs. RAL p-value	DRV(/r/c) N= 549	DTG vs. DRV(/r/c) p-value	RPV N= 690	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	221 (3.8%)	82 (4.2%)	84 (3.5%)	0.2329	5 (4.5%)	0.8077	30 (5.5%)	0.1982	20 (2.9%)	0.1663
	Underweight (BMI: <18.5)	103 (46.6%)	36 (43.9%)	43 (51.2%)	0.3146	1 (20.0%)	0.4206	11 (36.7%)	0.6493	12 (60.0%)	0.1177
	Normal (BMI: 18.5 – 24.9)	112 (50.7%)	45 (54.9%)	37 (44.0%)	.	4 (80.0%)	.	19 (63.3%)	.	7 (35.0%)	.
	Overweight (BMI: 25.0- 29.9)	3 (1.4%)	0 (0.0%)	2 (2.4%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (5.0%)	.
	Obese (BMI: ≥30)	3 (1.4%)	1 (1.2%)	2 (2.4%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.

		Overall N= 5,751	DTG N= 1,968	EVG/c N= 2,432	DTG vs. EVG p-value	RAL N= 112	DTG vs. RAL p-value	DRV(/r/c) N= 549	DTG vs. DRV(/r/c) p-value	RPV N= 690	DTG vs. RPV p-value
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	2744 (47.7%)	924 (47.0%)	1225 (50.4%)	0.0241	43 (38.4%)	0.0773	259 (47.2%)	0.9254	293 (42.5%)	0.0418
	Underweight (BMI: <18.5)	32 (1.2%)	10 (1.1%)	12 (1.0%)	0.2272	2 (4.7%)	0.1707	6 (2.3%)	0.0096	2 (0.7%)	0.7234
	Normal (BMI: 18.5 – 24.9)	2198 (80.1%)	760 (82.3%)	966 (78.9%)	.	33 (76.7%)	.	190 (73.4%)	.	249 (85.0%)	.
	Overweight (BMI: 25.0-29.9)	490 (17.9%)	146 (15.8%)	235 (19.2%)	.	8 (18.6%)	.	60 (23.2%)	.	41 (14.0%)	.
	Obese (BMI: ≥30)	24 (0.9%)	8 (0.9%)	12 (1.0%)	.	0 (0.0%)	.	3 (1.2%)	.	1 (0.3%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	1732 (30.1%)	601 (30.5%)	732 (30.1%)	0.7522	38 (33.9%)	0.4494	163 (29.7%)	0.7023	198 (28.7%)	0.3636
	Underweight (BMI: <18.5)	1 (0.1%)	0 (0.0%)	1 (0.1%)	0.6563	0 (0.0%)	0.3438	0 (0.0%)	0.0009	0 (0.0%)	0.2126
	Normal (BMI: 18.5 – 24.9)	130 (7.5%)	45 (7.5%)	50 (6.8%)	.	5 (13.2%)	.	22 (13.5%)	.	8 (4.0%)	.
	Overweight (BMI: 25.0-29.9)	1354 (78.2%)	470 (78.2%)	588 (80.3%)	.	29 (76.3%)	.	104 (63.8%)	.	163 (82.3%)	.

		Overall N= 5,751	DTG N= 1,968	EVG/c N= 2,432	DTG vs. EVG p-value	RAL N= 112	DTG vs. RAL p-value	DRV(/r/c) N= 549	DTG vs. DRV(/r/c) p-value	RPV N= 690	DTG vs. RPV p-value
	Obese (BMI: ≥30)	247 (14.3%)	86 (14.3%)	93 (12.7%)	.	4 (10.5%)	.	37 (22.7%)	.	27 (13.6%)	.
Change in BMI Category: Baseline Obese (BMI: ≥ 30)	Overall	1054 (18.3%)	361 (18.3%)	391 (16.1%)	0.0471	26 (23.2%)	0.1976	97 (17.7%)	0.7170	179 (25.9%)	<.0001
	Underweight (BMI: <18.5)	1 (0.1%)	0 (0.0%)	0 (0.0%)	0.7453	0 (0.0%)	0.7946	1 (1.0%)	0.2590	0 (0.0%)	0.4395
	Normal (BMI: 18.5 – 24.9)	9 (0.9%)	5 (1.4%)	3 (0.8%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (0.6%)	.
	Overweight (BMI: 25.0- 29.9)	77 (7.3%)	29 (8.0%)	31 (7.9%)	.	1 (3.8%)	.	6 (6.2%)	.	10 (5.6%)	.
	Obese (BMI: ≥30)	967 (91.7%)	327 (90.6%)	357 (91.3%)	.	25 (96.2%)	.	90 (92.8%)	.	168 (93.9%)	.

Table 28. Changes in backbone agent at 6-months follow-up in ART-naïve patients

		Overall N= 5,751	DTG N= 1,968	EVG/c N= 2,432	DTG vs. EVG p-value	RAL N= 112	DTG vs. RAL p-value	DRV(/r/c) N= 549	DTG vs. DRV(/r/c) p-value	RPV N= 690	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 6 months) : Baseline TAF	Overall	1581 (27.5%)	230 (11.7%)	1066 (43.8%)	<.0001	7 (6.3%)	0.0782	147 (26.8%)	<.0001	131 (19.0%)	<.0001
	TAF at 6 months	1533 (97.0%)	210 (91.3%)	1046 (98.1%)	<.0001	5 (71.4%)	0.1299	142 (96.6%)	0.0552	130 (99.2%)	0.0016
	No TAF at 6 months	48 (3.0%)	20 (8.7%)	20 (1.9%)	.	2 (28.6%)	.	5 (3.4%)	.	1 (0.8%)	.
Change in Backbone Agent (concurrent TAF use at 6 months) : No Baseline TAF	Overall	4170 (72.5%)	1738 (88.3%)	1366 (56.2%)	<.0001	105 (93.8%)	0.0782	402 (73.2%)	<.0001	559 (81.0%)	<.0001
	TAF at 6 months	130 (3.1%)	28 (1.6%)	75 (5.5%)	<.0001	0 (0.0%)	0.4024	17 (4.2%)	0.0029	10 (1.8%)	0.8487
	No TAF at 6 months	4040 (96.9%)	1710 (98.4%)	1291 (94.5%)	.	105 (100.0%)	.	385 (95.8%)	.	549 (98.2%)	.
Change in Backbone Agent (TAF use at any point during follow-up)	TAF during follow-up	1581 (100.0%)	230 (100.0%)	1066 (100.0%)	.	7 (100.0%)	.	147 (100.0%)	.	131 (100.0%)	.

		Overall N= 5,751	DTG N= 1,968	EVG/c N= 2,432	DTG vs. EVG p-value	RAL N= 112	DTG vs. RAL p-value	DRV(/r/c) N= 549	DTG vs. DRV(/r/c) p-value	RPV N= 690	DTG vs. RPV p-value
follow-up) : Baseline TAF											
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	134 (3.2%)	29 (1.7%)	78 (5.7%)	<.0001	0 (0.0%)	0.4066	17 (4.2%)	0.0034	10 (1.8%)	0.8512
	No TAF during follow-up	4036 (96.8%)	1709 (98.3%)	1288 (94.3%)	.	105 (100.0%)	.	385 (95.8%)	.	549 (98.2%)	.

*Table 29. Weight, BMI, lipids, and incident lipodystrophy at 6-months follow-up in ART-naïve patients with at least one lipid test available*

		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
Weight, kg	Median (IQR)	77.4 (68.0, 90.0)	77.1 (67.6, 89.8)	77.1 (68.4, 88.9)	0.7302	79.8 (65.8, 92.6)	0.9408	77.3 (67.0, 89.8)	0.9558	80.7 (68.9, 94.0)	0.0114



		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
Change in weight from baseline, kg	Median (IQR)	1.8 (-0.9, 4.8)	1.8 (-0.9, 5.0)	1.8 (-0.6, 4.6)	0.8371	1.8 (-1.4, 4.5)	0.4822	2.6 (0.0, 6.4)	0.0133	1.2 (-0.9, 3.4)	0.0094
	Mean (SD)	2.4 (5.9)	2.5 (6.1)	2.4 (6.0)	.	1.6 (4.2)	.	3.5 (6.2)	.	1.5 (4.5)	.
	No change ( $\pm$ <3 kg)	1475 (51.3%)	477 (49.3%)	635 (52.8%)	0.0559	30 (51.7%)	0.8243	109 (41.0%)	0.1243	224 (58.6%)	0.0067
	Weight increase 3 to <5 kg	438 (15.2%)	140 (14.5%)	193 (16.1%)	.	10 (17.2%)	.	43 (16.2%)	.	52 (13.6%)	.
	Weight increase $\geq$ 5 kg	671 (23.3%)	239 (24.7%)	276 (23.0%)	.	11 (19.0%)	.	83 (31.2%)	.	62 (16.2%)	.
	Weight decrease 3 to <5 kg	161 (5.6%)	61 (6.3%)	57 (4.7%)	.	3 (5.2%)	.	19 (7.1%)	.	21 (5.5%)	.
	Weight decrease $\geq$ 5 kg	130 (4.5%)	50 (5.2%)	41 (3.4%)	.	4 (6.9%)	.	12 (4.5%)	.	23 (6.0%)	.
Change in weight from baseline, %	Median (IQR)	2.3 (-1.0, 6.2)	2.4 (-1.2, 6.7)	2.3 (-0.8, 6.2)	0.8787	2.1 (-1.9, 5.3)	0.3950	3.5 (0.0, 8.5)	0.0097	1.5 (-1.1, 4.5)	0.0042
	Mean (SD)	3.4 (8.0)	3.5 (8.1)	3.4 (8.3)	.	2.2 (5.9)	.	4.9 (9.1)	.	2.0 (6.1)	.
	No change ( $\pm$ <5%)	1787 (62.2%)	590 (61.0%)	754 (62.7%)	0.4229	35 (60.3%)	0.6422	138 (51.9%)	0.0210	270 (70.7%)	0.0010
	Weight increase $\geq$ 5%	894 (31.1%)	308 (31.9%)	378 (31.4%)	.	17 (29.3%)	.	108 (40.6%)	.	83 (21.7%)	.
	Weight decrease $\geq$ 5%	194 (6.7%)	69 (7.1%)	70 (5.8%)	.	6 (10.3%)	.	20 (7.5%)	.	29 (7.6%)	.

		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
BMI	Median (IQR)	25.9 (22.9, 29.7)	26.0 (23.0, 29.9)	25.7 (22.8, 28.7)	0.0187	27.1 (22.7, 31.4)	0.6327	25.6 (22.8, 30.1)	0.4482	26.7 (23.0, 31.1)	0.0701
Change in BMI from baseline	Median (IQR)	0.6 (-0.3, 1.6)	0.6 (-0.3, 1.8)	0.6 (-0.2, 1.5)	0.9348	0.7 (-0.5, 1.4)	0.4461	0.9 (0.0, 2.1)	0.0135	0.4 (-0.3, 1.2)	0.0115
	Mean (SD)	0.8 (2.1)	0.9 (2.2)	0.8 (2.1)	.	0.5 (1.5)	.	1.2 (2.3)	.	0.4 (1.7)	.
Number of patients without lipodystrophy at baseline	Yes	2872 (99.9%)	966 (99.9%)	1201 (99.9%)	1.0000	58 (100.0%)	1.0000	265 (99.6%)	0.3851	382 (100.0%)	1.0000
Number of incident cases of lipodystrophy	Yes	4 (0.1%)	2 (0.2%)	1 (0.1%)	0.5890	0 (0.0%)	1.0000	1 (0.4%)	0.5171	0 (0.0%)	1.0000
Incident lipodystrophy	% (95% CI)	0.14 (0.04, 0.36)	0.21 (0.03, 0.75)	0.08 (0.00, 0.46)	.		.	0.38 (0.01, 2.08)	.		.
Total Cholesterol, mg/dL	Median (IQR)	167.0 (144.0, 193.0)	167.0 (144.0, 191.0)	168.0 (146.0, 196.0)	0.1711	155.0 (129.0, 177.0)	0.0038	177.0 (148.0, 201.0)	0.0023	159.0 (138.0, 183.0)	0.0079
	Normal (<200 mg/dl)	2283 (79.4%)	775 (80.1%)	935 (77.8%)	0.3195	53 (91.4%)	0.2247	196 (73.7%)	0.0170	324 (84.8%)	0.0326
	Borderline Abnormal (≥200 to <240 mg/dl)	449 (15.6%)	147 (15.2%)	195 (16.2%)	.	5 (8.6%)	.	54 (20.3%)	.	48 (12.6%)	.

		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
	Dyslipidemia (>=240 to <280 mg/dl)	114 (4.0%)	35 (3.6%)	54 (4.5%)	.	0 (0.0%)	.	16 (6.0%)	.	9 (2.4%)	.
	Severe Dyslipidemia (>=280 mg/dl)	24 (0.8%)	10 (1.0%)	14 (1.2%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
	Missing	5 (0.2%)	0 (0.0%)	4 (0.3%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (0.3%)	.
LDL, mg/dL	Median (IQR)	92.4 (73.0, 114.0)	92.0 (72.0, 113.8)	94.0 (74.0, 115.6)	0.2562	85.0 (59.0, 99.0)	0.0143	95.0 (76.8, 120.0)	0.0500	90.0 (72.8, 108.0)	0.3514
	Normal (<100 mg/dl)	1652 (57.5%)	562 (58.1%)	677 (56.3%)	0.8206	43 (74.1%)	0.2711	133 (50.0%)	0.0137	237 (62.0%)	0.3711
	Borderline Abnormal (>=100 to <130 mg/dl)	750 (26.1%)	249 (25.7%)	316 (26.3%)	.	10 (17.2%)	.	78 (29.3%)	.	97 (25.4%)	.
	Dyslipidemia (>=130 to <160 mg/dl)	302 (10.5%)	98 (10.1%)	135 (11.2%)	.	3 (5.2%)	.	31 (11.7%)	.	35 (9.2%)	.
	Severe Dyslipidemia (>=160 to <190 mg/dl)	54 (1.9%)	16 (1.7%)	23 (1.9%)	.	1 (1.7%)	.	10 (3.8%)	.	4 (1.0%)	.
	Very Severe Dyslipidemia (>=190 mg/dl)	23 (0.8%)	12 (1.2%)	10 (0.8%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (0.3%)	.
	Missing	94 (3.3%)	30 (3.1%)	41 (3.4%)	.	1 (1.7%)	.	14 (5.3%)	.	8 (2.1%)	.

		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
HDL, mg/dL	Median (IQR)	45.0 (37.0, 54.0)	45.0 (36.0, 54.0)	44.0 (37.0, 54.0)	0.9986	40.5 (32.0, 50.0)	0.0181	46.0 (37.0, 56.0)	0.4073	45.0 (37.0, 54.0)	0.8022
	Normal ( $\geq 60$ mg/dl)	472 (16.4%)	149 (15.4%)	205 (17.1%)	0.5899	5 (8.6%)	0.1333	53 (19.9%)	0.3485	60 (15.7%)	0.4793
	Borderline Abnormal ( $\geq 40$ to $< 60$ mg/dl)	1430 (49.7%)	488 (50.5%)	595 (49.5%)	.	25 (43.1%)	.	126 (47.4%)	.	196 (51.3%)	.
	Dyslipidemia ( $< 40$ mg/dl)	960 (33.4%)	323 (33.4%)	397 (33.0%)	.	28 (48.3%)	.	86 (32.3%)	.	126 (33.0%)	.
	Missing	13 (0.5%)	7 (0.7%)	5 (0.4%)	.	0 (0.0%)	.	1 (0.4%)	.	0 (0.0%)	.
Triglycerides, mg/dL	Median (IQR)	114.0 (81.0, 176.0)	110.0 (79.5, 173.5)	118.0 (84.5, 179.0)	0.0296	123.0 (80.0, 191.0)	0.5716	125.0 (89.0, 193.0)	0.0044	102.0 (68.0, 148.0)	0.0006
	Normal ( $< 150$ mg/dl)	1903 (66.2%)	639 (66.1%)	773 (64.3%)	0.7656	38 (65.5%)	0.9009	163 (61.3%)	0.4669	290 (75.9%)	0.0045
	Borderline Abnormal ( $\geq 150$ to $< 200$ mg/dl)	412 (14.3%)	137 (14.2%)	186 (15.5%)	.	7 (12.1%)	.	38 (14.3%)	.	44 (11.5%)	.
	Dyslipidemia ( $\geq 200$ to $< 500$ mg/dl)	510 (17.7%)	171 (17.7%)	223 (18.6%)	.	12 (20.7%)	.	59 (22.2%)	.	45 (11.8%)	.
	Severe Dyslipidemia ( $\geq 500$ mg/dl)	43 (1.5%)	17 (1.8%)	18 (1.5%)	.	1 (1.7%)	.	5 (1.9%)	.	2 (0.5%)	.

		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
	Missing	7 (0.2%)	3 (0.3%)	2 (0.2%)	.	0 (0.0%)	.	1 (0.4%)	.	1 (0.3%)	.

*Table 30. Changes in BMI category at 6-months follow-up in ART-naïve patients with at least one lipid test available*

		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	102 (3.5%)	34 (3.5%)	36 (3.0%)	0.5417	3 (5.2%)	0.4608	14 (5.3%)	0.2096	15 (3.9%)	0.7471
	Underweight (BMI: <18.5)	50 (49.0%)	18 (52.9%)	20 (55.6%)	1.0000	0 (0.0%)	0.2297	3 (21.4%)	0.0596	9 (60.0%)	0.3091
	Normal (BMI: 18.5 – 24.9)	51 (50.0%)	16 (47.1%)	16 (44.4%)	.	3 (100.0%)	.	11 (78.6%)	.	5 (33.3%)	.
	Overweight (BMI: 25.0- 29.9)	1 (1.0%)	0 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (6.7%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	1299 (45.2%)	412 (42.6%)	598 (49.8%)	0.0009	20 (34.5%)	0.2236	125 (47.0%)	0.2013	144 (37.7%)	0.0988

		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
	Underweight (BMI: <18.5)	14 (1.1%)	4 (1.0%)	6 (1.0%)	0.3869	1 (5.0%)	0.4174	2 (1.6%)	0.4347	1 (0.7%)	0.8637
	Normal (BMI: 18.5 – 24.9)	1025 (78.9%)	334 (81.1%)	459 (76.8%)	.	16 (80.0%)	.	94 (75.2%)	.	122 (84.7%)	.
	Overweight (BMI: 25.0- 29.9)	245 (18.9%)	69 (16.7%)	126 (21.1%)	.	3 (15.0%)	.	27 (21.6%)	.	20 (13.9%)	.
	Obese (BMI: ≥30)	15 (1.2%)	5 (1.2%)	7 (1.2%)	.	0 (0.0%)	.	2 (1.6%)	.	1 (0.7%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	893 (31.1%)	314 (32.5%)	371 (30.9%)	0.4237	21 (36.2%)	0.5558	77 (28.9%)	0.2740	110 (28.8%)	0.1901
	Underweight (BMI: <18.5)	1 (0.1%)	0 (0.0%)	1 (0.3%)	0.6729	0 (0.0%)	0.6385	0 (0.0%)	0.0044	0 (0.0%)	0.2588
	Normal (BMI: 18.5 – 24.9)	61 (6.8%)	22 (7.0%)	22 (5.9%)	.	2 (9.5%)	.	12 (15.6%)	.	3 (2.7%)	.
	Overweight (BMI: 25.0- 29.9)	700 (78.4%)	247 (78.7%)	302 (81.4%)	.	15 (71.4%)	.	47 (61.0%)	.	89 (80.9%)	.
	Obese (BMI: ≥30)	131 (14.7%)	45 (14.3%)	46 (12.4%)	.	4 (19.0%)	.	18 (23.4%)	.	18 (16.4%)	.
Change in BMI	Overall	581 (20.2%)	207 (21.4%)	197 (16.4%)	0.0029	14 (24.1%)	0.6232	50 (18.8%)	0.3535	113 (29.6%)	0.0015

		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
Category: Baseline Obese (BMI: ≥ 30)											
	Normal (BMI: 18.5 – 24.9)	5 (0.9%)	2 (1.0%)	3 (1.5%)	0.7003	0 (0.0%)	1.0000	0 (0.0%)	0.5994	0 (0.0%)	0.8508
	Overweight (BMI: 25.0- 29.9)	44 (7.6%)	18 (8.7%)	14 (7.1%)	.	1 (7.1%)	.	2 (4.0%)	.	9 (8.0%)	.
	Obese (BMI: ≥30)	532 (91.6%)	187 (90.3%)	180 (91.4%)	.	13 (92.9%)	.	48 (96.0%)	.	104 (92.0%)	.

*Table 31. Changes in backbone agent at 6-months follow-up in ART-naïve patients with at least one lipid test available*

		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 6 months) : Baseline TAF	Overall	788 (27.4%)	101 (10.4%)	517 (43.0%)	<.0001	4 (6.9%)	0.5061	87 (32.7%)	<.0001	79 (20.7%)	<.0001

		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
	TAF at 6 months	764 (97.0%)	89 (88.1%)	508 (98.3%)	<.0001	3 (75.0%)	0.4155	86 (98.9%)	0.0034	78 (98.7%)	0.0071
	No TAF at 6 months	24 (3.0%)	12 (11.9%)	9 (1.7%)	.	1 (25.0%)	.	1 (1.1%)	.	1 (1.3%)	.
Change in Backbone Agent (concurrent TAF use at 6 months) : No Baseline TAF	Overall	2087 (72.6%)	866 (89.6%)	685 (57.0%)	<.0001	54 (93.1%)	0.5061	179 (67.3%)	<.0001	303 (79.3%)	<.0001
	TAF at 6 months	67 (3.2%)	13 (1.5%)	35 (5.1%)	<.0001	0 (0.0%)	1.0000	12 (6.7%)	0.0003	7 (2.3%)	0.4386
	No TAF at 6 months	2020 (96.8%)	853 (98.5%)	650 (94.9%)	.	54 (100.0%)	.	167 (93.3%)	.	296 (97.7%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : Baseline TAF	TAF during follow-up	788 (100.0%)	101 (100.0%)	517 (100.0%)	.	4 (100.0%)	.	87 (100.0%)	.	79 (100.0%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	68 (3.3%)	13 (1.5%)	36 (5.3%)	<.0001	0 (0.0%)	1.0000	12 (6.7%)	0.0003	7 (2.3%)	0.4386



		Overall N= 2,875	DTG N= 967	EVG/c N= 1,202	DTG vs. EVG p-value	RAL N= 58	DTG vs. RAL p-value	DRV(/r/c) N= 266	DTG vs. DRV(/r/c) p-value	RPV N= 382	DTG vs. RPV p-value
	No TAF during follow-up	2019 (96.7%)	853 (98.5%)	649 (94.7%)	.	54 (100.0%)	.	167 (93.3%)	.	296 (97.7%)	.

### 1.3.2.2. Treatment-experienced patients

Table 32. Weight, BMI, and incident lipodystrophy at 6-months follow-up in ART-experienced patients

		Overall N= 14,208	DTG N= 4,732	EVG/c N= 5,166	DTG vs. EVG p-value	RAL N= 625	DTG vs. RAL p-value	DRV(/r/c) N= 1,379	DTG vs. DRV(/r/c) p-value	RPV N= 2,306	DTG vs. RPV p-value
Weight, kg	Median (IQR)	79.8 (70.0, 91.2)	79.4 (69.5, 90.8)	79.4 (70.3, 90.7)	0.3876	79.6 (70.3, 91.9)	0.3436	79.4 (69.1, 90.7)	0.6434	80.7 (71.2, 92.1)	0.0014
Change in weight from baseline, kg	Median (IQR)	1.0 (-1.2, 3.6)	1.0 (-0.9, 3.6)	1.0 (-1.1, 3.6)	0.2140	0.7 (-1.8, 3.2)	0.0014	0.7 (-1.8, 3.6)	0.0006	1.2 (-1.0, 3.3)	0.3667
	Mean (SD)	1.2 (5.5)	1.4 (5.2)	1.2 (5.4)	.	0.8 (5.3)	.	0.8 (6.2)	.	1.1 (5.8)	.
	No change ( $\pm$ <3 kg)	8161 (57.4%)	2748 (58.1%)	2965 (57.4%)	0.4385	357 (57.1%)	0.0214	749 (54.3%)	<.0001	1342 (58.2%)	0.0003
	Weight increase 3 to <5 kg	2067 (14.5%)	666 (14.1%)	751 (14.5%)	.	86 (13.8%)	.	172 (12.5%)	.	392 (17.0%)	.

		Overall N= 14,208	DTG N= 4,732	EVG/c N= 5,166	DTG vs. EVG p-value	RAL N= 625	DTG vs. RAL p-value	DRV(/r/c) N= 1,379	DTG vs. DRV(/r/c) p-value	RPV N= 2,306	DTG vs. RPV p-value
	Weight increase $\geq 5$ kg	2115 (14.9%)	747 (15.8%)	773 (15.0%)	.	82 (13.1%)	.	227 (16.5%)	.	286 (12.4%)	.
	Weight decrease 3 to $< 5$ kg	987 (6.9%)	308 (6.5%)	365 (7.1%)	.	47 (7.5%)	.	106 (7.7%)	.	161 (7.0%)	.
	Weight decrease $\geq 5$ kg	878 (6.2%)	263 (5.6%)	312 (6.0%)	.	53 (8.5%)	.	125 (9.1%)	.	125 (5.4%)	.
Change in weight from baseline, %	Median (IQR)	1.3 (-1.5, 4.5)	1.4 (-1.3, 4.7)	1.4 (-1.4, 4.4)	0.1700	0.9 (-2.2, 4.0)	0.0007	0.8 (-2.3, 4.4)	0.0003	1.4 (-1.4, 4.3)	0.2073
	Mean (SD)	1.7 (7.1)	2.0 (6.8)	1.7 (6.7)	.	1.1 (7.0)	.	1.3 (8.0)	.	1.5 (8.0)	.
	No change ( $\pm < 5\%$ )	9830 (69.2%)	3280 (69.3%)	3577 (69.2%)	0.1496	431 (69.0%)	0.0075	893 (64.8%)	$< .0001$	1649 (71.5%)	0.0526
	Weight increase $\geq 5\%$	3126 (22.0%)	1081 (22.8%)	1133 (21.9%)	.	124 (19.8%)	.	320 (23.2%)	.	468 (20.3%)	.
	Weight decrease $\geq 5\%$	1252 (8.8%)	371 (7.8%)	456 (8.8%)	.	70 (11.2%)	.	166 (12.0%)	.	189 (8.2%)	.
BMI	Median (IQR)	26.3 (23.4, 29.9)	26.3 (23.5, 29.8)	26.2 (23.3, 29.7)	0.3018	26.5 (23.2, 30.1)	0.6728	26.5 (23.4, 30.0)	0.3718	26.7 (23.6, 30.5)	0.0063
Change in BMI from baseline	Median (IQR)	0.3 (-0.4, 1.2)	0.4 (-0.4, 1.2)	0.3 (-0.4, 1.2)	0.1648	0.2 (-0.6, 1.0)	0.0009	0.2 (-0.6, 1.2)	0.0010	0.4 (-0.4, 1.1)	0.2752
	Mean (SD)	0.4 (2.0)	0.5 (1.9)	0.4 (2.0)	.	0.2 (2.0)	.	0.3 (2.1)	.	0.3 (2.2)	.

		Overall N= 14,208	DTG N= 4,732	EVG/c N= 5,166	DTG vs. EVG p-value	RAL N= 625	DTG vs. RAL p-value	DRV(/r/c) N= 1,379	DTG vs. DRV(/r/c) p-value	RPV N= 2,306	DTG vs. RPV p-value
Number of patients without lipodystrophy at baseline	Yes	14072 (99.0%)	4680 (98.9%)	5129 (99.3%)	0.0439	606 (97.0%)	<.0001	1367 (99.1%)	0.4629	2290 (99.3%)	0.1030
Number of incident cases of lipodystrophy	Yes	38 (0.3%)	15 (0.3%)	13 (0.3%)	0.5737	1 (0.2%)	1.0000	5 (0.4%)	0.7901	4 (0.2%)	0.3352
Incident lipodystrophy	% (95% CI)	0.27 (0.19, 0.37)	0.32 (0.18, 0.53)	0.25 (0.14, 0.43)	.	0.17 (0.00, 0.92)	.	0.37 (0.12, 0.85)	.	0.17 (0.05, 0.45)	.

*Table 33. Changes in BMI category at 6-months follow-up in ART-experienced patients*

		Overall N= 14,208	DTG N= 4,732	EVG/c N= 5,166	DTG vs. EVG p-value	RAL N= 625	DTG vs. RAL p-value	DRV(/r/c) N= 1,379	DTG vs. DRV(/r/c) p-value	RPV N= 2,306	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	350 (2.5%)	120 (2.5%)	136 (2.6%)	0.7621	16 (2.6%)	0.9713	32 (2.3%)	0.6513	46 (2.0%)	0.1603
	Underweight (BMI: <18.5)	174 (49.7%)	57 (47.5%)	69 (50.7%)	0.2083	9 (56.3%)	0.8891	16 (50.0%)	0.7588	23 (50.0%)	0.0956
	Normal (BMI: 18.5 – 24.9)	168 (48.0%)	58 (48.3%)	66 (48.5%)	.	7 (43.8%)	.	16 (50.0%)	.	21 (45.7%)	.

		Overall N= 14,208	DTG N= 4,732	EVG/c N= 5,166	DTG vs. EVG p-value	RAL N= 625	DTG vs. RAL p-value	DRV(/r/c) N= 1,379	DTG vs. DRV(/r/c) p-value	RPV N= 2,306	DTG vs. RPV p-value
	Overweight (BMI: 25.0- 29.9)	6 (1.7%)	5 (4.2%)	1 (0.7%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
	Obese (BMI: ≥30)	2 (0.6%)	0 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	2 (4.3%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	5553 (39.1%)	1890 (39.9%)	2059 (39.9%)	0.9320	223 (35.7%)	0.0405	516 (37.4%)	0.0916	865 (37.5%)	0.0499
	Underweight (BMI: <18.5)	86 (1.5%)	26 (1.4%)	28 (1.4%)	0.9292	6 (2.7%)	0.3812	9 (1.7%)	0.7580	17 (2.0%)	0.6560
	Normal (BMI: 18.5 – 24.9)	4544 (81.8%)	1548 (81.9%)	1692 (82.2%)	.	182 (81.6%)	.	414 (80.2%)	.	708 (81.8%)	.
	Overweight (BMI: 25.0- 29.9)	902 (16.2%)	307 (16.2%)	332 (16.1%)	.	35 (15.7%)	.	91 (17.6%)	.	137 (15.8%)	.
	Obese (BMI: ≥30)	21 (0.4%)	9 (0.5%)	7 (0.3%)	.	0 (0.0%)	.	2 (0.4%)	.	3 (0.3%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	5174 (36.4%)	1712 (36.2%)	1880 (36.4%)	0.8261	243 (38.9%)	0.1874	506 (36.7%)	0.7268	833 (36.1%)	0.9634
	Underweight (BMI: <18.5)	11 (0.2%)	3 (0.2%)	3 (0.2%)	0.9809	0 (0.0%)	0.3273	4 (0.8%)	0.0977	1 (0.1%)	0.5943

		Overall N= 14,208	DTG N= 4,732	EVG/c N= 5,166	DTG vs. EVG p-value	RAL N= 625	DTG vs. RAL p-value	DRV(/r/c) N= 1,379	DTG vs. DRV(/r/c) p-value	RPV N= 2,306	DTG vs. RPV p-value
	Normal (BMI: 18.5 – 24.9)	431 (8.3%)	140 (8.2%)	159 (8.5%)	.	26 (10.7%)	.	49 (9.7%)	.	57 (6.8%)	.
	Overweight (BMI: 25.0- 29.9)	4148 (80.2%)	1379 (80.5%)	1506 (80.1%)	.	185 (76.1%)	.	404 (79.8%)	.	674 (80.9%)	.
	Obese (BMI: ≥30)	584 (11.3%)	190 (11.1%)	212 (11.3%)	.	32 (13.2%)	.	49 (9.7%)	.	101 (12.1%)	.
Change in BMI Category: Baseline Obese (BMI: ≥ 30)	Overall	3131 (22.0%)	1010 (21.3%)	1091 (21.1%)	0.7843	143 (22.9%)	0.3799	325 (23.6%)	0.0786	562 (24.4%)	0.0042
	Underweight (BMI: <18.5)	6 (0.2%)	1 (0.1%)	1 (0.1%)	0.0841	1 (0.7%)	0.1137	0 (0.0%)	0.9732	3 (0.5%)	0.0659
	Normal (BMI: 18.5 – 24.9)	24 (0.8%)	4 (0.4%)	15 (1.4%)	.	2 (1.4%)	.	1 (0.3%)	.	2 (0.4%)	.
	Overweight (BMI: 25.0- 29.9)	264 (8.4%)	90 (8.9%)	99 (9.1%)	.	11 (7.7%)	.	30 (9.2%)	.	34 (6.0%)	.
	Obese (BMI: ≥30)	2837 (90.6%)	915 (90.6%)	976 (89.5%)	.	129 (90.2%)	.	294 (90.5%)	.	523 (93.1%)	.

Table 34. Changes in backbone agent at 6-months follow-up in ART-experienced patients

		Overall N= 14,208	DTG N= 4,732	EVG/c N= 5,166	DTG vs. EVG p-value	RAL N= 625	DTG vs. RAL p-value	DRV(/r/c) N= 1,379	DTG vs. DRV(/r/c) p-value	RPV N= 2,306	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 6 months) : Baseline TAF	Overall	4335 (30.5%)	496 (10.5%)	2718 (52.6%)	<.0001	30 (4.8%)	<.0001	218 (15.8%)	<.0001	873 (37.9%)	<.0001
	TAF at 6 months	4277 (98.7%)	478 (96.4%)	2691 (99.0%)	<.0001	30 (100.0%)	0.6153	217 (99.5%)	0.0115	861 (98.6%)	0.0111
	No TAF at 6 months	58 (1.3%)	18 (3.6%)	27 (1.0%)	.	0 (0.0%)	.	1 (0.5%)	.	12 (1.4%)	.
Change in Backbone Agent (concurrent TAF use at 6 months) : No Baseline TAF	Overall	9873 (69.5%)	4236 (89.5%)	2448 (47.4%)	<.0001	595 (95.2%)	<.0001	1161 (84.2%)	<.0001	1433 (62.1%)	<.0001
	TAF at 6 months	373 (3.8%)	57 (1.3%)	190 (7.8%)	<.0001	11 (1.8%)	0.3293	39 (3.4%)	<.0001	76 (5.3%)	<.0001
	No TAF at 6 months	9500 (96.2%)	4179 (98.7%)	2258 (92.2%)	.	584 (98.2%)	.	1122 (96.6%)	.	1357 (94.7%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : Baseline TAF	TAF during follow-up	4335 (100.0%)	496 (100.0%)	2718 (100.0%)	.	30 (100.0%)	.	218 (100.0%)	.	873 (100.0%)	.

		Overall N= 14,208	DTG N= 4,732	EVG/c N= 5,166	DTG vs. EVG p-value	RAL N= 625	DTG vs. RAL p-value	DRV(/r/c) N= 1,379	DTG vs. DRV(/r/c) p-value	RPV N= 2,306	DTG vs. RPV p-value
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	382 (3.9%)	58 (1.4%)	193 (7.9%)	<.0001	11 (1.8%)	0.3560	41 (3.5%)	<.0001	79 (5.5%)	<.0001
	No TAF during follow-up	9491 (96.1%)	4178 (98.6%)	2255 (92.1%)	.	584 (98.2%)	.	1120 (96.5%)	.	1354 (94.5%)	.

Table 35. Weight, BMI, lipids, and incident lipodystrophy at 6-months follow-up in ART-experienced patients with at least one lipid test available

		Overall N= 8,361	DTG N= 2,763	EVG/c N= 3,057	DTG vs. EVG p-value	RAL N= 378	DTG vs. RAL p-value	DRV(/r/c) N= 790	DTG vs. DRV(/r/c) p-value	RPV N= 1,373	DTG vs. RPV p-value
Weight, kg	Median (IQR)	80.3 (70.8, 91.6)	80.3 (70.8, 91.6)	79.8 (70.9, 90.7)	0.4821	82.1 (72.6, 93.9)	0.0537	79.4 (69.9, 90.7)	0.1768	82.1 (71.7, 93.9)	0.0054
Change in weight from baseline, kg	Median (IQR)	1.0 (-1.1, 3.4)	1.0 (-0.9, 3.6)	1.0 (-1.0, 3.5)	0.7175	0.5 (-2.0, 3.2)	0.0009	0.5 (-1.8, 3.0)	0.0002	1.4 (-0.9, 3.3)	0.5994
	Mean (SD)	1.2 (5.4)	1.4 (5.0)	1.2 (5.4)	.	0.4 (4.8)	.	0.6 (6.0)	.	1.2 (5.8)	.
	No change ( $\pm$ <3 kg)	4892 (58.5%)	1641 (59.4%)	1765 (57.7%)	0.2894	217 (57.4%)	0.0545	457 (57.8%)	0.0001	812 (59.1%)	0.0031

		Overall N= 8,361	DTG N= 2,763	EVG/c N= 3,057	DTG vs. EVG p-value	RAL N= 378	DTG vs. RAL p-value	DRV(/r/c) N= 790	DTG vs. DRV(/r/c) p-value	RPV N= 1,373	DTG vs. RPV p-value
	Weight increase 3 to <5 kg	1178 (14.1%)	363 (13.1%)	445 (14.6%)	.	54 (14.3%)	.	84 (10.6%)	.	232 (16.9%)	.
	Weight increase ≥5 kg	1230 (14.7%)	437 (15.8%)	459 (15.0%)	.	46 (12.2%)	.	114 (14.4%)	.	174 (12.7%)	.
	Weight decrease 3 to <5 kg	566 (6.8%)	181 (6.6%)	210 (6.9%)	.	32 (8.5%)	.	62 (7.8%)	.	81 (5.9%)	.
	Weight decrease ≥5 kg	495 (5.9%)	141 (5.1%)	178 (5.8%)	.	29 (7.7%)	.	73 (9.2%)	.	74 (5.4%)	.
Change in weight from baseline, %	Median (IQR)	1.3 (-1.4, 4.3)	1.4 (-1.3, 4.4)	1.4 (-1.4, 4.3)	0.6653	0.5 (-2.4, 3.6)	0.0003	0.6 (-2.3, 3.7)	<.0001	1.6 (-1.1, 4.3)	0.8184
	Mean (SD)	1.7 (6.9)	1.9 (6.4)	1.7 (6.7)	.	0.7 (6.1)	.	1.0 (7.6)	.	1.7 (8.0)	.
	No change (± <5%)	5901 (70.6%)	1965 (71.1%)	2140 (70.0%)	0.1423	269 (71.2%)	0.0369	535 (67.7%)	<.0001	992 (72.3%)	0.3280
	Weight increase ≥5%	1766 (21.1%)	604 (21.9%)	660 (21.6%)	.	70 (18.5%)	.	157 (19.9%)	.	275 (20.0%)	.
	Weight decrease ≥5%	694 (8.3%)	194 (7.0%)	257 (8.4%)	.	39 (10.3%)	.	98 (12.4%)	.	106 (7.7%)	.
BMI	Median (IQR)	26.5 (23.8, 30.0)	26.6 (23.9, 30.0)	26.2 (23.5, 29.8)	0.0130	26.8 (23.9, 30.4)	0.2509	26.4 (23.5, 29.8)	0.2460	26.9 (24.0, 30.8)	0.0192
Change in BMI from baseline	Median (IQR)	0.3 (-0.4, 1.1)	0.4 (-0.4, 1.2)	0.3 (-0.4, 1.2)	0.6357	0.1 (-0.6, 1.0)	0.0005	0.2 (-0.7, 1.0)	0.0002	0.4 (-0.3, 1.1)	0.7960
	Mean (SD)	0.4 (2.0)	0.4 (1.8)	0.4 (2.0)	.	0.1 (1.6)	.	0.2 (2.1)	.	0.4 (2.1)	.



		Overall N= 8,361	DTG N= 2,763	EVG/c N= 3,057	DTG vs. EVG p-value	RAL N= 378	DTG vs. RAL p-value	DRV(/r/c) N= 790	DTG vs. DRV(/r/c) p-value	RPV N= 1,373	DTG vs. RPV p-value
Number of patients without lipodystrophy at baseline	Yes	8271 (98.9%)	2730 (98.8%)	3033 (99.2%)	0.1134	366 (96.8%)	0.0024	781 (98.9%)	0.8994	1361 (99.1%)	0.3497
Number of incident cases of lipodystrophy	Yes	26 (0.3%)	8 (0.3%)	11 (0.4%)	0.8188	1 (0.3%)	1.0000	2 (0.3%)	1.0000	4 (0.3%)	1.0000
Incident lipodystrophy	% (95% CI)	0.31 (0.21, 0.46)	0.29 (0.13, 0.58)	0.36 (0.18, 0.65)	.	0.27 (0.01, 1.51)	.	0.26 (0.03, 0.92)	.	0.29 (0.08, 0.75)	.
Total Cholesterol, mg/dL	Median (IQR)	174.0 (150.0, 200.0)	172.0 (148.0, 198.0)	179.0 (154.0, 206.0)	<.0001	168.0 (142.0, 198.0)	0.0689	177.0 (150.0, 204.0)	0.0027	168.0 (144.0, 192.0)	0.0002
	Normal (<200 mg/dl)	6211 (74.3%)	2102 (76.1%)	2137 (69.9%)	<.0001	285 (75.4%)	0.9343	567 (71.8%)	0.0144	1120 (81.6%)	0.0006
	Borderline Abnormal (>=200 to <240 mg/dl)	1602 (19.2%)	501 (18.1%)	679 (22.2%)	.	69 (18.3%)	.	161 (20.4%)	.	192 (14.0%)	.
	Dyslipidemia (>=240 to <280 mg/dl)	418 (5.0%)	130 (4.7%)	182 (6.0%)	.	19 (5.0%)	.	43 (5.4%)	.	44 (3.2%)	.
	Severe Dyslipidemia (>=280 mg/dl)	107 (1.3%)	24 (0.9%)	50 (1.6%)	.	4 (1.1%)	.	17 (2.2%)	.	12 (0.9%)	.
	Missing	23 (0.3%)	6 (0.2%)	9 (0.3%)	.	1 (0.3%)	.	2 (0.3%)	.	5 (0.4%)	.

		Overall N= 8,361	DTG N= 2,763	EVG/c N= 3,057	DTG vs. EVG p-value	RAL N= 378	DTG vs. RAL p-value	DRV(/r/c) N= 790	DTG vs. DRV(/r/c) p-value	RPV N= 1,373	DTG vs. RPV p-value
LDL, mg/dL	Median (IQR)	97.0 (77.0, 119.0)	95.8 (76.0, 118.0)	100.0 (80.0, 122.0)	<.0001	93.5 (72.0, 116.0)	0.0959	98.0 (78.0, 121.0)	0.1183	95.0 (76.0, 116.0)	0.2431
	Normal (<100 mg/dl)	4279 (51.2%)	1477 (53.5%)	1447 (47.3%)	<.0001	204 (54.0%)	0.3242	398 (50.4%)	0.0883	753 (54.8%)	0.0524
	Borderline Abnormal (≥100 to <130 mg/dl)	2450 (29.3%)	764 (27.7%)	936 (30.6%)	.	97 (25.7%)	.	240 (30.4%)	.	413 (30.1%)	.
	Dyslipidemia (≥130 to <160 mg/dl)	1004 (12.0%)	343 (12.4%)	398 (13.0%)	.	41 (10.8%)	.	83 (10.5%)	.	139 (10.1%)	.
	Severe Dyslipidemia (≥160 to <190 mg/dl)	265 (3.2%)	74 (2.7%)	117 (3.8%)	.	14 (3.7%)	.	29 (3.7%)	.	31 (2.3%)	.
	Very Severe Dyslipidemia (≥190 mg/dl)	77 (0.9%)	21 (0.8%)	32 (1.0%)	.	4 (1.1%)	.	10 (1.3%)	.	10 (0.7%)	.
	Missing	286 (3.4%)	84 (3.0%)	127 (4.2%)	.	18 (4.8%)	.	30 (3.8%)	.	27 (2.0%)	.
HDL, mg/dL	Median (IQR)	45.0 (37.0, 56.0)	45.0 (37.0, 56.0)	46.0 (38.0, 57.0)	0.0041	42.5 (35.0, 53.0)	0.0003	46.0 (37.0, 57.0)	0.5139	44.0 (36.0, 53.0)	0.0090
	Normal (≥60 mg/dl)	1540 (18.4%)	503 (18.2%)	631 (20.6%)	0.0249	50 (13.2%)	0.0049	157 (19.9%)	0.1544	199 (14.5%)	0.0239

		Overall N= 8,361	DTG N= 2,763	EVG/c N= 3,057	DTG vs. EVG p-value	RAL N= 378	DTG vs. RAL p-value	DRV(/r/c) N= 790	DTG vs. DRV(/r/c) p-value	RPV N= 1,373	DTG vs. RPV p-value
	Borderline Abnormal ( $\geq 40$ to $< 60$ mg/dl)	4084 (48.8%)	1339 (48.5%)	1505 (49.2%)	.	172 (45.5%)	.	382 (48.4%)	.	686 (50.0%)	.
	Dyslipidemia ( $< 40$ mg/dl)	2667 (31.9%)	894 (32.4%)	895 (29.3%)	.	154 (40.7%)	.	249 (31.5%)	.	475 (34.6%)	.
	Missing	70 (0.8%)	27 (1.0%)	26 (0.9%)	.	2 (0.5%)	.	2 (0.3%)	.	13 (0.9%)	.
Triglycerides, mg/dL	Median (IQR)	124.0 (86.0, 186.0)	122.0 (84.0, 185.0)	130.0 (90.0, 191.0)	$<.0001$	126.5 (85.0, 198.0)	0.1391	127.0 (89.0, 190.0)	0.0351	110.0 (77.0, 164.0)	$<.0001$
	Normal ( $< 150$ mg/dl)	5180 (62.0%)	1731 (62.6%)	1804 (59.0%)	0.0505	229 (60.6%)	0.2825	470 (59.5%)	0.3980	946 (68.9%)	0.0012
	Borderline Abnormal ( $\geq 150$ to $< 200$ mg/dl)	1398 (16.7%)	440 (15.9%)	558 (18.3%)	.	56 (14.8%)	.	147 (18.6%)	.	197 (14.3%)	.
	Dyslipidemia ( $\geq 200$ to $< 500$ mg/dl)	1643 (19.7%)	546 (19.8%)	640 (20.9%)	.	82 (21.7%)	.	161 (20.4%)	.	214 (15.6%)	.
	Severe Dyslipidemia ( $\geq 500$ mg/dl)	130 (1.6%)	42 (1.5%)	52 (1.7%)	.	11 (2.9%)	.	11 (1.4%)	.	14 (1.0%)	.
	Missing	10 (0.1%)	4 (0.1%)	3 (0.1%)	.	0 (0.0%)	.	1 (0.1%)	.	2 (0.1%)	.

Table 36. Changes in BMI category at 6-months follow-up in ART-experienced patients with at least one lipid test available

		Overall N= 8,361	DTG N= 2,763	EVG/c N= 3,057	DTG vs. EVG p-value	RAL N= 378	DTG vs. RAL p-value	DRV(/r/c) N= 790	DTG vs. DRV(/r/c) p-value	RPV N= 1,373	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	168 (2.0%)	49 (1.8%)	73 (2.4%)	0.1022	7 (1.9%)	0.9139	15 (1.9%)	0.8154	24 (1.7%)	0.9533
	Underweight (BMI: <18.5)	81 (48.2%)	23 (46.9%)	31 (42.5%)	0.2055	4 (57.1%)	1.0000	11 (73.3%)	0.2149	12 (50.0%)	0.5562
	Normal (BMI: 18.5 – 24.9)	84 (50.0%)	24 (49.0%)	42 (57.5%)	.	3 (42.9%)	.	4 (26.7%)	.	11 (45.8%)	.
	Overweight (BMI: 25.0- 29.9)	2 (1.2%)	2 (4.1%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
	Obese (BMI: ≥30)	1 (0.6%)	0 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (4.2%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	3110 (37.2%)	1012 (36.6%)	1202 (39.3%)	0.0346	117 (31.0%)	0.0311	302 (38.2%)	0.4111	477 (34.7%)	0.2342
	Underweight (BMI: <18.5)	45 (1.4%)	12 (1.2%)	19 (1.6%)	0.8085	4 (3.4%)	0.2282	6 (2.0%)	0.5672	4 (0.8%)	0.9438
	Normal (BMI: 18.5 – 24.9)	2532 (81.4%)	826 (81.6%)	978 (81.4%)	.	96 (82.1%)	.	239 (79.1%)	.	393 (82.4%)	.
	Overweight (BMI: 25.0- 29.9)	524 (16.8%)	170 (16.8%)	202 (16.8%)	.	17 (14.5%)	.	56 (18.5%)	.	79 (16.6%)	.

		Overall N= 8,361	DTG N= 2,763	EVG/c N= 3,057	DTG vs. EVG p-value	RAL N= 378	DTG vs. RAL p-value	DRV(/r/c) N= 790	DTG vs. DRV(/r/c) p-value	RPV N= 1,373	DTG vs. RPV p-value
	Obese (BMI: ≥30)	9 (0.3%)	4 (0.4%)	3 (0.2%)	.	0 (0.0%)	.	1 (0.3%)	.	1 (0.2%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	3149 (37.7%)	1077 (39.0%)	1130 (37.0%)	0.1136	153 (40.5%)	0.5760	284 (35.9%)	0.1224	505 (36.8%)	0.1707
	Underweight (BMI: <18.5)	7 (0.2%)	2 (0.2%)	2 (0.2%)	0.9669	0 (0.0%)	0.6456	2 (0.7%)	0.1778	1 (0.2%)	0.2780
	Normal (BMI: 18.5 – 24.9)	232 (7.4%)	82 (7.6%)	82 (7.3%)	.	15 (9.8%)	.	27 (9.5%)	.	26 (5.1%)	.
	Overweight (BMI: 25.0- 29.9)	2571 (81.6%)	875 (81.2%)	926 (81.9%)	.	120 (78.4%)	.	231 (81.3%)	.	419 (83.0%)	.
	Obese (BMI: ≥30)	339 (10.8%)	118 (11.0%)	120 (10.6%)	.	18 (11.8%)	.	24 (8.5%)	.	59 (11.7%)	.
Change in BMI Category: Baseline Obese (BMI: ≥ 30)	Overall	1934 (23.1%)	625 (22.6%)	652 (21.3%)	0.2342	101 (26.7%)	0.0762	189 (23.9%)	0.4419	367 (26.7%)	0.0036
	Underweight (BMI: <18.5)	2 (0.1%)	0 (0.0%)	0 (0.0%)	0.0439	0 (0.0%)	0.0432	0 (0.0%)	0.3875	2 (0.5%)	0.0237
	Normal (BMI: 18.5 – 24.9)	13 (0.7%)	1 (0.2%)	8 (1.2%)	.	2 (2.0%)	.	1 (0.5%)	.	1 (0.3%)	.

		Overall N= 8,361	DTG N= 2,763	EVG/c N= 3,057	DTG vs. EVG p-value	RAL N= 378	DTG vs. RAL p-value	DRV(/r/c) N= 790	DTG vs. DRV(/r/c) p-value	RPV N= 1,373	DTG vs. RPV p-value
	Overweight (BMI: 25.0- 29.9)	164 (8.5%)	61 (9.8%)	53 (8.1%)	.	7 (6.9%)	.	21 (11.1%)	.	22 (6.0%)	.
	Obese (BMI: ≥30)	1755 (90.7%)	563 (90.1%)	591 (90.6%)	.	92 (91.1%)	.	167 (88.4%)	.	342 (93.2%)	.

Table 37. Changes in backbone agent at 6-months follow-up in ART-experienced patients with at least one lipid test available

		Overall N= 8,361	DTG N= 2,763	EVG/c N= 3,057	DTG vs. EVG p-value	RAL N= 378	DTG vs. RAL p-value	DRV(/r/c) N= 790	DTG vs. DRV(/r/c) p-value	RPV N= 1,373	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 6 months) : Baseline TAF	Overall	2571 (30.7%)	277 (10.0%)	1616 (52.9%)	<.0001	13 (3.4%)	<.0001	129 (16.3%)	<.0001	536 (39.0%)	<.0001
	TAF at 6 months	2539 (98.8%)	268 (96.8%)	1599 (98.9%)	0.0086	13 (100.0%)	1.0000	129 (100.0%)	0.0627	530 (98.9%)	0.0504
	No TAF at 6 months	32 (1.2%)	9 (3.2%)	17 (1.1%)	.	0 (0.0%)	.	0 (0.0%)	.	6 (1.1%)	.
Change in Backbone Agent (concurrent TAF use at 6	Overall	5790 (69.3%)	2486 (90.0%)	1441 (47.1%)	<.0001	365 (96.6%)	<.0001	661 (83.7%)	<.0001	837 (61.0%)	<.0001

		Overall N= 8,361	DTG N= 2,763	EVG/c N= 3,057	DTG vs. EVG p-value	RAL N= 378	DTG vs. RAL p-value	DRV(/r/c) N= 790	DTG vs. DRV(/r/c) p-value	RPV N= 1,373	DTG vs. RPV p-value
months) : No Baseline TAF											
	TAF at 6 months	240 (4.1%)	32 (1.3%)	131 (9.1%)	<.0001	4 (1.1%)	1.0000	26 (3.9%)	<.0001	47 (5.6%)	<.0001
	No TAF at 6 months	5550 (95.9%)	2454 (98.7%)	1310 (90.9%)	.	361 (98.9%)	.	635 (96.1%)	.	790 (94.4%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : Baseline TAF	TAF during follow-up	2571 (100.0%)	277 (100.0%)	1616 (100.0%)	.	13 (100.0%)	.	129 (100.0%)	.	536 (100.0%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	247 (4.3%)	32 (1.3%)	134 (9.3%)	<.0001	4 (1.1%)	1.0000	27 (4.1%)	<.0001	50 (6.0%)	<.0001
	No TAF during follow-up	5543 (95.7%)	2454 (98.7%)	1307 (90.7%)	.	361 (98.9%)	.	634 (95.9%)	.	787 (94.0%)	.

### 1.3.2.3. Treatment-experienced, suppressed patients

Table 38. Weight, BMI, and incident lipodystrophy at 6-months follow-up in ART-experienced, suppressed patients

		Overall N= 9,980	DTG N= 3,273	EVG/c N= 3,484	DTG vs. EVG p-value	RAL N= 513	DTG vs. RAL p-value	DRV(/r/c) N= 880	DTG vs. DRV(/r/c) p-value	RPV N= 1,830	DTG vs. RPV p-value
Weight, kg	Median (IQR)	80.3 (70.9, 91.6)	80.3 (70.3, 91.4)	80.3 (71.2, 91.6)	0.1988	80.3 (70.8, 91.2)	0.7914	80.7 (70.8, 91.6)	0.2944	81.2 (71.7, 92.1)	0.0404
Change in weight from baseline, kg	Median (IQR)	0.9 (-1.3, 3.2)	0.9 (-1.0, 3.2)	0.9 (-1.1, 3.2)	0.8976	0.5 (-1.8, 2.7)	0.0020	0.5 (-2.0, 2.7)	<.0001	1.3 (-0.9, 3.4)	0.0408
	Mean (SD)	0.9 (5.1)	1.0 (4.8)	1.0 (5.0)	.	0.4 (4.8)	.	0.1 (6.1)	.	1.2 (5.5)	.
	No change ( $\pm$ <3 kg)	5974 (59.9%)	2000 (61.1%)	2068 (59.4%)	0.3382	310 (60.4%)	0.0833	516 (58.6%)	<.0001	1080 (59.0%)	0.0277
	Weight increase 3 to <5 kg	1446 (14.5%)	447 (13.7%)	512 (14.7%)	.	70 (13.6%)	.	109 (12.4%)	.	308 (16.8%)	.
	Weight increase ≥5 kg	1256 (12.6%)	431 (13.2%)	445 (12.8%)	.	53 (10.3%)	.	95 (10.8%)	.	232 (12.7%)	.
	Weight decrease 3 to <5 kg	685 (6.9%)	205 (6.3%)	250 (7.2%)	.	37 (7.2%)	.	73 (8.3%)	.	120 (6.6%)	.
	Weight decrease ≥5 kg	619 (6.2%)	190 (5.8%)	209 (6.0%)	.	43 (8.4%)	.	87 (9.9%)	.	90 (4.9%)	.



		Overall N= 9,980	DTG N= 3,273	EVG/c N= 3,484	DTG vs. EVG p-value	RAL N= 513	DTG vs. RAL p-value	DRV(/r/c) N= 880	DTG vs. DRV(/r/c) p-value	RPV N= 1,830	DTG vs. RPV p-value
Change in weight from baseline, %	Median (IQR)	1.2 (-1.5, 4.0)	1.2 (-1.4, 4.1)	1.3 (-1.4, 4.1)	0.9540	0.6 (-2.2, 3.5)	0.0010	0.5 (-2.4, 3.3)	<.0001	1.5 (-1.2, 4.3)	0.0907
	Mean (SD)	1.3 (6.5)	1.5 (6.2)	1.4 (6.2)	.	0.6 (6.2)	.	0.3 (7.2)	.	1.7 (7.6)	.
	No change (± <5%)	7195 (72.1%)	2386 (72.9%)	2496 (71.6%)	0.1278	369 (71.9%)	0.0215	618 (70.2%)	<.0001	1326 (72.5%)	0.8890
	Weight increase ≥5%	1923 (19.3%)	640 (19.6%)	678 (19.5%)	.	88 (17.2%)	.	149 (16.9%)	.	368 (20.1%)	.
	Weight decrease ≥5%	862 (8.6%)	247 (7.5%)	310 (8.9%)	.	56 (10.9%)	.	113 (12.8%)	.	136 (7.4%)	.
BMI	Median (IQR)	26.5 (23.7, 30.0)	26.5 (23.7, 29.9)	26.4 (23.7, 29.9)	0.9104	26.5 (23.3, 30.0)	0.7255	26.8 (23.9, 30.5)	0.0517	26.7 (23.8, 30.5)	0.0791
Change in BMI from baseline	Median (IQR)	0.3 (-0.4, 1.1)	0.3 (-0.4, 1.1)	0.3 (-0.4, 1.1)	0.8845	0.2 (-0.6, 0.9)	0.0015	0.1 (-0.7, 0.9)	<.0001	0.4 (-0.3, 1.1)	0.0620
	Mean (SD)	0.3 (1.9)	0.3 (1.7)	0.3 (1.8)	.	0.1 (1.7)	.	-0.0 (2.1)	.	0.4 (2.0)	.
Number of patients without lipodystrophy at baseline	Yes	9849 (98.7%)	3224 (98.5%)	3448 (99.0%)	0.0873	494 (96.3%)	0.0005	869 (98.8%)	0.5855	1814 (99.1%)	0.0571
Number of incident cases	Yes	31 (0.3%)	10 (0.3%)	12 (0.3%)	0.8336	1 (0.2%)	1.0000	5 (0.6%)	0.3372	3 (0.2%)	0.3997

		Overall N= 9,980	DTG N= 3,273	EVG/c N= 3,484	DTG vs. EVG p-value	RAL N= 513	DTG vs. RAL p-value	DRV(/r/c) N= 880	DTG vs. DRV(/r/c) p-value	RPV N= 1,830	DTG vs. RPV p-value
of lipodystrophy											
Incident lipodystrophy	% (95% CI)	0.31 (0.21, 0.45)	0.31 (0.15, 0.57)	0.35 (0.18, 0.61)	.	0.20 (0.01, 1.12)	.	0.58 (0.19, 1.34)	.	0.17 (0.03, 0.48)	.

Table 39. Changes in BMI category at 6-months follow-up in ART-experienced, suppressed patients

		Overall N= 9,980	DTG N= 3,273	EVG/c N= 3,484	DTG vs. EVG p-value	RAL N= 513	DTG vs. RAL p-value	DRV(/r/c) N= 880	DTG vs. DRV(/r/c) p-value	RPV N= 1,830	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	189 (1.9%)	61 (1.9%)	71 (2.0%)	0.6052	12 (2.3%)	0.4665	11 (1.3%)	0.2156	34 (1.9%)	0.9883
	Underweight (BMI: <18.5)	102 (54.0%)	33 (54.1%)	36 (50.7%)	0.4128	9 (75.0%)	0.4426	8 (72.7%)	0.7015	16 (47.1%)	0.2526
	Normal (BMI: 18.5 – 24.9)	82 (43.4%)	25 (41.0%)	34 (47.9%)	.	3 (25.0%)	.	3 (27.3%)	.	17 (50.0%)	.
	Overweight (BMI: 25.0- 29.9)	4 (2.1%)	3 (4.9%)	1 (1.4%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.

		Overall N= 9,980	DTG N= 3,273	EVG/c N= 3,484	DTG vs. EVG p-value	RAL N= 513	DTG vs. RAL p-value	DRV(/r/c) N= 880	DTG vs. DRV(/r/c) p-value	RPV N= 1,830	DTG vs. RPV p-value
	Obese (BMI: ≥30)	1 (0.5%)	0 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (2.9%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	3660 (36.7%)	1215 (37.1%)	1288 (37.0%)	0.8965	177 (34.5%)	0.2527	299 (34.0%)	0.0853	681 (37.2%)	0.9484
	Underweight (BMI: <18.5)	55 (1.5%)	15 (1.2%)	17 (1.3%)	0.5746	6 (3.4%)	0.1923	4 (1.3%)	0.7910	13 (1.9%)	0.3763
	Normal (BMI: 18.5 – 24.9)	3022 (82.6%)	1017 (83.7%)	1062 (82.5%)	.	145 (81.9%)	.	245 (81.9%)	.	553 (81.2%)	.
	Overweight (BMI: 25.0- 29.9)	576 (15.7%)	180 (14.8%)	208 (16.1%)	.	26 (14.7%)	.	50 (16.7%)	.	112 (16.4%)	.
	Obese (BMI: ≥30)	7 (0.2%)	3 (0.2%)	1 (0.1%)	.	0 (0.0%)	.	0 (0.0%)	.	3 (0.4%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	3832 (38.4%)	1278 (39.0%)	1346 (38.6%)	0.7278	208 (40.5%)	0.5180	336 (38.2%)	0.6403	664 (36.3%)	0.0513
	Underweight (BMI: <18.5)	9 (0.2%)	3 (0.2%)	2 (0.1%)	0.8737	0 (0.0%)	0.7180	3 (0.9%)	0.1094	1 (0.2%)	0.2619
	Normal (BMI: 18.5 – 24.9)	287 (7.5%)	101 (7.9%)	99 (7.4%)	.	21 (10.1%)	.	29 (8.6%)	.	37 (5.6%)	.

		Overall N= 9,980	DTG N= 3,273	EVG/c N= 3,484	DTG vs. EVG p-value	RAL N= 513	DTG vs. RAL p-value	DRV(/r/c) N= 880	DTG vs. DRV(/r/c) p-value	RPV N= 1,830	DTG vs. RPV p-value
	Overweight (BMI: 25.0- 29.9)	3123 (81.5%)	1036 (81.1%)	1093 (81.2%)	.	165 (79.3%)	.	278 (82.7%)	.	551 (83.0%)	.
	Obese (BMI: ≥30)	413 (10.8%)	138 (10.8%)	152 (11.3%)	.	22 (10.6%)	.	26 (7.7%)	.	75 (11.3%)	.
Change in BMI Category: Baseline Obese (BMI: ≥ 30)	Overall	2299 (23.0%)	719 (22.0%)	779 (22.4%)	0.6984	116 (22.6%)	0.7434	234 (26.6%)	0.0038	451 (24.6%)	0.0291
	Underweight (BMI: <18.5)	2 (0.1%)	0 (0.0%)	0 (0.0%)	0.0556	0 (0.0%)	0.0773	0 (0.0%)	0.6402	2 (0.4%)	0.0134
	Normal (BMI: 18.5 – 24.9)	16 (0.7%)	2 (0.3%)	11 (1.4%)	.	2 (1.7%)	.	1 (0.4%)	.	0 (0.0%)	.
	Overweight (BMI: 25.0- 29.9)	206 (9.0%)	71 (9.9%)	73 (9.4%)	.	8 (6.9%)	.	26 (11.1%)	.	28 (6.2%)	.
	Obese (BMI: ≥30)	2075 (90.3%)	646 (89.8%)	695 (89.2%)	.	106 (91.4%)	.	207 (88.5%)	.	421 (93.3%)	.

Table 40. Changes in backbone agent at 6-months follow-up in ART-experienced, suppressed patients

		Overall N= 9,980	DTG N= 3,273	EVG/c N= 3,484	DTG vs. EVG p-value	RAL N= 513	DTG vs. RAL p-value	DRV(/r/c) N= 880	DTG vs. DRV(/r/c) p-value	RPV N= 1,830	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 6 months) : Baseline TAF	Overall	3167 (31.7%)	340 (10.4%)	1950 (56.0%)	<.0001	26 (5.1%)	0.0001	123 (14.0%)	0.0027	728 (39.8%)	<.0001
	TAF at 6 months	3132 (98.9%)	331 (97.4%)	1932 (99.1%)	0.0125	26 (100.0%)	1.0000	123 (100.0%)	0.1207	720 (98.9%)	0.0689
	No TAF at 6 months	35 (1.1%)	9 (2.6%)	18 (0.9%)	.	0 (0.0%)	.	0 (0.0%)	.	8 (1.1%)	.
Change in Backbone Agent (concurrent TAF use at 6 months) : No Baseline TAF	Overall	6813 (68.3%)	2933 (89.6%)	1534 (44.0%)	<.0001	487 (94.9%)	0.0001	757 (86.0%)	0.0027	1102 (60.2%)	<.0001
	TAF at 6 months	293 (4.3%)	44 (1.5%)	143 (9.3%)	<.0001	11 (2.3%)	0.2178	29 (3.8%)	<.0001	66 (6.0%)	<.0001
	No TAF at 6 months	6520 (95.7%)	2889 (98.5%)	1391 (90.7%)	.	476 (97.7%)	.	728 (96.2%)	.	1036 (94.0%)	.
Change in Backbone Agent (TAF use at any point during follow-up)	TAF during follow-up	3167 (100.0%)	340 (100.0%)	1950 (100.0%)	.	26 (100.0%)	.	123 (100.0%)	.	728 (100.0%)	.

		Overall N= 9,980	DTG N= 3,273	EVG/c N= 3,484	DTG vs. EVG p-value	RAL N= 513	DTG vs. RAL p-value	DRV(/r/c) N= 880	DTG vs. DRV(/r/c) p-value	RPV N= 1,830	DTG vs. RPV p-value
follow-up) : Baseline TAF											
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	300 (4.4%)	45 (1.5%)	144 (9.4%)	<.0001	11 (2.3%)	0.2434	31 (4.1%)	<.0001	69 (6.3%)	<.0001
	No TAF during follow-up	6513 (95.6%)	2888 (98.5%)	1390 (90.6%)	.	476 (97.7%)	.	726 (95.9%)	.	1033 (93.7%)	.

*Table 41. Weight, BMI, lipids, and incident lipodystrophy at 6-months follow-up in ART-experienced, suppressed patients with at least one lipid test available*

		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
Weight, kg	Median (IQR)	81.0 (71.7, 92.1)	80.7 (71.2, 92.0)	80.3 (71.7, 91.6)	0.9119	82.1 (72.6, 92.7)	0.3143	80.7 (70.8, 92.1)	0.9148	82.1 (72.1, 93.9)	0.0332
Change in weight from baseline, kg	Median (IQR)	0.9 (-1.1, 3.2)	0.9 (-1.0, 3.2)	0.9 (-1.0, 3.2)	0.5845	0.3 (-1.9, 2.7)	0.0028	0.2 (-2.0, 2.4)	<.0001	1.4 (-0.9, 3.4)	0.0105

		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
	Mean (SD)	1.0 (5.1)	1.0 (4.8)	1.0 (4.9)	.	0.2 (4.5)	.	-0.1 (6.0)	.	1.3 (5.6)	.
	No change ( $\pm$ <3 kg)	3776 (60.5%)	1276 (61.7%)	1283 (59.3%)	0.3402	194 (60.6%)	0.1732	330 (61.6%)	0.0003	693 (60.1%)	0.0300
	Weight increase 3 to <5 kg	878 (14.1%)	264 (12.8%)	313 (14.5%)	.	46 (14.4%)	.	62 (11.6%)	.	193 (16.7%)	.
	Weight increase $\geq$ 5 kg	792 (12.7%)	281 (13.6%)	284 (13.1%)	.	31 (9.7%)	.	48 (9.0%)	.	148 (12.8%)	.
	Weight decrease 3 to <5 kg	428 (6.9%)	136 (6.6%)	157 (7.3%)	.	27 (8.4%)	.	45 (8.4%)	.	63 (5.5%)	.
	Weight decrease $\geq$ 5 kg	366 (5.9%)	111 (5.4%)	126 (5.8%)	.	22 (6.9%)	.	51 (9.5%)	.	56 (4.9%)	.
Change in weight from baseline, %	Median (IQR)	1.2 (-1.4, 3.9)	1.2 (-1.3, 4.0)	1.3 (-1.3, 4.1)	0.6961	0.4 (-2.3, 3.4)	0.0012	0.3 (-2.4, 2.8)	<.0001	1.6 (-1.0, 4.3)	0.0266
	Mean (SD)	1.3 (6.5)	1.5 (6.0)	1.4 (6.0)	.	0.4 (5.6)	.	0.1 (7.1)	.	1.8 (7.9)	.
	No change ( $\pm$ <5%)	4553 (73.0%)	1528 (73.9%)	1552 (71.8%)	0.0917	239 (74.7%)	0.2287	393 (73.3%)	<.0001	841 (72.9%)	0.8366
	Weight increase $\geq$ 5%	1176 (18.8%)	396 (19.1%)	423 (19.6%)	.	52 (16.3%)	.	75 (14.0%)	.	230 (19.9%)	.
	Weight decrease $\geq$ 5%	511 (8.2%)	144 (7.0%)	188 (8.7%)	.	29 (9.1%)	.	68 (12.7%)	.	82 (7.1%)	.

		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
BMI	Median (IQR)	26.7 (24.0, 30.2)	26.7 (24.0, 29.9)	26.5 (23.8, 29.9)	0.3164	26.8 (23.9, 30.3)	0.6275	26.6 (23.8, 30.4)	0.7852	26.8 (24.1, 30.9)	0.0732
Change in BMI from baseline	Median (IQR)	0.3 (-0.4, 1.1)	0.3 (-0.4, 1.1)	0.3 (-0.4, 1.1)	0.7618	0.1 (-0.6, 0.9)	0.0018	0.1 (-0.7, 0.8)	<.0001	0.4 (-0.3, 1.1)	0.0269
	Mean (SD)	0.3 (1.9)	0.3 (1.8)	0.3 (1.9)	.	0.0 (1.5)	.	-0.1 (2.2)	.	0.4 (2.1)	.
Number of patients without lipodystrophy at baseline	Yes	6154 (98.6%)	2037 (98.5%)	2140 (98.9%)	0.2069	308 (96.3%)	0.0048	528 (98.5%)	0.9912	1141 (99.0%)	0.2773
Number of incident cases of lipodystrophy	Yes	23 (0.4%)	6 (0.3%)	11 (0.5%)	0.3338	1 (0.3%)	1.0000	2 (0.4%)	0.6717	3 (0.3%)	1.0000
Incident lipodystrophy	% (95% CI)	0.37 (0.24, 0.56)	0.29 (0.11, 0.64)	0.51 (0.26, 0.92)	.	0.32 (0.01, 1.80)	.	0.38 (0.05, 1.36)	.	0.26 (0.05, 0.77)	.
Total Cholesterol, mg/dL	Median (IQR)	176.0 (151.0, 202.0)	174.0 (149.0, 200.0)	181.0 (158.0, 211.0)	<.0001	169.0 (142.0, 198.0)	0.0310	182.0 (157.0, 206.0)	0.0001	169.0 (144.0, 193.0)	<.0001
	Normal (<200 mg/dl)	4544 (72.8%)	1550 (75.0%)	1455 (67.3%)	<.0001	241 (75.3%)	0.5289	370 (69.0%)	0.0113	928 (80.5%)	0.0004
	Borderline Abnormal (≥200 to <240 mg/dl)	1269 (20.3%)	395 (19.1%)	526 (24.3%)	.	58 (18.1%)	.	120 (22.4%)	.	170 (14.7%)	.



		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
	Dyslipidemia (≥240 to <280 mg/dl)	331 (5.3%)	102 (4.9%)	139 (6.4%)	.	16 (5.0%)	.	33 (6.2%)	.	41 (3.6%)	.
	Severe Dyslipidemia (≥280 mg/dl)	84 (1.3%)	20 (1.0%)	39 (1.8%)	.	4 (1.3%)	.	12 (2.2%)	.	9 (0.8%)	.
	Missing	12 (0.2%)	1 (0.0%)	4 (0.2%)	.	1 (0.3%)	.	1 (0.2%)	.	5 (0.4%)	.
LDL, mg/dL	Median (IQR)	98.4 (78.0, 121.0)	96.6 (76.0, 119.0)	102.0 (82.0, 125.0)	<.0001	94.0 (72.0, 116.0)	0.0917	102.0 (80.7, 122.6)	0.0107	95.0 (76.2, 116.3)	0.1773
	Normal (<100 mg/dl)	3081 (49.4%)	1075 (52.0%)	963 (44.5%)	<.0001	172 (53.8%)	0.2465	242 (45.1%)	0.0013	629 (54.6%)	0.0569
	Borderline Abnormal (≥100 to <130 mg/dl)	1885 (30.2%)	589 (28.5%)	685 (31.7%)	.	80 (25.0%)	.	188 (35.1%)	.	343 (29.7%)	.
	Dyslipidemia (≥130 to <160 mg/dl)	786 (12.6%)	273 (13.2%)	301 (13.9%)	.	37 (11.6%)	.	55 (10.3%)	.	120 (10.4%)	.
	Severe Dyslipidemia (≥160 to <190 mg/dl)	209 (3.3%)	52 (2.5%)	94 (4.3%)	.	13 (4.1%)	.	19 (3.5%)	.	31 (2.7%)	.
	Very Severe Dyslipidemia (≥190 mg/dl)	62 (1.0%)	15 (0.7%)	27 (1.2%)	.	3 (0.9%)	.	8 (1.5%)	.	9 (0.8%)	.

		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
	Missing	217 (3.5%)	64 (3.1%)	93 (4.3%)	.	15 (4.7%)	.	24 (4.5%)	.	21 (1.8%)	.
HDL, mg/dL	Median (IQR)	46.0 (37.0, 56.0)	46.0 (37.0, 56.0)	47.0 (38.0, 58.0)	0.0027	43.0 (35.0, 52.0)	0.0004	47.0 (38.0, 57.0)	0.1130	44.0 (37.0, 53.0)	0.0064
	Normal ( $\geq 60$ mg/dl)	1179 (18.9%)	389 (18.8%)	469 (21.7%)	0.0335	41 (12.8%)	0.0069	110 (20.5%)	0.3160	170 (14.7%)	0.0263
	Borderline Abnormal ( $\geq 40$ to $< 60$ mg/dl)	3066 (49.1%)	1005 (48.6%)	1063 (49.1%)	.	151 (47.2%)	.	271 (50.6%)	.	576 (50.0%)	.
	Dyslipidemia ( $< 40$ mg/dl)	1942 (31.1%)	656 (31.7%)	611 (28.2%)	.	127 (39.7%)	.	153 (28.5%)	.	395 (34.3%)	.
	Missing	53 (0.8%)	18 (0.9%)	20 (0.9%)	.	1 (0.3%)	.	2 (0.4%)	.	12 (1.0%)	.
Triglycerides, mg/dL	Median (IQR)	126.0 (87.0, 189.0)	125.0 (87.0, 192.0)	134.0 (93.0, 193.0)	0.0010	129.0 (86.5, 200.5)	0.3755	131.0 (93.0, 196.0)	0.0501	113.5 (79.0, 166.5)	$< .0001$
	Normal ( $< 150$ mg/dl)	3790 (60.7%)	1261 (61.0%)	1240 (57.3%)	0.1051	193 (60.3%)	0.4363	312 (58.2%)	0.6404	784 (68.0%)	0.0005
	Borderline Abnormal ( $\geq 150$ to $< 200$ mg/dl)	1057 (16.9%)	335 (16.2%)	410 (19.0%)	.	47 (14.7%)	.	96 (17.9%)	.	169 (14.7%)	.
	Dyslipidemia ( $\geq 200$ to $< 500$ mg/dl)	1284 (20.6%)	435 (21.0%)	473 (21.9%)	.	70 (21.9%)	.	117 (21.8%)	.	189 (16.4%)	.

		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
	Severe Dyslipidemia ( $\geq 500$ mg/dl)	102 (1.6%)	35 (1.7%)	37 (1.7%)	.	10 (3.1%)	.	10 (1.9%)	.	10 (0.9%)	.
	Missing	7 (0.1%)	2 (0.1%)	3 (0.1%)	.	0 (0.0%)	.	1 (0.2%)	.	1 (0.1%)	.

Table 42. Changes in BMI category at 6-months follow-up in ART-experienced, suppressed patients with at least one lipid test available

		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	97 (1.6%)	26 (1.3%)	38 (1.8%)	0.1833	6 (1.9%)	0.3711	6 (1.1%)	0.7963	21 (1.8%)	0.2006
	Underweight (BMI: <18.5)	48 (49.5%)	13 (50.0%)	16 (42.1%)	0.1498	4 (66.7%)	0.7854	5 (83.3%)	0.4602	10 (47.6%)	0.6013
	Normal (BMI: 18.5 – 24.9)	46 (47.4%)	11 (42.3%)	22 (57.9%)	.	2 (33.3%)	.	1 (16.7%)	.	10 (47.6%)	.
	Overweight (BMI: 25.0- 29.9)	2 (2.1%)	2 (7.7%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
	Obese (BMI: $\geq 30$ )	1 (1.0%)	0 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (4.8%)	.
Change in BMI Category:	Overall	2191 (35.1%)	716 (34.6%)	792 (36.6%)	0.1760	97 (30.3%)	0.1300	186 (34.7%)	0.9728	400 (34.7%)	0.9684

		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
Baseline Normal (BMI: 18.5 – 24.9)											
	Underweight (BMI: <18.5)	30 (1.4%)	6 (0.8%)	13 (1.6%)	0.5244	4 (4.1%)	0.0788	4 (2.2%)	0.3369	3 (0.8%)	0.9687
	Normal (BMI: 18.5 – 24.9)	1791 (81.7%)	590 (82.4%)	647 (81.7%)	.	79 (81.4%)	.	148 (79.6%)	.	327 (81.8%)	.
	Overweight (BMI: 25.0- 29.9)	366 (16.7%)	118 (16.5%)	131 (16.5%)	.	14 (14.4%)	.	34 (18.3%)	.	69 (17.3%)	.
	Obese (BMI: ≥30)	4 (0.2%)	2 (0.3%)	1 (0.1%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (0.3%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	2457 (39.4%)	857 (41.4%)	849 (39.3%)	0.1466	133 (41.6%)	0.9673	198 (36.9%)	0.0586	420 (36.4%)	0.0053
	Underweight (BMI: <18.5)	6 (0.2%)	2 (0.2%)	1 (0.1%)	0.7597	0 (0.0%)	0.8062	2 (1.0%)	0.1207	1 (0.2%)	0.1586
	Normal (BMI: 18.5 – 24.9)	167 (6.8%)	63 (7.4%)	57 (6.7%)	.	12 (9.0%)	.	17 (8.6%)	.	18 (4.3%)	.
	Overweight (BMI: 25.0- 29.9)	2037 (82.9%)	708 (82.6%)	698 (82.2%)	.	109 (82.0%)	.	167 (84.3%)	.	355 (84.5%)	.
	Obese (BMI: ≥30)	247 (10.1%)	84 (9.8%)	93 (11.0%)	.	12 (9.0%)	.	12 (6.1%)	.	46 (11.0%)	.

		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
Change in BMI Category: Baseline Obese (BMI: >= 30)	Overall	1495 (24.0%)	469 (22.7%)	484 (22.4%)	0.8138	84 (26.3%)	0.1588	146 (27.2%)	0.0268	312 (27.1%)	0.0054
	Underweight (BMI: <18.5)	2 (0.1%)	0 (0.0%)	0 (0.0%)	0.0414	0 (0.0%)	0.0054	0 (0.0%)	0.1638	2 (0.6%)	0.0155
	Normal (BMI: 18.5 – 24.9)	7 (0.5%)	0 (0.0%)	4 (0.8%)	.	2 (2.4%)	.	1 (0.7%)	.	0 (0.0%)	.
	Overweight (BMI: 25.0-29.9)	133 (8.9%)	51 (10.9%)	39 (8.1%)	.	4 (4.8%)	.	19 (13.0%)	.	20 (6.4%)	.
	Obese (BMI: >=30)	1353 (90.5%)	418 (89.1%)	441 (91.1%)	.	78 (92.9%)	.	126 (86.3%)	.	290 (92.9%)	.

Table 43. Changes in backbone agent at 6-months follow-up in ART-experienced, suppressed patients with at least one lipid test available

		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 6 months) : Baseline TAF	Overall	1971 (31.6%)	205 (9.9%)	1217 (56.3%)	<.0001	11 (3.4%)	0.0002	76 (14.2%)	0.0046	462 (40.1%)	<.0001

		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
	TAF at 6 months	1952 (99.0%)	200 (97.6%)	1207 (99.2%)	0.0524	11 (100.0%)	1.0000	76 (100.0%)	0.3282	458 (99.1%)	0.1424
	No TAF at 6 months	19 (1.0%)	5 (2.4%)	10 (0.8%)	.	0 (0.0%)	.	0 (0.0%)	.	4 (0.9%)	.
Change in Backbone Agent (concurrent TAF use at 6 months) : No Baseline TAF	Overall	4269 (68.4%)	1863 (90.1%)	946 (43.7%)	<.0001	309 (96.6%)	0.0002	460 (85.8%)	0.0046	691 (59.9%)	<.0001
	TAF at 6 months	183 (4.3%)	27 (1.4%)	93 (9.8%)	<.0001	4 (1.3%)	1.0000	19 (4.1%)	0.0010	40 (5.8%)	<.0001
	No TAF at 6 months	4086 (95.7%)	1836 (98.6%)	853 (90.2%)	.	305 (98.7%)	.	441 (95.9%)	.	651 (94.2%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : Baseline TAF	TAF during follow-up	1971 (100.0%)	205 (100.0%)	1217 (100.0%)	.	11 (100.0%)	.	76 (100.0%)	.	462 (100.0%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	188 (4.4%)	27 (1.4%)	94 (9.9%)	<.0001	4 (1.3%)	1.0000	20 (4.3%)	0.0003	43 (6.2%)	<.0001

		Overall N= 6,240	DTG N= 2,068	EVG/c N= 2,163	DTG vs. EVG p-value	RAL N= 320	DTG vs. RAL p-value	DRV(/r/c) N= 536	DTG vs. DRV(/r/c) p-value	RPV N= 1,153	DTG vs. RPV p-value
	No TAF during follow-up	4081 (95.6%)	1836 (98.6%)	852 (90.1%)	.	305 (98.7%)	.	440 (95.7%)	.	648 (93.8%)	.

#### 1.4. Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 12-months of follow-up (stratified by ART experience)

##### 1.4.1. Identification of the study population (subset of patients with a weight measurement between >9 and ≤15 months after core agent initiation)

Table 44. Identification of the study population

		Patients Included	%	Patients Excluded	%
1	Patients in Population 1b	21,554	.	0	.
2	Patients with follow-up measurement for weight available between >9 and ≤15 months after core agent initiation where the follow-up value for weight is <500 kg and the value for change in weight from baseline is <450 kg	16,122	74.8	5,432	25.2

Table 45. Study population by core agent of interest and ART experience

Core Agent	N (%)	ART experience	N (%)
DTG	5,493 (34.1%)	ART-naïve	1,562 (28.4%)
		ART-experienced	3,931 (71.6%)
		ART-experienced, suppressed	2,757 (50.2%)
EVG/c	6,160 (38.2%)	ART-naïve	2,026 (32.9%)
		ART-experienced	4,134 (67.1%)
		ART-experienced, suppressed	2,774 (45.0%)
RAL	550 ( 3.4%)	ART-naïve	62 (11.3%)
		ART-experienced	488 (88.7%)
		ART-experienced, suppressed	402 (73.1%)
RPV	2,468 (15.3%)	ART-naïve	574 (23.3%)
		ART-experienced	1,894 (76.7%)
		ART-experienced, suppressed	1,513 (61.3%)
DRV/r or DRV/c	1,451 ( 9.0%)	ART-naïve	382 (26.3%)
		ART-experienced	1,069 (73.7%)



Core Agent	N (%)	ART experience	N (%)
		ART-experienced, suppressed	697 (48.0%)

### 1.4.2. Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 12-months of follow-up (stratified by ART experience)

#### 1.4.2.1. Treatment-naïve patients

Table 46. Weight, BMI, and incident lipodystrophy at 12-months follow-up in ART-naïve patients

		Overall N= 4,606	DTG N= 1,562	EVG/c N= 2,026	DTG vs. EVG p-value	RAL N= 62	DTG vs. RAL p-value	DRV(/r/c) N= 382	DTG vs. DRV(/r/c) p-value	RPV N= 574	DTG vs. RPV p-value
Weight, kg	Median (IQR)	78.5 (68.5, 90.7)	77.1 (67.6, 89.8)	78.5 (68.9, 90.7)	0.0762	83.9 (70.3, 95.3)	0.0423	79.2 (67.3, 93.3)	0.2609	80.8 (69.9, 95.0)	0.0002
Change in weight from baseline, kg	Median (IQR)	2.3 (-0.5, 6.4)	2.6 (-0.5, 6.4)	2.3 (-0.5, 6.6)	0.5931	2.3 (-1.4, 6.6)	0.5397	3.6 (-0.3, 8.8)	0.0100	1.8 (-1.4, 4.5)	<.0001
	Mean (SD)	3.4 (7.7)	3.6 (7.6)	3.5 (7.8)	.	2.9 (6.4)	.	4.7 (8.8)	.	2.1 (6.5)	.
	No change (± <3 kg)	1924 (41.8%)	639 (40.9%)	857 (42.3%)	0.6988	24 (38.7%)	0.7870	134 (35.1%)	0.0037	270 (47.0%)	0.0005
	Weight increase 3 to <5 kg	624 (13.5%)	218 (14.0%)	274 (13.5%)	.	7 (11.3%)	.	44 (11.5%)	.	81 (14.1%)	.
	Weight increase ≥5 kg	1484 (32.2%)	511 (32.7%)	662 (32.7%)	.	20 (32.3%)	.	158 (41.4%)	.	133 (23.2%)	.
	Weight decrease 3 to <5 kg	295 (6.4%)	107 (6.9%)	117 (5.8%)	.	6 (9.7%)	.	17 (4.5%)	.	48 (8.4%)	.
	Weight decrease ≥5 kg	279 (6.1%)	87 (5.6%)	116 (5.7%)	.	5 (8.1%)	.	29 (7.6%)	.	42 (7.3%)	.

		Overall N= 4,606	DTG N= 1,562	EVG/c N= 2,026	DTG vs. EVG p-value	RAL N= 62	DTG vs. RAL p-value	DRV(/r/c) N= 382	DTG vs. DRV(/r/c) p-value	RPV N= 574	DTG vs. RPV p-value
Change in weight from baseline, %	Median (IQR)	3.3 (-0.8, 8.5)	3.4 (-0.7, 8.8)	3.2 (-0.7, 8.6)	0.4393	3.0 (-1.6, 8.0)	0.3848	4.8 (-0.3, 12.4)	0.0075	2.2 (-2.1, 6.1)	<.0001
	Mean (SD)	4.9 (10.9)	5.1 (11.3)	4.9 (11.0)	.	3.9 (8.7)	.	6.9 (12.0)	.	2.8 (8.4)	.
	No change (± <5%)	2365 (51.3%)	782 (50.1%)	1054 (52.0%)	0.4259	32 (51.6%)	0.1832	157 (41.1%)	0.0072	340 (59.2%)	<.0001
	Weight increase ≥5%	1823 (39.6%)	648 (41.5%)	797 (39.3%)	.	21 (33.9%)	.	187 (49.0%)	.	170 (29.6%)	.
	Weight decrease ≥5%	418 (9.1%)	132 (8.5%)	175 (8.6%)	.	9 (14.5%)	.	38 (9.9%)	.	64 (11.1%)	.
BMI	Median (IQR)	26.0 (23.0, 29.8)	25.8 (22.8, 29.8)	25.9 (22.9, 29.4)	0.9166	27.7 (24.4, 32.1)	0.0126	26.1 (23.1, 30.5)	0.4027	26.9 (23.3, 31.2)	0.0037
Change in BMI from baseline	Median (IQR)	0.8 (-0.3, 2.2)	0.8 (-0.3, 2.2)	0.8 (-0.2, 2.2)	0.9779	0.7 (-0.4, 1.9)	0.5858	1.1 (-0.1, 2.9)	0.0061	0.6 (-0.5, 1.6)	<.0001
	Mean (SD)	1.1 (2.8)	1.2 (2.7)	1.2 (2.7)	.	0.9 (2.3)	.	1.6 (3.1)	.	0.5 (3.1)	.
Number of patients without lipodystrophy at baseline	Yes	4602 (99.9%)	1561 (99.9%)	2024 (99.9%)	1.0000	62 (100.0%)	1.0000	381 (99.7%)	0.3545	574 (100.0%)	1.0000
Number of incident cases of lipodystrophy	Yes	4 (0.1%)	1 (0.1%)	2 (0.1%)	1.0000	0 (0.0%)	1.0000	1 (0.3%)	0.3540	0 (0.0%)	1.0000

		Overall N= 4,606	DTG N= 1,562	EVG/c N= 2,026	DTG vs. EVG p-value	RAL N= 62	DTG vs. RAL p-value	DRV(/r/c) N= 382	DTG vs. DRV(/r/c) p-value	RPV N= 574	DTG vs. RPV p-value
Incident lipodystrophy	% (95% CI)	0.09 (0.02, 0.22)	0.06 (0.00, 0.36)	0.10 (0.01, 0.36)	.		.	0.26 (0.01, 1.45)	.		.

*Table 47. Changes in BMI category at 12-months follow-up in ART-naïve patients*

		Overall N= 4,606	DTG N= 1,562	EVG/c N= 2,026	DTG vs. EVG p-value	RAL N= 62	DTG vs. RAL p-value	DRV(/r/c) N= 382	DTG vs. DRV(/r/c) p-value	RPV N= 574	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	174 (3.8%)	60 (3.8%)	73 (3.6%)	0.7221	1 (1.6%)	0.7275	26 (6.8%)	0.0174	14 (2.4%)	0.1415
	Underweight (BMI: <18.5)	73 (42.0%)	19 (31.7%)	38 (52.1%)	0.0540	0 (0.0%)	1.0000	9 (34.6%)	1.0000	7 (50.0%)	0.7269
	Normal (BMI: 18.5 – 24.9)	91 (52.3%)	37 (61.7%)	30 (41.1%)	.	1 (100.0%)	.	16 (61.5%)	.	7 (50.0%)	.
	Overweight (BMI: 25.0- 29.9)	7 (4.0%)	2 (3.3%)	4 (5.5%)	.	0 (0.0%)	.	1 (3.8%)	.	0 (0.0%)	.
	Obese (BMI: ≥30)	3 (1.7%)	2 (3.3%)	1 (1.4%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.

		Overall N= 4,606	DTG N= 1,562	EVG/c N= 2,026	DTG vs. EVG p-value	RAL N= 62	DTG vs. RAL p-value	DRV(/r/c) N= 382	DTG vs. DRV(/r/c) p-value	RPV N= 574	DTG vs. RPV p-value
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	2167 (47.0%)	731 (46.8%)	1008 (49.8%)	0.0792	20 (32.3%)	0.0243	175 (45.8%)	0.7287	233 (40.6%)	0.0106
	Underweight (BMI: <18.5)	29 (1.3%)	11 (1.5%)	11 (1.1%)	0.4566	0 (0.0%)	0.8987	3 (1.7%)	0.5265	4 (1.7%)	0.9255
	Normal (BMI: 18.5 – 24.9)	1589 (73.3%)	546 (74.7%)	727 (72.1%)	.	15 (75.0%)	.	123 (70.3%)	.	178 (76.4%)	.
	Overweight (BMI: 25.0- 29.9)	501 (23.1%)	158 (21.6%)	248 (24.6%)	.	5 (25.0%)	.	43 (24.6%)	.	47 (20.2%)	.
	Obese (BMI: ≥30)	48 (2.2%)	16 (2.2%)	22 (2.2%)	.	0 (0.0%)	.	6 (3.4%)	.	4 (1.7%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	1396 (30.3%)	485 (31.0%)	607 (30.0%)	0.4820	25 (40.3%)	0.1229	110 (28.8%)	0.3915	169 (29.4%)	0.4749
	Normal (BMI: 18.5 – 24.9)	138 (9.9%)	50 (10.3%)	53 (8.7%)	0.2412	5 (20.0%)	0.2620	14 (12.7%)	0.0297	16 (9.5%)	0.0673
	Overweight (BMI: 25.0- 29.9)	970 (69.5%)	328 (67.6%)	439 (72.3%)	.	14 (56.0%)	.	60 (54.5%)	.	129 (76.3%)	.

		Overall N= 4,606	DTG N= 1,562	EVG/c N= 2,026	DTG vs. EVG p-value	RAL N= 62	DTG vs. RAL p-value	DRV(/r/c) N= 382	DTG vs. DRV(/r/c) p-value	RPV N= 574	DTG vs. RPV p-value
	Obese (BMI: ≥30)	288 (20.6%)	107 (22.1%)	115 (18.9%)	.	6 (24.0%)	.	36 (32.7%)	.	24 (14.2%)	.
Change in BMI Category: Baseline Obese (BMI: ≥ 30)	Overall	869 (18.9%)	286 (18.3%)	338 (16.7%)	0.2025	16 (25.8%)	0.1368	71 (18.6%)	0.9004	158 (27.5%)	<.0001
	Underweight (BMI: <18.5)	3 (0.3%)	0 (0.0%)	1 (0.3%)	0.3098	0 (0.0%)	0.7167	1 (1.4%)	0.2224	1 (0.6%)	0.1718
	Normal (BMI: 18.5 – 24.9)	7 (0.8%)	5 (1.7%)	2 (0.6%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
	Overweight (BMI: 25.0- 29.9)	80 (9.2%)	24 (8.4%)	36 (10.7%)	.	0 (0.0%)	.	4 (5.6%)	.	16 (10.1%)	.
	Obese (BMI: ≥30)	779 (89.6%)	257 (89.9%)	299 (88.5%)	.	16 (100.0%)	.	66 (93.0%)	.	141 (89.2%)	.

Table 48. Changes in backbone agent at 12-months follow-up in ART-naïve patients

		Overall N= 4,606	DTG N= 1,562	EVG/c N= 2,026	DTG vs. EVG p-value	RAL N= 62	DTG vs. RAL p-value	DRV(/r/c) N= 382	DTG vs. DRV(/r/c) p-value	RPV N= 574	DTG vs. RPV p-value
Change in Backbone Agent	Overall	1264 (27.4%)	183 (11.7%)	865 (42.7%)	<.0001	5 (8.1%)	0.5419	106 (27.7%)	<.0001	105 (18.3%)	0.0001

		Overall N= 4,606	DTG N= 1,562	EVG/c N= 2,026	DTG vs. EVG p-value	RAL N= 62	DTG vs. RAL p-value	DRV(/r/c) N= 382	DTG vs. DRV(/r/c) p-value	RPV N= 574	DTG vs. RPV p-value
(concurrent TAF use at 12 months) : Baseline TAF											
	TAF at 12 months	1231 (97.4%)	168 (91.8%)	852 (98.5%)	<.0001	4 (80.0%)	0.3622	104 (98.1%)	0.0358	103 (98.1%)	0.0360
	No TAF at 12 months	33 (2.6%)	15 (8.2%)	13 (1.5%)	.	1 (20.0%)	.	2 (1.9%)	.	2 (1.9%)	.
Change in Backbone Agent (concurrent TAF use at 12 months) : No Baseline TAF	Overall	3342 (72.6%)	1379 (88.3%)	1161 (57.3%)	<.0001	57 (91.9%)	0.5419	276 (72.3%)	<.0001	469 (81.7%)	0.0001
	TAF at 12 months	258 (7.7%)	32 (2.3%)	172 (14.8%)	<.0001	1 (1.8%)	1.0000	28 (10.1%)	<.0001	25 (5.3%)	0.0019
	No TAF at 12 months	3084 (92.3%)	1347 (97.7%)	989 (85.2%)	.	56 (98.2%)	.	248 (89.9%)	.	444 (94.7%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : Baseline TAF	TAF during follow-up	1264 (100.0%)	183 (100.0%)	865 (100.0%)	.	5 (100.0%)	.	106 (100.0%)	.	105 (100.0%)	.
Change in Backbone Agent (TAF	TAF during follow-up	270 (8.1%)	35 (2.5%)	178 (15.3%)	<.0001	1 (1.8%)	1.0000	29 (10.5%)	<.0001	27 (5.8%)	0.0016

		Overall N= 4,606	DTG N= 1,562	EVG/c N= 2,026	DTG vs. EVG p-value	RAL N= 62	DTG vs. RAL p-value	DRV(/r/c) N= 382	DTG vs. DRV(/r/c) p-value	RPV N= 574	DTG vs. RPV p-value
use at any point during follow-up) : No Baseline TAF											
	No TAF during follow-up	3072 (91.9%)	1344 (97.5%)	983 (84.7%)	.	56 (98.2%)	.	247 (89.5%)	.	442 (94.2%)	.

*Table 49. Weight, BMI, lipids, and incident lipodystrophy at 12-months follow-up in ART-naïve patients with at least one lipid test available*

		Overall N= 2,731	DTG N= 902	EVG/c N= 1,208	DTG vs. EVG p-value	RAL N= 36	DTG vs. RAL p-value	DRV(/r/c) N= 222	DTG vs. DRV(/r/c) p-value	RPV N= 363	DTG vs. RPV p-value
Weight, kg	Median (IQR)	79.0 (69.0, 91.6)	78.0 (68.5, 89.9)	78.7 (69.4, 90.7)	0.3533	86.4 (75.9, 98.0)	0.0085	80.1 (67.6, 97.5)	0.1296	82.1 (70.3, 95.7)	0.0011
Change in weight from baseline, kg	Median (IQR)	2.4 (-0.5, 6.4)	2.7 (-0.5, 6.6)	2.3 (-0.5, 6.5)	0.4201	3.2 (-1.0, 8.8)	0.5698	3.2 (-0.1, 8.6)	0.0445	2.0 (-1.3, 5.0)	0.0029
	Mean (SD)	3.4 (7.2)	3.5 (7.1)	3.3 (7.1)	.	4.2 (6.4)	.	5.0 (8.2)	.	2.4 (6.9)	.
	No change ( $\pm$ <3 kg)	1154 (42.3%)	381 (42.2%)	513 (42.5%)	0.5853	14 (38.9%)	0.8940	80 (36.0%)	0.1137	166 (45.7%)	0.0398



		Overall N= 2,731	DTG N= 902	EVG/c N= 1,208	DTG vs. EVG p-value	RAL N= 36	DTG vs. RAL p-value	DRV(/r/c) N= 222	DTG vs. DRV(/r/c) p-value	RPV N= 363	DTG vs. RPV p-value
	Weight increase 3 to <5 kg	366 (13.4%)	123 (13.6%)	161 (13.3%)	.	4 (11.1%)	.	27 (12.2%)	.	51 (14.0%)	.
	Weight increase ≥5 kg	883 (32.3%)	296 (32.8%)	392 (32.5%)	.	14 (38.9%)	.	91 (41.0%)	.	90 (24.8%)	.
	Weight decrease 3 to <5 kg	169 (6.2%)	59 (6.5%)	67 (5.5%)	.	3 (8.3%)	.	10 (4.5%)	.	30 (8.3%)	.
	Weight decrease ≥5 kg	159 (5.8%)	43 (4.8%)	75 (6.2%)	.	1 (2.8%)	.	14 (6.3%)	.	26 (7.2%)	.
Change in weight from baseline, %	Median (IQR)	3.3 (-0.7, 8.4)	3.4 (-0.6, 9.1)	3.2 (-0.8, 8.4)	0.3092	3.5 (-1.2, 11.9)	0.8387	4.7 (-0.1, 12.6)	0.0440	2.3 (-1.8, 6.4)	0.0005
	Mean (SD)	4.8 (10.0)	4.9 (9.8)	4.7 (10.0)	.	5.5 (9.0)	.	7.2 (11.5)	.	3.2 (9.0)	.
	No change (± <5%)	1409 (51.6%)	464 (51.4%)	627 (51.9%)	0.3129	19 (52.8%)	0.9401	96 (43.2%)	0.0872	203 (55.9%)	0.0015
	Weight increase ≥5%	1084 (39.7%)	373 (41.4%)	474 (39.2%)	.	14 (38.9%)	.	106 (47.7%)	.	117 (32.2%)	.
	Weight decrease ≥5%	238 (8.7%)	65 (7.2%)	107 (8.9%)	.	3 (8.3%)	.	20 (9.0%)	.	43 (11.8%)	.
BMI	Median (IQR)	26.2 (23.2, 30.1)	26.1 (23.2, 30.0)	25.9 (23.1, 29.5)	0.4474	28.1 (25.0, 32.8)	0.0181	26.7 (23.5, 31.1)	0.2540	27.1 (23.4, 31.5)	0.0475
Change in BMI from baseline	Median (IQR)	0.8 (-0.2, 2.2)	0.8 (-0.2, 2.3)	0.8 (-0.3, 2.2)	0.6316	1.2 (-0.3, 3.0)	0.5323	1.1 (-0.1, 3.0)	0.0267	0.6 (-0.4, 1.7)	0.0043
	Mean (SD)	1.1 (2.6)	1.1 (2.5)	1.1 (2.5)	.	1.4 (2.3)	.	1.7 (3.2)	.	0.7 (2.5)	.

		Overall N= 2,731	DTG N= 902	EVG/c N= 1,208	DTG vs. EVG p-value	RAL N= 36	DTG vs. RAL p-value	DRV(/r/c) N= 222	DTG vs. DRV(/r/c) p-value	RPV N= 363	DTG vs. RPV p-value
Number of patients without lipodystrophy at baseline	Yes	2727 (99.9%)	901 (99.9%)	1206 (99.8%)	1.0000	36 (100.0%)	1.0000	221 (99.5%)	0.3561	363 (100.0%)	1.0000
Number of incident cases of lipodystrophy	Yes	2 (0.1%)	0 (0.0%)	1 (0.1%)	1.0000	0 (0.0%)	.	1 (0.5%)	0.1970	0 (0.0%)	.
Incident lipodystrophy	% (95% CI)	0.07 (0.01, 0.26)		0.08 (0.00, 0.46)	.		.	0.45 (0.01, 2.50)	.		.
Total Cholesterol, mg/dL	Median (IQR)	168.0 (144.0, 194.0)	166.0 (144.0, 190.0)	174.0 (148.0, 198.0)	<.0001	151.0 (133.0, 176.5)	0.0630	178.5 (148.0, 207.0)	0.0035	157.0 (139.0, 182.0)	0.0016
	Normal (<200 mg/dl)	2161 (79.1%)	742 (82.3%)	918 (76.0%)	0.0078	33 (91.7%)	0.6659	155 (69.8%)	0.0007	313 (86.2%)	0.3544
	Borderline Abnormal (>=200 to <240 mg/dl)	421 (15.4%)	118 (13.1%)	208 (17.2%)	.	3 (8.3%)	.	51 (23.0%)	.	41 (11.3%)	.
	Dyslipidemia (>=240 to <280 mg/dl)	121 (4.4%)	32 (3.5%)	67 (5.5%)	.	0 (0.0%)	.	14 (6.3%)	.	8 (2.2%)	.
	Severe Dyslipidemia (>=280 mg/dl)	25 (0.9%)	9 (1.0%)	13 (1.1%)	.	0 (0.0%)	.	2 (0.9%)	.	1 (0.3%)	.
	Missing	3 (0.1%)	1 (0.1%)	2 (0.2%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.

		Overall N= 2,731	DTG N= 902	EVG/c N= 1,208	DTG vs. EVG p-value	RAL N= 36	DTG vs. RAL p-value	DRV(/r/c) N= 222	DTG vs. DRV(/r/c) p-value	RPV N= 363	DTG vs. RPV p-value
LDL, mg/dL	Median (IQR)	93.2 (74.0, 116.0)	91.0 (71.2, 112.0)	97.2 (78.0, 119.6)	<.0001	90.0 (71.0, 112.0)	0.5094	96.0 (73.0, 123.0)	0.0544	89.0 (73.0, 108.0)	0.4207
	Normal (<100 mg/dl)	1524 (55.8%)	538 (59.6%)	615 (50.9%)	0.0012	21 (58.3%)	0.5067	114 (51.4%)	0.0438	236 (65.0%)	0.4704
	Borderline Abnormal (≥100 to <130 mg/dl)	737 (27.0%)	232 (25.7%)	347 (28.7%)	.	13 (36.1%)	.	59 (26.6%)	.	86 (23.7%)	.
	Dyslipidemia (≥130 to <160 mg/dl)	287 (10.5%)	84 (9.3%)	145 (12.0%)	.	1 (2.8%)	.	32 (14.4%)	.	25 (6.9%)	.
	Severe Dyslipidemia (≥160 to <190 mg/dl)	74 (2.7%)	21 (2.3%)	44 (3.6%)	.	0 (0.0%)	.	4 (1.8%)	.	5 (1.4%)	.
	Very Severe Dyslipidemia (≥190 mg/dl)	27 (1.0%)	8 (0.9%)	11 (0.9%)	.	0 (0.0%)	.	5 (2.3%)	.	3 (0.8%)	.
	Missing	82 (3.0%)	19 (2.1%)	46 (3.8%)	.	1 (2.8%)	.	8 (3.6%)	.	8 (2.2%)	.
HDL, mg/dL	Median (IQR)	45.0 (37.0, 54.0)	45.0 (37.0, 55.0)	45.0 (38.0, 55.0)	0.8289	44.0 (32.0, 52.5)	0.1398	43.5 (34.0, 53.0)	0.0221	44.0 (37.0, 54.0)	0.3271
	Normal (≥60 mg/dl)	429 (15.7%)	145 (16.1%)	194 (16.1%)	0.9669	5 (13.9%)	0.5414	34 (15.3%)	0.1534	51 (14.0%)	0.8239
	Borderline Abnormal	1401 (51.3%)	470 (52.1%)	625 (51.7%)	.	16 (44.4%)	.	101 (45.5%)	.	189 (52.1%)	.

		Overall N= 2,731	DTG N= 902	EVG/c N= 1,208	DTG vs. EVG p-value	RAL N= 36	DTG vs. RAL p-value	DRV(/r/c) N= 222	DTG vs. DRV(/r/c) p-value	RPV N= 363	DTG vs. RPV p-value
	(>=40 to <60 mg/dl)										
	Dyslipidemia <40 mg/dl)	891 (32.6%)	284 (31.5%)	383 (31.7%)	.	15 (41.7%)	.	87 (39.2%)	.	122 (33.6%)	.
	Missing	10 (0.4%)	3 (0.3%)	6 (0.5%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (0.3%)	.
Triglycerides, mg/dL	Median (IQR)	116.0 (80.0, 174.0)	110.0 (78.0, 171.0)	123.0 (85.0, 179.0)	0.0014	112.0 (75.5, 171.0)	0.9106	132.0 (95.0, 203.0)	<.0001	99.0 (69.0, 147.0)	0.0003
	Normal (<150 mg/dl)	1828 (66.9%)	621 (68.8%)	776 (64.2%)	0.0191	25 (69.4%)	0.9524	131 (59.0%)	0.0370	275 (75.8%)	0.0572
	Borderline Abnormal >=150 to <200 mg/dl)	384 (14.1%)	110 (12.2%)	193 (16.0%)	.	5 (13.9%)	.	35 (15.8%)	.	41 (11.3%)	.
	Dyslipidemia >=200 to <500 mg/dl)	475 (17.4%)	161 (17.8%)	212 (17.5%)	.	6 (16.7%)	.	52 (23.4%)	.	44 (12.1%)	.
	Severe Dyslipidemia >=500 mg/dl)	41 (1.5%)	10 (1.1%)	24 (2.0%)	.	0 (0.0%)	.	4 (1.8%)	.	3 (0.8%)	.
	Missing	3 (0.1%)	0 (0.0%)	3 (0.2%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.

Table 50. Changes in BMI category at 12-months follow-up in ART-naïve patients with at least one lipid test available

		Overall N= 2,731	DTG N= 902	EVG/c N= 1,208	DTG vs. EVG p-value	RAL N= 36	DTG vs. RAL p-value	DRV(/r/c) N= 222	DTG vs. DRV(/r/c) p-value	RPV N= 363	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	96 (3.5%)	33 (3.7%)	38 (3.1%)	0.5431	0 (0.0%)	0.6332	13 (5.9%)	0.1829	12 (3.3%)	0.8674
	Underweight (BMI: <18.5)	39 (40.6%)	11 (33.3%)	19 (50.0%)	0.2487	0	.	3 (23.1%)	0.5215	6 (50.0%)	0.6252
	Normal (BMI: 18.5 – 24.9)	52 (54.2%)	21 (63.6%)	16 (42.1%)	.	0	.	9 (69.2%)	.	6 (50.0%)	.
	Overweight (BMI: 25.0-29.9)	4 (4.2%)	1 (3.0%)	2 (5.3%)	.	0	.	1 (7.7%)	.	0 (0.0%)	.
	Obese (BMI: ≥30)	1 (1.0%)	0 (0.0%)	1 (2.6%)	.	0	.	0 (0.0%)	.	0 (0.0%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	1239 (45.4%)	403 (44.7%)	583 (48.3%)	0.1027	12 (33.3%)	0.1790	101 (45.5%)	0.8264	140 (38.6%)	0.0470
	Underweight (BMI: <18.5)	16 (1.3%)	5 (1.2%)	5 (0.9%)	0.9091	0 (0.0%)	0.4475	2 (2.0%)	0.2947	4 (2.9%)	0.4639
	Normal (BMI: 18.5 – 24.9)	901 (72.7%)	294 (73.0%)	425 (72.9%)	.	7 (58.3%)	.	70 (69.3%)	.	105 (75.0%)	.

		Overall N= 2,731	DTG N= 902	EVG/c N= 1,208	DTG vs. EVG p-value	RAL N= 36	DTG vs. RAL p-value	DRV(/r/c) N= 222	DTG vs. DRV(/r/c) p-value	RPV N= 363	DTG vs. RPV p-value
	Overweight (BMI: 25.0- 29.9)	296 (23.9%)	96 (23.8%)	143 (24.5%)	.	5 (41.7%)	.	24 (23.8%)	.	28 (20.0%)	.
	Obese (BMI: ≥30)	26 (2.1%)	8 (2.0%)	10 (1.7%)	.	0 (0.0%)	.	5 (5.0%)	.	3 (2.1%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	851 (31.2%)	287 (31.8%)	378 (31.3%)	0.7967	15 (41.7%)	0.2149	61 (27.5%)	0.2102	110 (30.3%)	0.5994
	Normal (BMI: 18.5 – 24.9)	78 (9.2%)	23 (8.0%)	40 (10.6%)	0.4434	2 (13.3%)	0.4579	4 (6.6%)	0.1235	9 (8.2%)	0.6686
	Overweight (BMI: 25.0- 29.9)	595 (69.9%)	202 (70.4%)	266 (70.4%)	.	9 (60.0%)	.	36 (59.0%)	.	82 (74.5%)	.
	Obese (BMI: ≥30)	178 (20.9%)	62 (21.6%)	72 (19.0%)	.	4 (26.7%)	.	21 (34.4%)	.	19 (17.3%)	.
Change in BMI Category: Baseline Obese (BMI: ≥ 30)	Overall	545 (20.0%)	179 (19.8%)	209 (17.3%)	0.1357	9 (25.0%)	0.4486	47 (21.2%)	0.6587	101 (27.8%)	0.0020
	Underweight (BMI: <18.5)	1 (0.2%)	0 (0.0%)	1 (0.5%)	0.6322	0 (0.0%)	1.0000	0 (0.0%)	0.2746	0 (0.0%)	0.4270

		Overall N= 2,731	DTG N= 902	EVG/c N= 1,208	DTG vs. EVG p-value	RAL N= 36	DTG vs. RAL p-value	DRV(/r/c) N= 222	DTG vs. DRV(/r/c) p-value	RPV N= 363	DTG vs. RPV p-value
	Normal (BMI: 18.5 – 24.9)	6 (1.1%)	4 (2.2%)	2 (1.0%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
	Overweight (BMI: 25.0- 29.9)	44 (8.1%)	15 (8.4%)	19 (9.1%)	.	0 (0.0%)	.	1 (2.1%)	.	9 (8.9%)	.
	Obese (BMI: ≥30)	494 (90.6%)	160 (89.4%)	187 (89.5%)	.	9 (100.0%)	.	46 (97.9%)	.	92 (91.1%)	.

*Table 51. Changes in backbone agent at 12-months follow-up in ART-naïve patients with at least one lipid test available*

		Overall N= 2,731	DTG N= 902	EVG/c N= 1,208	DTG vs. EVG p-value	RAL N= 36	DTG vs. RAL p-value	DRV(/r/c) N= 222	DTG vs. DRV(/r/c) p-value	RPV N= 363	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 12 months) : Baseline TAF	Overall	747 (27.4%)	97 (10.8%)	519 (43.0%)	<.0001	4 (11.1%)	1.0000	63 (28.4%)	<.0001	64 (17.6%)	0.0014
	TAF at 12 months	725 (97.1%)	87 (89.7%)	511 (98.5%)	<.0001	3 (75.0%)	0.3742	62 (98.4%)	0.0511	62 (96.9%)	0.1265
	No TAF at 12 months	22 (2.9%)	10 (10.3%)	8 (1.5%)	.	1 (25.0%)	.	1 (1.6%)	.	2 (3.1%)	.
Change in Backbone	Overall	1984 (72.6%)	805 (89.2%)	689 (57.0%)	<.0001	32 (88.9%)	1.0000	159 (71.6%)	<.0001	299 (82.4%)	0.0014

		Overall N= 2,731	DTG N= 902	EVG/c N= 1,208	DTG vs. EVG p-value	RAL N= 36	DTG vs. RAL p-value	DRV(/r/c) N= 222	DTG vs. DRV(/r/c) p-value	RPV N= 363	DTG vs. RPV p-value
Agent (concurrent TAF use at 12 months) : No Baseline TAF											
	TAF at 12 months	169 (8.5%)	16 (2.0%)	110 (16.0%)	<.0001	1 (3.1%)	0.4879	24 (15.1%)	<.0001	18 (6.0%)	0.0013
	No TAF at 12 months	1815 (91.5%)	789 (98.0%)	579 (84.0%)	.	31 (96.9%)	.	135 (84.9%)	.	281 (94.0%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : Baseline TAF	TAF during follow-up	747 (100.0%)	97 (100.0%)	519 (100.0%)	.	4 (100.0%)	.	63 (100.0%)	.	64 (100.0%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	179 (9.0%)	18 (2.2%)	115 (16.7%)	<.0001	1 (3.1%)	0.5271	25 (15.7%)	<.0001	20 (6.7%)	0.0007
	No TAF during follow-up	1805 (91.0%)	787 (97.8%)	574 (83.3%)	.	31 (96.9%)	.	134 (84.3%)	.	279 (93.3%)	.



## 1.4.2.2. Treatment-experienced patients

Table 52. Weight, BMI, and incident lipodystrophy at 12-months follow-up in ART-experienced patients

		Overall N= 11,516	DTG N= 3,931	EVG/c N= 4,134	DTG vs. EVG p-value	RAL N= 488	DTG vs. RAL p-value	DRV(/t/c) N= 1,069	DTG vs. DRV(/t/c) p-value	RPV N= 1,894	DTG vs. RPV p-value
Weight, kg	Median (IQR)	80.4 (70.3, 92.1)	80.3 (70.0, 91.8)	80.0 (70.8, 91.6)	0.5508	81.2 (71.2, 92.3)	0.3186	80.7 (69.8, 92.2)	0.9691	81.2 (71.2, 93.0)	0.0273
Change in weight from baseline, kg	Median (IQR)	1.4 (-1.4, 4.5)	1.5 (-1.4, 4.5)	1.5 (-1.4, 4.5)	0.4351	0.9 (-2.0, 4.1)	0.0096	1.0 (-2.3, 5.0)	0.0155	1.6 (-1.0, 4.9)	0.3527
	Mean (SD)	1.8 (6.6)	1.8 (6.8)	1.9 (6.5)	.	1.1 (6.0)	.	1.6 (7.1)	.	1.9 (6.3)	.
	No change ( $\pm$ <3 kg)	5482 (47.6%)	1895 (48.2%)	1958 (47.4%)	0.4947	229 (46.9%)	0.0801	491 (45.9%)	0.0013	909 (48.0%)	0.0920
	Weight increase 3 to <5 kg	1658 (14.4%)	555 (14.1%)	631 (15.3%)	.	79 (16.2%)	.	118 (11.0%)	.	275 (14.5%)	.
	Weight increase $\geq$ 5 kg	2568 (22.3%)	865 (22.0%)	933 (22.6%)	.	87 (17.8%)	.	244 (22.8%)	.	439 (23.2%)	.
	Weight decrease 3 to <5 kg	890 (7.7%)	308 (7.8%)	308 (7.5%)	.	49 (10.0%)	.	113 (10.6%)	.	112 (5.9%)	.
	Weight decrease $\geq$ 5 kg	918 (8.0%)	308 (7.8%)	304 (7.4%)	.	44 (9.0%)	.	103 (9.6%)	.	159 (8.4%)	.
Change in weight from baseline, %	Median (IQR)	1.9 (-1.7, 5.9)	1.9 (-1.7, 5.9)	2.0 (-1.6, 6.0)	0.6178	1.4 (-2.5, 5.2)	0.0081	1.4 (-2.8, 5.9)	0.0090	2.0 (-1.3, 6.0)	0.5043

		Overall N= 11,516	DTG N= 3,931	EVG/c N= 4,134	DTG vs. EVG p-value	RAL N= 488	DTG vs. RAL p-value	DRV(/r/c) N= 1,069	DTG vs. DRV(/r/c) p-value	RPV N= 1,894	DTG vs. RPV p-value
	Mean (SD)	2.5 (8.5)	2.5 (8.8)	2.6 (7.9)	.	1.8 (7.9)	.	2.3 (9.8)	.	2.6 (8.4)	.
	No change ( $\pm <5\%$ )	6805 (59.1%)	2347 (59.7%)	2434 (58.9%)	0.6065	290 (59.4%)	0.0403	617 (57.7%)	0.0759	1117 (59.0%)	0.7399
	Weight increase $\geq 5\%$	3435 (29.8%)	1159 (29.5%)	1261 (30.5%)	.	128 (26.2%)	.	310 (29.0%)	.	577 (30.5%)	.
	Weight decrease $\geq 5\%$	1276 (11.1%)	425 (10.8%)	439 (10.6%)	.	70 (14.3%)	.	142 (13.3%)	.	200 (10.6%)	.
BMI	Median (IQR)	26.5 (23.6, 30.2)	26.5 (23.7, 30.0)	26.3 (23.5, 30.0)	0.3847	26.6 (23.5, 30.1)	0.8276	26.5 (23.7, 30.5)	0.3578	26.9 (23.7, 30.6)	0.0244
Change in BMI from baseline	Median (IQR)	0.5 (-0.5, 1.6)	0.5 (-0.5, 1.5)	0.5 (-0.4, 1.6)	0.3310	0.3 (-0.7, 1.3)	0.0112	0.4 (-0.8, 1.6)	0.0322	0.6 (-0.4, 1.6)	0.3565
	Mean (SD)	0.6 (2.4)	0.5 (2.5)	0.6 (2.3)	.	0.3 (2.3)	.	0.5 (2.5)	.	0.6 (2.4)	.
Number of patients without lipodystrophy at baseline	Yes	11404 (99.0%)	3887 (98.9%)	4106 (99.3%)	0.0349	470 (96.3%)	<.0001	1059 (99.1%)	0.6061	1882 (99.4%)	0.0751
Number of incident cases of lipodystrophy	Yes	56 (0.5%)	25 (0.6%)	18 (0.4%)	0.2242	2 (0.4%)	0.7621	7 (0.7%)	1.0000	4 (0.2%)	0.0292
Incident lipodystrophy	% (95% CI)	0.49 (0.37, 0.64)	0.64 (0.42, 0.95)	0.44 (0.26, 0.69)	.	0.43 (0.05, 1.53)	.	0.66 (0.27, 1.36)	.	0.21 (0.06, 0.54)	.

Table 53. Changes in BMI category at 12-months follow-up in ART-experienced patients

		Overall N= 11,516	DTG N= 3,931	EVG/c N= 4,134	DTG vs. EVG p-value	RAL N= 488	DTG vs. RAL p-value	DRV(/r/c) N= 1,069	DTG vs. DRV(/r/c) p-value	RPV N= 1,894	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	268 (2.3%)	99 (2.5%)	93 (2.2%)	0.4286	11 (2.3%)	0.7237	22 (2.1%)	0.3850	43 (2.3%)	0.5652
	Underweight (BMI: <18.5)	120 (44.8%)	45 (45.5%)	39 (41.9%)	0.6155	6 (54.5%)	0.4361	12 (54.5%)	0.7176	18 (41.9%)	0.2993
	Normal (BMI: 18.5 – 24.9)	137 (51.1%)	49 (49.5%)	52 (55.9%)	.	4 (36.4%)	.	9 (40.9%)	.	23 (53.5%)	.
	Overweight (BMI: 25.0- 29.9)	8 (3.0%)	4 (4.0%)	2 (2.2%)	.	1 (9.1%)	.	1 (4.5%)	.	0 (0.0%)	.
	Obese (BMI: ≥30)	3 (1.1%)	1 (1.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	2 (4.7%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	4474 (38.9%)	1524 (38.8%)	1669 (40.4%)	0.1410	172 (35.2%)	0.1312	403 (37.7%)	0.5239	706 (37.3%)	0.2721
	Underweight (BMI: <18.5)	69 (1.5%)	24 (1.6%)	20 (1.2%)	0.5137	5 (2.9%)	0.2287	10 (2.5%)	0.2147	10 (1.4%)	0.5949
	Normal (BMI: 18.5 – 24.9)	3438 (76.8%)	1154 (75.7%)	1295 (77.6%)	.	137 (79.7%)	.	303 (75.2%)	.	549 (77.8%)	.
	Overweight (BMI: 25.0- 29.9)	934 (20.9%)	335 (22.0%)	340 (20.4%)	.	29 (16.9%)	.	90 (22.3%)	.	140 (19.8%)	.

		Overall N= 11,516	DTG N= 3,931	EVG/c N= 4,134	DTG vs. EVG p-value	RAL N= 488	DTG vs. RAL p-value	DRV(/r/c) N= 1,069	DTG vs. DRV(/r/c) p-value	RPV N= 1,894	DTG vs. RPV p-value
	Obese (BMI: ≥30)	33 (0.7%)	11 (0.7%)	14 (0.8%)	.	1 (0.6%)	.	0 (0.0%)	.	7 (1.0%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	4196 (36.4%)	1447 (36.8%)	1479 (35.8%)	0.3346	193 (39.5%)	0.2375	390 (36.5%)	0.8440	687 (36.3%)	0.6900
	Underweight (BMI: <18.5)	8 (0.2%)	5 (0.3%)	0 (0.0%)	0.1665	0 (0.0%)	0.6513	1 (0.3%)	0.0218	2 (0.3%)	0.2345
	Normal (BMI: 18.5 – 24.9)	412 (9.8%)	141 (9.7%)	142 (9.6%)	.	23 (11.9%)	.	57 (14.6%)	.	49 (7.1%)	.
	Overweight (BMI: 25.0- 29.9)	3133 (74.7%)	1088 (75.2%)	1112 (75.2%)	.	139 (72.0%)	.	267 (68.5%)	.	527 (76.7%)	.
	Obese (BMI: ≥30)	643 (15.3%)	213 (14.7%)	225 (15.2%)	.	31 (16.1%)	.	65 (16.7%)	.	109 (15.9%)	.
Change in BMI Category: Baseline Obese (BMI: ≥ 30)	Overall	2578 (22.4%)	861 (21.9%)	893 (21.6%)	0.7429	112 (23.0%)	0.5982	254 (23.8%)	0.1957	458 (24.2%)	0.0516
	Underweight (BMI: <18.5)	7 (0.3%)	2 (0.2%)	3 (0.3%)	0.5270	1 (0.9%)	0.1212	0 (0.0%)	0.8153	1 (0.2%)	0.7820
	Normal (BMI: 18.5 – 24.9)	24 (0.9%)	5 (0.6%)	11 (1.2%)	.	2 (1.8%)	.	2 (0.8%)	.	4 (0.9%)	.

		Overall N= 11,516	DTG N= 3,931	EVG/c N= 4,134	DTG vs. EVG p-value	RAL N= 488	DTG vs. RAL p-value	DRV(/r/c) N= 1,069	DTG vs. DRV(/r/c) p-value	RPV N= 1,894	DTG vs. RPV p-value
	Overweight (BMI: 25.0- 29.9)	259 (10.0%)	90 (10.5%)	90 (10.1%)	.	15 (13.4%)	.	23 (9.1%)	.	41 (9.0%)	.
	Obese (BMI: ≥30)	2288 (88.8%)	764 (88.7%)	789 (88.4%)	.	94 (83.9%)	.	229 (90.2%)	.	412 (90.0%)	.

Table 54. Changes in backbone agent at 12-months follow-up in ART-experienced patients

		Overall N= 11,516	DTG N= 3,931	EVG/c N= 4,134	DTG vs. EVG p-value	RAL N= 488	DTG vs. RAL p-value	DRV(/r/c) N= 1,069	DTG vs. DRV(/r/c) p-value	RPV N= 1,894	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 12 months) : Baseline TAF	Overall	3473 (30.2%)	403 (10.3%)	2152 (52.1%)	<.0001	20 (4.1%)	<.0001	169 (15.8%)	<.0001	729 (38.5%)	<.0001
	TAF at 12 months	3415 (98.3%)	387 (96.0%)	2123 (98.7%)	0.0013	19 (95.0%)	0.5682	167 (98.8%)	0.1135	719 (98.6%)	0.0068
	No TAF at 12 months	58 (1.7%)	16 (4.0%)	29 (1.3%)	.	1 (5.0%)	.	2 (1.2%)	.	10 (1.4%)	.
Change in Backbone Agent (concurrent TAF use at	Overall	8043 (69.8%)	3528 (89.7%)	1982 (47.9%)	<.0001	468 (95.9%)	<.0001	900 (84.2%)	<.0001	1165 (61.5%)	<.0001

		Overall N= 11,516	DTG N= 3,931	EVG/c N= 4,134	DTG vs. EVG p-value	RAL N= 488	DTG vs. RAL p-value	DRV(/r/c) N= 1,069	DTG vs. DRV(/r/c) p-value	RPV N= 1,894	DTG vs. RPV p-value
12 months) : No Baseline TAF											
	TAF at 12 months	765 (9.5%)	133 (3.8%)	396 (20.0%)	<.0001	21 (4.5%)	0.4487	79 (8.8%)	<.0001	136 (11.7%)	<.0001
	No TAF at 12 months	7278 (90.5%)	3395 (96.2%)	1586 (80.0%)	.	447 (95.5%)	.	821 (91.2%)	.	1029 (88.3%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : Baseline TAF	TAF during follow-up	3473 (100.0%)	403 (100.0%)	2152 (100.0%)	.	20 (100.0%)	.	169 (100.0%)	.	729 (100.0%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	789 (9.8%)	134 (3.8%)	410 (20.7%)	<.0001	22 (4.7%)	0.3435	80 (8.9%)	<.0001	143 (12.3%)	<.0001
	No TAF during follow-up	7254 (90.2%)	3394 (96.2%)	1572 (79.3%)	.	446 (95.3%)	.	820 (91.1%)	.	1022 (87.7%)	.

Table 55. Weight, BMI, lipids, and incident lipodystrophy at 12-months follow-up in ART-experienced patients with at least one lipid test available

		Overall N= 7,223	DTG N= 2,451	EVG/c N= 2,622	DTG vs. EVG p-value	RAL N= 304	DTG vs. RAL p-value	DRV(/r/c) N= 663	DTG vs. DRV(/r/c) p-value	RPV N= 1,183	DTG vs. RPV p-value
Weight, kg	Median (IQR)	81.1 (71.2, 93.0)	80.7 (70.7, 92.7)	80.7 (71.6, 92.1)	0.6340	81.9 (72.5, 94.6)	0.1005	82.1 (70.8, 94.3)	0.1854	81.9 (72.1, 93.4)	0.0515
Change in weight from baseline, kg	Median (IQR)	1.5 (-1.4, 4.5)	1.5 (-1.3, 4.5)	1.8 (-1.1, 4.5)	0.2356	0.8 (-1.8, 4.1)	0.0158	1.0 (-2.3, 4.9)	0.0117	1.4 (-1.1, 4.5)	0.9112
	Mean (SD)	1.8 (6.6)	1.8 (6.8)	2.0 (6.6)	.	1.1 (6.1)	.	1.5 (7.1)	.	1.9 (6.1)	.
	No change ( $\pm$ <3 kg)	3467 (48.0%)	1190 (48.6%)	1257 (47.9%)	0.1725	145 (47.7%)	0.3400	308 (46.5%)	0.0028	567 (47.9%)	0.1814
	Weight increase 3 to <5 kg	1063 (14.7%)	344 (14.0%)	423 (16.1%)	.	47 (15.5%)	.	69 (10.4%)	.	180 (15.2%)	.
	Weight increase $\geq$ 5 kg	1589 (22.0%)	541 (22.1%)	584 (22.3%)	.	55 (18.1%)	.	147 (22.2%)	.	262 (22.1%)	.
	Weight decrease 3 to <5 kg	548 (7.6%)	193 (7.9%)	180 (6.9%)	.	28 (9.2%)	.	76 (11.5%)	.	71 (6.0%)	.
	Weight decrease $\geq$ 5 kg	556 (7.7%)	183 (7.5%)	178 (6.8%)	.	29 (9.5%)	.	63 (9.5%)	.	103 (8.7%)	.
Change in weight from baseline, %	Median (IQR)	1.9 (-1.7, 5.8)	1.9 (-1.6, 5.9)	2.1 (-1.4, 5.9)	0.3468	0.8 (-2.4, 5.1)	0.0110	1.3 (-2.8, 5.5)	0.0056	1.9 (-1.4, 5.7)	0.8875
	Mean (SD)	2.5 (8.5)	2.5 (8.9)	2.7 (7.8)	.	1.8 (8.0)	.	2.1 (9.7)	.	2.5 (8.3)	.
	No change ( $\pm$ <5%)	4318 (59.8%)	1470 (60.0%)	1566 (59.7%)	0.5575	184 (60.5%)	0.1239	394 (59.4%)	0.1632	704 (59.5%)	0.9638

		Overall N= 7,223	DTG N= 2,451	EVG/c N= 2,622	DTG vs. EVG p-value	RAL N= 304	DTG vs. RAL p-value	DRV(/r/c) N= 663	DTG vs. DRV(/r/c) p-value	RPV N= 1,183	DTG vs. RPV p-value
	Weight increase ≥5%	2140 (29.6%)	724 (29.5%)	801 (30.5%)	.	78 (25.7%)	.	183 (27.6%)	.	354 (29.9%)	.
	Weight decrease ≥5%	765 (10.6%)	257 (10.5%)	255 (9.7%)	.	42 (13.8%)	.	86 (13.0%)	.	125 (10.6%)	.
BMI	Median (IQR)	26.7 (23.9, 30.3)	26.7 (23.8, 30.2)	26.5 (23.8, 30.1)	0.4767	27.3 (23.7, 30.8)	0.1711	27.1 (24.1, 31.0)	0.0501	27.1 (24.0, 30.8)	0.0527
Change in BMI from baseline	Median (IQR)	0.5 (-0.4, 1.5)	0.5 (-0.4, 1.5)	0.6 (-0.4, 1.6)	0.1864	0.2 (-0.6, 1.3)	0.0231	0.4 (-0.8, 1.6)	0.0285	0.5 (-0.4, 1.6)	0.9227
	Mean (SD)	0.6 (2.4)	0.6 (2.5)	0.7 (2.3)	.	0.3 (2.3)	.	0.5 (2.5)	.	0.6 (2.4)	.
Number of patients without lipodystrophy at baseline	Yes	7140 (98.9%)	2421 (98.8%)	2599 (99.1%)	0.2248	291 (95.7%)	<.0001	656 (98.9%)	0.7229	1173 (99.2%)	0.3053
Number of incident cases of lipodystrophy	Yes	38 (0.5%)	17 (0.7%)	14 (0.5%)	0.4768	2 (0.7%)	1.0000	4 (0.6%)	1.0000	1 (0.1%)	0.0110
Incident lipodystrophy	% (95% CI)	0.53 (0.38, 0.73)	0.70 (0.41, 1.12)	0.54 (0.29, 0.90)	.	0.69 (0.08, 2.46)	.	0.61 (0.17, 1.55)	.	0.09 (0.00, 0.47)	.
Total Cholesterol, mg/dL	Median (IQR)	174.0 (150.0, 202.0)	171.0 (148.0, 199.5)	180.0 (156.0, 207.0)	<.0001	167.0 (143.0, 196.0)	0.0613	177.0 (156.0, 205.0)	<.0001	166.5 (146.0, 194.0)	0.0009
	Normal (<200 mg/dl)	5261 (72.8%)	1836 (74.9%)	1786 (68.1%)	<.0001	232 (76.3%)	0.8482	471 (71.0%)	0.0064	936 (79.1%)	0.0468



		Overall N= 7,223	DTG N= 2,451	EVG/c N= 2,622	DTG vs. EVG p-value	RAL N= 304	DTG vs. RAL p-value	DRV(/r/c) N= 663	DTG vs. DRV(/r/c) p-value	RPV N= 1,183	DTG vs. RPV p-value
	Borderline Abnormal (≥200 to <240 mg/dl)	1480 (20.5%)	479 (19.5%)	611 (23.3%)	.	54 (17.8%)	.	134 (20.2%)	.	202 (17.1%)	.
	Dyslipidemia (≥240 to <280 mg/dl)	373 (5.2%)	109 (4.4%)	169 (6.4%)	.	14 (4.6%)	.	45 (6.8%)	.	36 (3.0%)	.
	Severe Dyslipidemia (≥280 mg/dl)	95 (1.3%)	24 (1.0%)	51 (1.9%)	.	4 (1.3%)	.	8 (1.2%)	.	8 (0.7%)	.
	Missing	14 (0.2%)	3 (0.1%)	5 (0.2%)	.	0 (0.0%)	.	5 (0.8%)	.	1 (0.1%)	.
LDL, mg/dL	Median (IQR)	97.0 (78.0, 121.0)	95.0 (76.6, 119.0)	100.3 (80.0, 124.0)	<.0001	93.0 (73.0, 116.0)	0.0752	101.0 (79.0, 123.8)	0.0007	94.0 (76.0, 116.6)	0.4212
	Normal (<100 mg/dl)	3712 (51.4%)	1328 (54.2%)	1235 (47.1%)	<.0001	170 (55.9%)	0.1032	313 (47.2%)	0.0027	666 (56.3%)	0.1891
	Borderline Abnormal (≥100 to <130 mg/dl)	2027 (28.1%)	651 (26.6%)	771 (29.4%)	.	88 (28.9%)	.	199 (30.0%)	.	318 (26.9%)	.
	Dyslipidemia (≥130 to <160 mg/dl)	920 (12.7%)	296 (12.1%)	374 (14.3%)	.	23 (7.6%)	.	92 (13.9%)	.	135 (11.4%)	.
	Severe Dyslipidemia (≥160 to <190 mg/dl)	245 (3.4%)	71 (2.9%)	96 (3.7%)	.	10 (3.3%)	.	35 (5.3%)	.	33 (2.8%)	.

		Overall N= 7,223	DTG N= 2,451	EVG/c N= 2,622	DTG vs. EVG p-value	RAL N= 304	DTG vs. RAL p-value	DRV(/r/c) N= 663	DTG vs. DRV(/r/c) p-value	RPV N= 1,183	DTG vs. RPV p-value
	Very Severe Dyslipidemia (≥190 mg/dl)	73 (1.0%)	23 (0.9%)	34 (1.3%)	.	0 (0.0%)	.	7 (1.1%)	.	9 (0.8%)	.
	Missing	246 (3.4%)	82 (3.3%)	112 (4.3%)	.	13 (4.3%)	.	17 (2.6%)	.	22 (1.9%)	.
HDL, mg/dL	Median (IQR)	46.0 (38.0, 56.0)	45.0 (37.0, 55.0)	47.0 (39.0, 57.0)	<.0001	43.0 (35.0, 52.0)	0.0161	45.0 (37.0, 56.0)	0.6638	44.0 (37.0, 54.0)	0.1984
	Normal (≥60 mg/dl)	1298 (18.0%)	442 (18.0%)	502 (19.1%)	0.0084	47 (15.5%)	0.0773	130 (19.6%)	0.5593	177 (15.0%)	0.1015
	Borderline Abnormal (≥40 to <60 mg/dl)	3621 (50.1%)	1200 (49.0%)	1369 (52.2%)	.	141 (46.4%)	.	307 (46.3%)	.	604 (51.1%)	.
	Dyslipidemia (<40 mg/dl)	2256 (31.2%)	788 (32.2%)	735 (28.0%)	.	116 (38.2%)	.	222 (33.5%)	.	395 (33.4%)	.
	Missing	48 (0.7%)	21 (0.9%)	16 (0.6%)	.	0 (0.0%)	.	4 (0.6%)	.	7 (0.6%)	.
Triglycerides, mg/dL	Median (IQR)	125.0 (87.0, 186.0)	125.0 (86.0, 185.0)	130.0 (90.0, 194.0)	0.0051	132.0 (90.0, 194.0)	0.2346	127.0 (96.0, 190.0)	0.0462	111.0 (78.0, 162.0)	<.0001
	Normal (<150 mg/dl)	4463 (61.8%)	1527 (62.3%)	1531 (58.4%)	0.0398	183 (60.2%)	0.3305	407 (61.4%)	0.6248	815 (68.9%)	0.0001
	Borderline Abnormal (≥150 to <200 mg/dl)	1204 (16.7%)	404 (16.5%)	472 (18.0%)	.	49 (16.1%)	.	107 (16.1%)	.	172 (14.5%)	.

		Overall N= 7,223	DTG N= 2,451	EVG/c N= 2,622	DTG vs. EVG p-value	RAL N= 304	DTG vs. RAL p-value	DRV(/r/c) N= 663	DTG vs. DRV(/r/c) p-value	RPV N= 1,183	DTG vs. RPV p-value
	Dyslipidemia ( $\geq 200$ to $< 500$ mg/dl)	1423 (19.7%)	479 (19.5%)	557 (21.2%)	.	63 (20.7%)	.	141 (21.3%)	.	183 (15.5%)	.
	Severe Dyslipidemia ( $\geq 500$ mg/dl)	122 (1.7%)	39 (1.6%)	59 (2.3%)	.	8 (2.6%)	.	7 (1.1%)	.	9 (0.8%)	.
	Missing	11 (0.2%)	2 (0.1%)	3 (0.1%)	.	1 (0.3%)	.	1 (0.2%)	.	4 (0.3%)	.

Table 56. Changes in BMI category at 12-months follow-up in ART-experienced patients with at least one lipid test available

		Overall N= 7,223	DTG N= 2,451	EVG/c N= 2,622	DTG vs. EVG p-value	RAL N= 304	DTG vs. RAL p-value	DRV(/r/c) N= 663	DTG vs. DRV(/r/c) p-value	RPV N= 1,183	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: $< 18.5$ )	Overall	144 (2.0%)	55 (2.2%)	47 (1.8%)	0.2523	6 (2.0%)	0.7626	10 (1.5%)	0.2398	26 (2.2%)	0.9296
	Underweight (BMI: $< 18.5$ )	57 (39.6%)	23 (41.8%)	17 (36.2%)	0.3906	5 (83.3%)	0.0758	5 (50.0%)	0.8095	7 (26.9%)	0.2009
	Normal (BMI: 18.5 – 24.9)	78 (54.2%)	27 (49.1%)	29 (61.7%)	.	0 (0.0%)	.	4 (40.0%)	.	18 (69.2%)	.

		Overall N= 7,223	DTG N= 2,451	EVG/c N= 2,622	DTG vs. EVG p-value	RAL N= 304	DTG vs. RAL p-value	DRV(/r/c) N= 663	DTG vs. DRV(/r/c) p-value	RPV N= 1,183	DTG vs. RPV p-value
	Overweight (BMI: 25.0- 29.9)	7 (4.9%)	4 (7.3%)	1 (2.1%)	.	1 (16.7%)	.	1 (10.0%)	.	0 (0.0%)	.
	Obese (BMI: ≥30)	2 (1.4%)	1 (1.8%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (3.8%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	2688 (37.2%)	916 (37.4%)	1034 (39.4%)	0.1312	100 (32.9%)	0.1269	223 (33.6%)	0.0763	415 (35.1%)	0.1790
	Underweight (BMI: <18.5)	35 (1.3%)	13 (1.4%)	10 (1.0%)	0.6304	3 (3.0%)	0.3606	2 (0.9%)	0.7723	7 (1.7%)	0.4176
	Normal (BMI: 18.5 – 24.9)	2040 (75.9%)	690 (75.3%)	781 (75.5%)	.	79 (79.0%)	.	173 (77.6%)	.	317 (76.4%)	.
	Overweight (BMI: 25.0- 29.9)	590 (21.9%)	207 (22.6%)	232 (22.4%)	.	18 (18.0%)	.	48 (21.5%)	.	85 (20.5%)	.
	Obese (BMI: ≥30)	23 (0.9%)	6 (0.7%)	11 (1.1%)	.	0 (0.0%)	.	0 (0.0%)	.	6 (1.4%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	2679 (37.1%)	913 (37.3%)	959 (36.6%)	0.6186	118 (38.8%)	0.5947	252 (38.0%)	0.7201	437 (36.9%)	0.8561
	Underweight (BMI: <18.5)	6 (0.2%)	3 (0.3%)	0 (0.0%)	0.4188	0 (0.0%)	0.4278	1 (0.4%)	0.0564	2 (0.5%)	0.7089

		Overall N= 7,223	DTG N= 2,451	EVG/c N= 2,622	DTG vs. EVG p-value	RAL N= 304	DTG vs. RAL p-value	DRV(/r/c) N= 663	DTG vs. DRV(/r/c) p-value	RPV N= 1,183	DTG vs. RPV p-value
	Normal (BMI: 18.5 – 24.9)	250 (9.3%)	82 (9.0%)	83 (8.7%)	.	14 (11.9%)	.	37 (14.7%)	.	34 (7.8%)	.
	Overweight (BMI: 25.0- 29.9)	2023 (75.5%)	698 (76.5%)	733 (76.4%)	.	83 (70.3%)	.	178 (70.6%)	.	331 (75.7%)	.
	Obese (BMI: ≥30)	400 (14.9%)	130 (14.2%)	143 (14.9%)	.	21 (17.8%)	.	36 (14.3%)	.	70 (16.0%)	.
Change in BMI Category: Baseline Obese (BMI: ≥ 30)	Overall	1712 (23.7%)	567 (23.1%)	582 (22.2%)	0.4258	80 (26.3%)	0.2170	178 (26.8%)	0.0467	305 (25.8%)	0.0798
	Underweight (BMI: <18.5)	3 (0.2%)	1 (0.2%)	2 (0.3%)	0.5303	0 (0.0%)	0.4212	0 (0.0%)	0.6539	0 (0.0%)	0.8356
	Normal (BMI: 18.5 – 24.9)	16 (0.9%)	3 (0.5%)	8 (1.4%)	.	1 (1.3%)	.	1 (0.6%)	.	3 (1.0%)	.
	Overweight (BMI: 25.0- 29.9)	184 (10.7%)	63 (11.1%)	62 (10.7%)	.	11 (13.8%)	.	15 (8.4%)	.	33 (10.8%)	.
	Obese (BMI: ≥30)	1509 (88.1%)	500 (88.2%)	510 (87.6%)	.	68 (85.0%)	.	162 (91.0%)	.	269 (88.2%)	.

Table 1. Changes in backbone agent at 12-months follow-up in ART-experienced patients with at least one lipid test available

		Overall N= 7,223	DTG N= 2,451	EVG/c N= 2,622	DTG vs. EVG p-value	RAL N= 304	DTG vs. RAL p-value	DRV(/r/c) N= 663	DTG vs. DRV(/r/c) p-value	RPV N= 1,183	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 12 months) : Baseline TAF	Overall	2194 (30.4%)	230 (9.4%)	1380 (52.6%)	<.0001	13 (4.3%)	0.0031	102 (15.4%)	<.0001	469 (39.6%)	<.0001
	TAF at 12 months	2162 (98.5%)	221 (96.1%)	1362 (98.7%)	0.0095	12 (92.3%)	0.4291	102 (100.0%)	0.0617	465 (99.1%)	0.0128
	No TAF at 12 months	32 (1.5%)	9 (3.9%)	18 (1.3%)	.	1 (7.7%)	.	0 (0.0%)	.	4 (0.9%)	.
Change in Backbone Agent (concurrent TAF use at 12 months) : No Baseline TAF	Overall	5029 (69.6%)	2221 (90.6%)	1242 (47.4%)	<.0001	291 (95.7%)	0.0031	561 (84.6%)	<.0001	714 (60.4%)	<.0001
	TAF at 12 months	540 (10.7%)	87 (3.9%)	278 (22.4%)	<.0001	15 (5.2%)	0.3146	63 (11.2%)	<.0001	97 (13.6%)	<.0001
	No TAF at 12 months	4489 (89.3%)	2134 (96.1%)	964 (77.6%)	.	276 (94.8%)	.	498 (88.8%)	.	617 (86.4%)	.
Change in Backbone Agent (TAF use at any point during follow-up)	TAF during follow-up	2194 (100.0%)	230 (100.0%)	1380 (100.0%)	.	13 (100.0%)	.	102 (100.0%)	.	469 (100.0%)	.

		Overall N= 7,223	DTG N= 2,451	EVG/c N= 2,622	DTG vs. EVG p-value	RAL N= 304	DTG vs. RAL p-value	DRV(/r/c) N= 663	DTG vs. DRV(/r/c) p-value	RPV N= 1,183	DTG vs. RPV p-value
follow-up) : Baseline TAF											
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	561 (11.2%)	88 (4.0%)	289 (23.3%)	<.0001	16 (5.5%)	0.2162	64 (11.4%)	<.0001	104 (14.6%)	<.0001
	No TAF during follow-up	4468 (88.8%)	2133 (96.0%)	953 (76.7%)	.	275 (94.5%)	.	497 (88.6%)	.	610 (85.4%)	.

### 1.4.2.3. Treatment-experienced, suppressed patients

Table 58. Weight, BMI, and incident lipodystrophy at 12-months follow-up in ART-experienced, suppressed patients

		Overall N= 8,143	DTG N= 2,757	EVG/c N= 2,774	DTG vs. EVG p-value	RAL N= 402	DTG vs. RAL p-value	DRV(/t/c) N= 697	DTG vs. DRV(/t/c) p-value	RPV N= 1,513	DTG vs. RPV p-value
Weight, kg	Median (IQR)	81.2 (71.2, 92.3)	80.9 (70.8, 92.1)	80.7 (71.2, 92.2)	0.4454	81.6 (71.2, 91.2)	0.7738	81.6 (70.8, 92.5)	0.6897	81.2 (71.9, 93.0)	0.1019
Change in weight from baseline, kg	Median (IQR)	1.4 (-1.4, 4.1)	1.4 (-1.4, 4.1)	1.4 (-1.4, 4.3)	0.1253	0.5 (-2.1, 3.6)	0.0170	0.5 (-2.7, 3.4)	<.0001	1.8 (-0.9, 4.5)	0.0055
	Mean (SD)	1.4 (6.3)	1.2 (6.6)	1.5 (6.2)	.	0.8 (5.8)	.	0.6 (6.1)	.	1.9 (6.1)	.
	No change ( $\pm$ <3 kg)	4005 (49.2%)	1383 (50.2%)	1342 (48.4%)	0.3637	200 (49.8%)	0.2493	349 (50.1%)	0.0010	731 (48.3%)	0.0265
	Weight increase 3 to <5 kg	1200 (14.7%)	402 (14.6%)	431 (15.5%)	.	62 (15.4%)	.	80 (11.5%)	.	225 (14.9%)	.
	Weight increase $\geq$ 5 kg	1605 (19.7%)	522 (18.9%)	569 (20.5%)	.	62 (15.4%)	.	112 (16.1%)	.	340 (22.5%)	.
	Weight decrease 3 to <5 kg	651 (8.0%)	218 (7.9%)	218 (7.9%)	.	42 (10.4%)	.	80 (11.5%)	.	93 (6.1%)	.
	Weight decrease $\geq$ 5 kg	682 (8.4%)	232 (8.4%)	214 (7.7%)	.	36 (9.0%)	.	76 (10.9%)	.	124 (8.2%)	.
Change in weight from baseline, %	Median (IQR)	1.7 (-1.9, 5.4)	1.6 (-1.8, 5.3)	1.9 (-1.7, 5.5)	0.2198	0.6 (-2.6, 4.8)	0.0148	0.6 (-3.1, 4.2)	<.0001	2.1 (-1.3, 5.8)	0.0097



		Overall N= 8,143	DTG N= 2,757	EVG/c N= 2,774	DTG vs. EVG p-value	RAL N= 402	DTG vs. RAL p-value	DRV(/r/c) N= 697	DTG vs. DRV(/r/c) p-value	RPV N= 1,513	DTG vs. RPV p-value
	Mean (SD)	1.9 (7.9)	1.8 (8.3)	2.1 (7.4)	.	1.3 (7.4)	.	0.9 (8.0)	.	2.6 (8.2)	.
	No change ( $\pm$ <5%)	5011 (61.5%)	1720 (62.4%)	1692 (61.0%)	0.4223	248 (61.7%)	0.1343	444 (63.7%)	0.0074	907 (59.9%)	0.0777
	Weight increase ≥5%	2200 (27.0%)	728 (26.4%)	776 (28.0%)	.	96 (23.9%)	.	152 (21.8%)	.	448 (29.6%)	.
	Weight decrease ≥5%	932 (11.4%)	309 (11.2%)	306 (11.0%)	.	58 (14.4%)	.	101 (14.5%)	.	158 (10.4%)	.
BMI	Median (IQR)	26.7 (23.9, 30.2)	26.7 (23.9, 30.0)	26.5 (23.8, 30.2)	0.9574	26.6 (23.6, 29.8)	0.7335	26.7 (24.1, 30.6)	0.2208	27.0 (23.8, 30.5)	0.0932
Change in BMI from baseline	Median (IQR)	0.4 (-0.5, 1.4)	0.4 (-0.5, 1.4)	0.5 (-0.5, 1.4)	0.1272	0.1 (-0.7, 1.3)	0.0213	0.1 (-0.9, 1.2)	0.0001	0.6 (-0.4, 1.6)	0.0061
	Mean (SD)	0.4 (2.3)	0.4 (2.4)	0.5 (2.3)	.	0.2 (2.1)	.	0.1 (2.2)	.	0.5 (2.4)	.
Number of patients without lipodystrophy at baseline	Yes	8038 (98.7%)	2716 (98.5%)	2748 (99.1%)	0.0616	384 (95.5%)	<.0001	688 (98.7%)	0.6989	1502 (99.3%)	0.0303
Number of incident cases of lipodystrophy	Yes	49 (0.6%)	21 (0.8%)	17 (0.6%)	0.5188	2 (0.5%)	1.0000	6 (0.9%)	0.8098	3 (0.2%)	0.0177
Incident lipodystrophy	% (95% CI)	0.61 (0.45, 0.81)	0.77 (0.48, 1.18)	0.62 (0.36, 0.99)	.	0.52 (0.06, 1.87)	.	0.87 (0.32, 1.89)	.	0.20 (0.04, 0.58)	.

Table 59. Changes in BMI category at 12-months follow-up in ART-experienced, suppressed patients

		Overall N= 8,143	DTG N= 2,757	EVG/c N= 2,774	DTG vs. EVG p-value	RAL N= 402	DTG vs. RAL p-value	DRV(/r/c) N= 697	DTG vs. DRV(/r/c) p-value	RPV N= 1,513	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	159 (2.0%)	48 (1.7%)	56 (2.0%)	0.4471	10 (2.5%)	0.2976	11 (1.6%)	0.7669	34 (2.2%)	0.2490
	Underweight (BMI: <18.5)	71 (44.7%)	22 (45.8%)	22 (39.3%)	0.6020	6 (60.0%)	0.4619	7 (63.6%)	0.6346	14 (41.2%)	0.2946
	Normal (BMI: 18.5 – 24.9)	81 (50.9%)	23 (47.9%)	32 (57.1%)	.	3 (30.0%)	.	4 (36.4%)	.	19 (55.9%)	.
	Overweight (BMI: 25.0- 29.9)	6 (3.8%)	3 (6.3%)	2 (3.6%)	.	1 (10.0%)	.	0 (0.0%)	.	0 (0.0%)	.
	Obese (BMI: ≥30)	1 (0.6%)	0 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (2.9%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	2962 (36.4%)	996 (36.1%)	1041 (37.5%)	0.2802	136 (33.8%)	0.3699	239 (34.3%)	0.3661	550 (36.4%)	0.8835
	Underweight (BMI: <18.5)	46 (1.6%)	21 (2.1%)	12 (1.2%)	0.1519	4 (2.9%)	0.6539	2 (0.8%)	0.5771	7 (1.3%)	0.0313
	Normal (BMI: 18.5 – 24.9)	2304 (77.8%)	772 (77.5%)	814 (78.2%)	.	108 (79.4%)	.	189 (79.1%)	.	421 (76.5%)	.
	Overweight (BMI: 25.0- 29.9)	600 (20.3%)	202 (20.3%)	210 (20.2%)	.	24 (17.6%)	.	48 (20.1%)	.	116 (21.1%)	.

		Overall N= 8,143	DTG N= 2,757	EVG/c N= 2,774	DTG vs. EVG p-value	RAL N= 402	DTG vs. RAL p-value	DRV(/r/c) N= 697	DTG vs. DRV(/r/c) p-value	RPV N= 1,513	DTG vs. RPV p-value
	Obese (BMI: ≥30)	12 (0.4%)	1 (0.1%)	5 (0.5%)	.	0 (0.0%)	.	0 (0.0%)	.	6 (1.1%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	3116 (38.3%)	1093 (39.6%)	1035 (37.3%)	0.0745	166 (41.3%)	0.5281	262 (37.6%)	0.3209	560 (37.0%)	0.0912
	Underweight (BMI: <18.5)	8 (0.3%)	5 (0.5%)	0 (0.0%)	0.0914	0 (0.0%)	0.7388	1 (0.4%)	0.1436	2 (0.4%)	0.1375
	Normal (BMI: 18.5 – 24.9)	295 (9.5%)	106 (9.7%)	95 (9.2%)	.	20 (12.0%)	.	38 (14.5%)	.	36 (6.4%)	.
	Overweight (BMI: 25.0- 29.9)	2376 (76.3%)	838 (76.7%)	783 (75.7%)	.	124 (74.7%)	.	189 (72.1%)	.	442 (78.9%)	.
	Obese (BMI: ≥30)	437 (14.0%)	144 (13.2%)	157 (15.2%)	.	22 (13.3%)	.	34 (13.0%)	.	80 (14.3%)	.
Change in BMI Category: Baseline Obese (BMI: ≥ 30)	Overall	1906 (23.4%)	620 (22.5%)	642 (23.1%)	0.5615	90 (22.4%)	0.9642	185 (26.5%)	0.0237	369 (24.4%)	0.1591
	Underweight (BMI: <18.5)	5 (0.3%)	1 (0.2%)	3 (0.5%)	0.1657	0 (0.0%)	0.2844	0 (0.0%)	0.6248	1 (0.3%)	0.5924
	Normal (BMI: 18.5 – 24.9)	18 (0.9%)	3 (0.5%)	10 (1.6%)	.	2 (2.2%)	.	2 (1.1%)	.	1 (0.3%)	.

		Overall N= 8,143	DTG N= 2,757	EVG/c N= 2,774	DTG vs. EVG p-value	RAL N= 402	DTG vs. RAL p-value	DRV(/r/c) N= 697	DTG vs. DRV(/r/c) p-value	RPV N= 1,513	DTG vs. RPV p-value
	Overweight (BMI: 25.0- 29.9)	210 (11.0%)	75 (12.1%)	68 (10.6%)	.	11 (12.2%)	.	20 (10.8%)	.	36 (9.8%)	.
	Obese (BMI: ≥30)	1673 (87.8%)	541 (87.3%)	561 (87.4%)	.	77 (85.6%)	.	163 (88.1%)	.	331 (89.7%)	.

Table 60. Changes in backbone agent at 12-months follow-up in ART-experienced, suppressed patients

		Overall N= 8,143	DTG N= 2,757	EVG/c N= 2,774	DTG vs. EVG p-value	RAL N= 402	DTG vs. RAL p-value	DRV(/r/c) N= 697	DTG vs. DRV(/r/c) p-value	RPV N= 1,513	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 12 months) : Baseline TAF	Overall	2549 (31.3%)	281 (10.2%)	1538 (55.4%)	<.0001	17 (4.2%)	0.0001	99 (14.2%)	0.0025	614 (40.6%)	<.0001
	TAF at 12 months	2510 (98.5%)	271 (96.4%)	1518 (98.7%)	0.0174	16 (94.1%)	0.4819	98 (99.0%)	0.3012	607 (98.9%)	0.0307
	No TAF at 12 months	39 (1.5%)	10 (3.6%)	20 (1.3%)	.	1 (5.9%)	.	1 (1.0%)	.	7 (1.1%)	.
Change in Backbone Agent (concurrent TAF use at	Overall	5594 (68.7%)	2476 (89.8%)	1236 (44.6%)	<.0001	385 (95.8%)	0.0001	598 (85.8%)	0.0025	899 (59.4%)	<.0001

		Overall N= 8,143	DTG N= 2,757	EVG/c N= 2,774	DTG vs. EVG p-value	RAL N= 402	DTG vs. RAL p-value	DRV(/r/c) N= 697	DTG vs. DRV(/r/c) p-value	RPV N= 1,513	DTG vs. RPV p-value
12 months) : No Baseline TAF											
	TAF at 12 months	570 (10.2%)	106 (4.3%)	266 (21.5%)	<.0001	20 (5.2%)	0.4163	60 (10.0%)	<.0001	118 (13.1%)	<.0001
	No TAF at 12 months	5024 (89.8%)	2370 (95.7%)	970 (78.5%)	.	365 (94.8%)	.	538 (90.0%)	.	781 (86.9%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : Baseline TAF	TAF during follow-up	2549 (100.0%)	281 (100.0%)	1538 (100.0%)	.	17 (100.0%)	.	99 (100.0%)	.	614 (100.0%)	.
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	587 (10.5%)	106 (4.3%)	276 (22.3%)	<.0001	21 (5.5%)	0.2983	61 (10.2%)	<.0001	123 (13.7%)	<.0001
	No TAF during follow-up	5007 (89.5%)	2370 (95.7%)	960 (77.7%)	.	364 (94.5%)	.	537 (89.8%)	.	776 (86.3%)	.

*Table 61. Weight, BMI, lipids, and incident lipodystrophy at 12-months follow-up in ART-experienced, suppressed patients with at least one lipid test available*

		Overall N= 5,279	DTG N= 1,788	EVG/c N= 1,823	DTG vs. EVG p-value	RAL N= 264	DTG vs. RAL p-value	DRV(/r/c) N= 444	DTG vs. DRV(/r/c) p-value	RPV N= 960	DTG vs. RPV p-value
Weight, kg	Median (IQR)	81.6 (71.9, 93.0)	81.4 (71.5, 92.5)	81.3 (72.1, 93.0)	0.3253	82.1 (72.6, 93.2)	0.2682	82.2 (71.2, 93.8)	0.4445	82.1 (72.6, 93.5)	0.1344
Change in weight from baseline, kg	Median (IQR)	1.4 (-1.4, 4.1)	1.4 (-1.4, 4.1)	1.5 (-1.3, 4.4)	0.0635	0.5 (-1.8, 3.9)	0.0650	0.3 (-2.7, 3.2)	<.0001	1.4 (-1.1, 4.4)	0.1559
	Mean (SD)	1.4 (6.3)	1.2 (6.6)	1.6 (6.2)	.	0.9 (6.0)	.	0.3 (5.7)	.	1.8 (6.1)	.
	No change ( $\pm$ <3 kg)	2632 (49.9%)	910 (50.9%)	900 (49.4%)	0.2150	130 (49.2%)	0.7174	227 (51.1%)	0.0005	465 (48.4%)	0.2438
	Weight increase 3 to <5 kg	785 (14.9%)	255 (14.3%)	296 (16.2%)	.	41 (15.5%)	.	47 (10.6%)	.	146 (15.2%)	.
	Weight increase $\geq$ 5 kg	1024 (19.4%)	339 (19.0%)	370 (20.3%)	.	44 (16.7%)	.	66 (14.9%)	.	205 (21.4%)	.
	Weight decrease 3 to <5 kg	416 (7.9%)	140 (7.8%)	133 (7.3%)	.	25 (9.5%)	.	58 (13.1%)	.	60 (6.3%)	.
	Weight decrease $\geq$ 5 kg	422 (8.0%)	144 (8.1%)	124 (6.8%)	.	24 (9.1%)	.	46 (10.4%)	.	84 (8.8%)	.
Change in weight from baseline, %	Median (IQR)	1.7 (-1.8, 5.3)	1.6 (-1.7, 5.2)	2.0 (-1.5, 5.5)	0.1143	0.6 (-2.4, 5.0)	0.0472	0.3 (-3.1, 3.7)	<.0001	1.9 (-1.5, 5.6)	0.2153
	Mean (SD)	2.0 (7.9)	1.8 (8.5)	2.2 (7.1)	.	1.5 (7.7)	.	0.5 (6.9)	.	2.5 (8.5)	.

		Overall N= 5,279	DTG N= 1,788	EVG/c N= 1,823	DTG vs. EVG p-value	RAL N= 264	DTG vs. RAL p-value	DRV(/r/c) N= 444	DTG vs. DRV(/r/c) p-value	RPV N= 960	DTG vs. RPV p-value
	No change ( $\pm$ <5%)	3303 (62.6%)	1124 (62.9%)	1140 (62.5%)	0.4575	162 (61.4%)	0.4022	294 (66.2%)	0.0054	583 (60.7%)	0.4127
	Weight increase ≥5%	1402 (26.6%)	470 (26.3%)	504 (27.6%)	.	66 (25.0%)	.	87 (19.6%)	.	275 (28.6%)	.
	Weight decrease ≥5%	574 (10.9%)	194 (10.9%)	179 (9.8%)	.	36 (13.6%)	.	63 (14.2%)	.	102 (10.6%)	.
BMI	Median (IQR)	26.8 (24.1, 30.4)	26.8 (24.1, 30.1)	26.6 (24.1, 30.4)	0.8372	27.2 (23.7, 30.7)	0.5213	27.2 (24.2, 30.9)	0.2028	27.1 (24.1, 30.8)	0.1627
Change in BMI from baseline	Median (IQR)	0.4 (-0.5, 1.4)	0.4 (-0.5, 1.4)	0.5 (-0.4, 1.4)	0.0561	0.1 (-0.7, 1.3)	0.0873	0.1 (-0.9, 1.2)	0.0003	0.5 (-0.4, 1.5)	0.1736
	Mean (SD)	0.4 (2.3)	0.4 (2.4)	0.5 (2.3)	.	0.2 (2.3)	.	0.1 (2.0)	.	0.6 (2.4)	.
Number of patients without lipodystrophy at baseline	Yes	5203 (98.6%)	1761 (98.5%)	1802 (98.8%)	0.3475	251 (95.1%)	0.0002	438 (98.6%)	0.8041	951 (99.1%)	0.2082
Number of incident cases of lipodystrophy	Yes	35 (0.7%)	15 (0.9%)	14 (0.8%)	0.8536	2 (0.8%)	1.0000	4 (0.9%)	0.7803	0 (0.0%)	0.0020
Incident lipodystrophy	% (95% CI)	0.67 (0.47, 0.93)	0.85 (0.48, 1.40)	0.78 (0.43, 1.30)	.	0.80 (0.10, 2.85)	.	0.91 (0.25, 2.32)	.	.	.
Total Cholesterol, mg/dL	Median (IQR)	176.0 (152.0, 204.0)	173.0 (149.0, 200.0)	183.0 (160.0, 210.0)	<.0001	167.0 (143.0, 194.0)	0.0137	183.0 (159.0, 210.0)	<.0001	168.0 (147.0, 195.5)	0.0102

		Overall N= 5,279	DTG N= 1,788	EVG/c N= 1,823	DTG vs. EVG p-value	RAL N= 264	DTG vs. RAL p-value	DRV(/r/c) N= 444	DTG vs. DRV(/r/c) p-value	RPV N= 960	DTG vs. RPV p-value
	Normal (<200 mg/dl)	3783 (71.7%)	1334 (74.6%)	1192 (65.4%)	<.0001	205 (77.7%)	0.6669	300 (67.6%)	0.0072	752 (78.3%)	0.0940
	Borderline Abnormal (≥200 to <240 mg/dl)	1138 (21.6%)	351 (19.6%)	469 (25.7%)	.	45 (17.0%)	.	101 (22.7%)	.	172 (17.9%)	.
	Dyslipidemia (≥240 to <280 mg/dl)	283 (5.4%)	82 (4.6%)	127 (7.0%)	.	10 (3.8%)	.	34 (7.7%)	.	30 (3.1%)	.
	Severe Dyslipidemia (≥280 mg/dl)	72 (1.4%)	20 (1.1%)	34 (1.9%)	.	4 (1.5%)	.	8 (1.8%)	.	6 (0.6%)	.
	Missing	3 (0.1%)	1 (0.1%)	1 (0.1%)	.	0 (0.0%)	.	1 (0.2%)	.	0 (0.0%)	.
LDL, mg/dL	Median (IQR)	98.0 (79.0, 122.0)	95.6 (77.0, 119.6)	102.4 (83.0, 126.0)	<.0001	91.6 (72.0, 111.0)	0.0116	104.8 (82.8, 127.6)	<.0001	95.0 (76.6, 118.0)	0.8827
	Normal (<100 mg/dl)	2632 (49.9%)	953 (53.3%)	808 (44.3%)	<.0001	152 (57.6%)	0.1026	195 (43.9%)	0.0005	524 (54.6%)	0.5184
	Borderline Abnormal (≥100 to <130 mg/dl)	1509 (28.6%)	488 (27.3%)	545 (29.9%)	.	75 (28.4%)	.	136 (30.6%)	.	265 (27.6%)	.
	Dyslipidemia (≥130 to <160 mg/dl)	714 (13.5%)	218 (12.2%)	294 (16.1%)	.	19 (7.2%)	.	67 (15.1%)	.	116 (12.1%)	.
	Severe Dyslipidemia	185 (3.5%)	55 (3.1%)	66 (3.6%)	.	7 (2.7%)	.	29 (6.5%)	.	28 (2.9%)	.



		Overall N= 5,279	DTG N= 1,788	EVG/c N= 1,823	DTG vs. EVG p-value	RAL N= 264	DTG vs. RAL p-value	DRV(/r/c) N= 444	DTG vs. DRV(/r/c) p-value	RPV N= 960	DTG vs. RPV p-value
	(>=160 to <190 mg/dl)										
	Very Severe Dyslipidemia (>=190 mg/dl)	59 (1.1%)	17 (1.0%)	27 (1.5%)	.	0 (0.0%)	.	6 (1.4%)	.	9 (0.9%)	.
	Missing	180 (3.4%)	57 (3.2%)	83 (4.6%)	.	11 (4.2%)	.	11 (2.5%)	.	18 (1.9%)	.
HDL, mg/dL	Median (IQR)	46.0 (38.0, 56.0)	45.0 (38.0, 55.0)	47.0 (39.0, 57.0)	0.0002	43.0 (35.0, 52.0)	0.0355	46.0 (38.0, 57.0)	0.1755	44.0 (37.0, 54.0)	0.0717
	Normal (>=60 mg/dl)	961 (18.2%)	322 (18.0%)	361 (19.8%)	0.0290	42 (15.9%)	0.0856	95 (21.4%)	0.1402	141 (14.7%)	0.1323
	Borderline Abnormal (>=40 to <60 mg/dl)	2646 (50.1%)	884 (49.4%)	951 (52.2%)	.	121 (45.8%)	.	203 (45.7%)	.	487 (50.7%)	.
	Dyslipidemia (<40 mg/dl)	1633 (30.9%)	565 (31.6%)	497 (27.3%)	.	101 (38.3%)	.	145 (32.7%)	.	325 (33.9%)	.
	Missing	39 (0.7%)	17 (1.0%)	14 (0.8%)	.	0 (0.0%)	.	1 (0.2%)	.	7 (0.7%)	.
Triglycerides, mg/dL	Median (IQR)	127.0 (88.0, 189.0)	127.0 (88.0, 188.0)	135.0 (92.5, 198.5)	0.0062	134.0 (89.5, 194.5)	0.3834	126.0 (96.0, 193.0)	0.4283	114.0 (80.0, 169.0)	<.0001
	Normal (<150 mg/dl)	3209 (60.8%)	1101 (61.6%)	1028 (56.4%)	0.0079	156 (59.1%)	0.6145	276 (62.2%)	0.6719	648 (67.5%)	0.0041
	Borderline Abnormal (>=150 to <200 mg/dl)	894 (16.9%)	297 (16.6%)	341 (18.7%)	.	45 (17.0%)	.	68 (15.3%)	.	143 (14.9%)	.

		Overall N= 5,279	DTG N= 1,788	EVG/c N= 1,823	DTG vs. EVG p-value	RAL N= 264	DTG vs. RAL p-value	DRV(/r/c) N= 444	DTG vs. DRV(/r/c) p-value	RPV N= 960	DTG vs. RPV p-value
	Dyslipidemia (≥200 to <500 mg/dl)	1074 (20.3%)	361 (20.2%)	404 (22.2%)	.	56 (21.2%)	.	95 (21.4%)	.	158 (16.5%)	.
	Severe Dyslipidemia (≥500 mg/dl)	92 (1.7%)	27 (1.5%)	47 (2.6%)	.	7 (2.7%)	.	4 (0.9%)	.	7 (0.7%)	.
	Missing	10 (0.2%)	2 (0.1%)	3 (0.2%)	.	0 (0.0%)	.	1 (0.2%)	.	4 (0.4%)	.

Table 62. Changes in BMI category at 12-months follow-up in ART-experienced, suppressed patients with at least one lipid test available

		Overall N= 5,279	DTG N= 1,788	EVG/c N= 1,823	DTG vs. EVG p-value	RAL N= 264	DTG vs. RAL p-value	DRV(/r/c) N= 444	DTG vs. DRV(/r/c) p-value	RPV N= 960	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	83 (1.6%)	26 (1.5%)	26 (1.4%)	1.0000	6 (2.3%)	0.2900	5 (1.1%)	0.8205	20 (2.1%)	0.2169
	Underweight (BMI: <18.5)	29 (34.9%)	9 (34.6%)	7 (26.9%)	0.4301	5 (83.3%)	0.0524	4 (80.0%)	0.1852	4 (20.0%)	0.1351
	Normal (BMI: 18.5 – 24.9)	48 (57.8%)	14 (53.8%)	18 (69.2%)	.	0 (0.0%)	.	1 (20.0%)	.	15 (75.0%)	.
	Overweight (BMI: 25.0- 29.9)	5 (6.0%)	3 (11.5%)	1 (3.8%)	.	1 (16.7%)	.	0 (0.0%)	.	0 (0.0%)	.

		Overall N= 5,279	DTG N= 1,788	EVG/c N= 1,823	DTG vs. EVG p-value	RAL N= 264	DTG vs. RAL p-value	DRV(/r/c) N= 444	DTG vs. DRV(/r/c) p-value	RPV N= 960	DTG vs. RPV p-value
	Obese (BMI: ≥30)	1 (1.2%)	0 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (5.0%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	1848 (35.0%)	623 (34.8%)	665 (36.5%)	0.3052	87 (33.0%)	0.5470	142 (32.0%)	0.2555	331 (34.5%)	0.8484
	Underweight (BMI: <18.5)	26 (1.4%)	10 (1.6%)	7 (1.1%)	0.6652	3 (3.4%)	0.3733	0 (0.0%)	0.4655	6 (1.8%)	0.1116
	Normal (BMI: 18.5 – 24.9)	1427 (77.2%)	481 (77.2%)	512 (77.0%)	.	69 (79.3%)	.	114 (80.3%)	.	251 (75.8%)	.
	Overweight (BMI: 25.0- 29.9)	386 (20.9%)	131 (21.0%)	143 (21.5%)	.	15 (17.2%)	.	28 (19.7%)	.	69 (20.8%)	.
	Obese (BMI: ≥30)	9 (0.5%)	1 (0.2%)	3 (0.5%)	.	0 (0.0%)	.	0 (0.0%)	.	5 (1.5%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	2044 (38.7%)	716 (40.0%)	695 (38.1%)	0.2369	102 (38.6%)	0.6626	170 (38.3%)	0.4984	361 (37.6%)	0.2115
	Underweight (BMI: <18.5)	6 (0.3%)	3 (0.4%)	0 (0.0%)	0.1055	0 (0.0%)	0.7197	1 (0.6%)	0.1021	2 (0.6%)	0.7069
	Normal (BMI: 18.5 – 24.9)	177 (8.7%)	63 (8.8%)	51 (7.3%)	.	11 (10.8%)	.	25 (14.7%)	.	27 (7.5%)	.

		Overall N= 5,279	DTG N= 1,788	EVG/c N= 1,823	DTG vs. EVG p-value	RAL N= 264	DTG vs. RAL p-value	DRV(/r/c) N= 444	DTG vs. DRV(/r/c) p-value	RPV N= 960	DTG vs. RPV p-value
	Overweight (BMI: 25.0- 29.9)	1581 (77.3%)	561 (78.4%)	537 (77.3%)	.	76 (74.5%)	.	127 (74.7%)	.	280 (77.6%)	.
	Obese (BMI: ≥30)	280 (13.7%)	89 (12.4%)	107 (15.4%)	.	15 (14.7%)	.	17 (10.0%)	.	52 (14.4%)	.
Change in BMI Category: Baseline Obese (BMI: ≥ 30)	Overall	1304 (24.7%)	423 (23.7%)	437 (24.0%)	0.8249	69 (26.1%)	0.3786	127 (28.6%)	0.0304	248 (25.8%)	0.2056
	Underweight (BMI: <18.5)	3 (0.2%)	1 (0.2%)	2 (0.5%)	0.1048	0 (0.0%)	0.4023	0 (0.0%)	0.5080	0 (0.0%)	1.0000
	Normal (BMI: 18.5 – 24.9)	11 (0.8%)	1 (0.2%)	8 (1.8%)	.	1 (1.4%)	.	1 (0.8%)	.	0 (0.0%)	.
	Overweight (BMI: 25.0- 29.9)	151 (11.6%)	51 (12.1%)	49 (11.2%)	.	9 (13.0%)	.	12 (9.4%)	.	30 (12.1%)	.
	Obese (BMI: ≥30)	1139 (87.3%)	370 (87.5%)	378 (86.5%)	.	59 (85.5%)	.	114 (89.8%)	.	218 (87.9%)	.

Table 63. Changes in backbone agent at 12-months follow-up in ART-experienced, suppressed patients with at least one lipid test available

		Overall N= 5,279	DTG N= 1,788	EVG/c N= 1,823	DTG vs. EVG p-value	RAL N= 264	DTG vs. RAL p-value	DRV(/r/c) N= 444	DTG vs. DRV(/r/c) p-value	RPV N= 960	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 12 months) : Baseline TAF	Overall	1661 (31.5%)	165 (9.2%)	1024 (56.2%)	<.0001	12 (4.5%)	0.0114	61 (13.7%)	0.0048	399 (41.6%)	<.0001
	TAF at 12 months	1638 (98.6%)	159 (96.4%)	1011 (98.7%)	0.0373	11 (91.7%)	0.3936	61 (100.0%)	0.1945	396 (99.2%)	0.0214
	No TAF at 12 months	23 (1.4%)	6 (3.6%)	13 (1.3%)	.	1 (8.3%)	.	0 (0.0%)	.	3 (0.8%)	.
Change in Backbone Agent (concurrent TAF use at 12 months) : No Baseline TAF	Overall	3618 (68.5%)	1623 (90.8%)	799 (43.8%)	<.0001	252 (95.5%)	0.0114	383 (86.3%)	0.0048	561 (58.4%)	<.0001
	TAF at 12 months	399 (11.0%)	71 (4.4%)	186 (23.3%)	<.0001	15 (6.0%)	0.2653	47 (12.3%)	<.0001	80 (14.3%)	<.0001
	No TAF at 12 months	3219 (89.0%)	1552 (95.6%)	613 (76.7%)	.	237 (94.0%)	.	336 (87.7%)	.	481 (85.7%)	.
Change in Backbone Agent (TAF use at any point during follow-up)	TAF during follow-up	1661 (100.0%)	165 (100.0%)	1024 (100.0%)	.	12 (100.0%)	.	61 (100.0%)	.	399 (100.0%)	.

		Overall N= 5,279	DTG N= 1,788	EVG/c N= 1,823	DTG vs. EVG p-value	RAL N= 264	DTG vs. RAL p-value	DRV(/r/c) N= 444	DTG vs. DRV(/r/c) p-value	RPV N= 960	DTG vs. RPV p-value
follow-up) : Baseline TAF											
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	415 (11.5%)	71 (4.4%)	195 (24.4%)	<.0001	16 (6.3%)	0.1656	48 (12.5%)	<.0001	85 (15.2%)	<.0001
	No TAF during follow-up	3203 (88.5%)	1552 (95.6%)	604 (75.6%)	.	236 (93.7%)	.	335 (87.5%)	.	476 (84.8%)	.

### 1.5. Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 24-months of follow-up (stratified by ART experience)

#### 1.5.1. Identification of the study population (subset of patients with a weight measurement between >21 and ≤27 months after core agent initiation)

Table 64. Identification of the study population

		Patients Included	%	Patients Excluded	%
1	Patients in Population 1b	21,554	.	0	.
2	Patients with follow-up measurement for weight available between >21 and ≤27 months after core agent initiation where the follow-up value for weight is <500 kg and the value for change in weight from baseline is <450 kg	8,640	40.1	12,914	59.9

Table 65. Study population by core agent of interest and ART experience

Core Agent	N (%)	ART experience	N (%)
DTG	2,986 (34.6%)	ART-naïve	811 (27.2%)
		ART-experienced	2,175 (72.8%)
		ART-experienced, suppressed	1,548 (51.8%)
EVG/c	3,272 (37.9%)	ART-naïve	1,058 (32.3%)
		ART-experienced	2,214 (67.7%)
		ART-experienced, suppressed	1,506 (46.0%)
RAL	292 ( 3.4%)	ART-naïve	31 (10.6%)
		ART-experienced	261 (89.4%)
		ART-experienced, suppressed	217 (74.3%)
RPV	1,370 (15.9%)	ART-naïve	361 (26.4%)
		ART-experienced	1,009 (73.6%)
		ART-experienced, suppressed	795 (58.0%)
DRV/r or DRV/c	720 ( 8.3%)	ART-naïve	166 (23.1%)
		ART-experienced	554 (76.9%)

Core Agent	N (%)	ART experience	N (%)
		ART-experienced, suppressed	370 (51.4%)



### 1.5.2. Description of BMI categories, weight, lipid levels, and incident lipodystrophy at 24-months of follow-up (stratified by ART experience)

#### 1.5.2.1. Treatment-naïve patients

Table 66. Weight, BMI, and incident lipodystrophy at 24-months follow-up in ART-naïve patients

		Overall N= 2,427	DTG N= 811	EVG/ c N= 1,058	DTG vs. EVG p- value	RAL N= 31	DTG vs. RAL p- value	DRV(/r/ c) N= 166	DTG vs. DRV(/r/ c) p-value	RPV N= 361	DTG vs. RPV p- value
Weight, kg	Median (IQR)	79.4 (69.0, 92.1)	79.4 (69.0, 93.9)	78.9 (68.9, 90.3)	0.22 51	86.2 (73.7, 99.8)	0.05 59	77.8 (66.4, 93.0)	0.1622	81.6 (71.1, 95.7)	0.126 7
Change in weight from baseline, kg	Median (IQR)	3.6 (0.0, 8.2)	4.1 (0.0, 9.3)	3.6 (0.0, 7.7)	0.02 26	1.8 (- 1.7, 5.6)	0.05 18	3.6 (- 0.0, 9.2)	0.7935	2.7 (- 1.8, 6.4)	<.00 01
	Mean (SD)	4.4 (8.3)	5.3 (9.0)	4.2 (7.7)	.	1.7 (9.2)	.	5.1 (10.1)	.	2.9 (6.9)	.
	No change (± <3 kg)	814 (33.5 %)	252 (31.1 %)	361 (34.1 %)	0.44 76	11 (35.5%)	0.13 31	59 (35.5%)	0.0119	131 (36.3%)	0.001 9
	Weight increase 3 to <5 kg	345 (14.2 %)	119 (14.7 %)	164 (15.5 %)	.	5 (16.1%)	.	13 (7.8%)	.	44 (12.2%)	.
	Weight increase ≥5 kg	954 (39.3 %)	346 (42.7 %)	406 (38.4 %)	.	9 (29.0%)	.	73 (44.0%)	.	120 (33.2%)	.
	Weight decrease 3 to <5 kg	149 (6.1%)	47 (5.8%)	65 (6.1%)	.	1 (3.2%)	.	4 (2.4%)	.	32 (8.9%)	.
	Weight decrease ≥5 kg	165 (6.8%)	47 (5.8%)	62 (5.9%)	.	5 (16.1%)	.	17 (10.2%)	.	34 (9.4%)	.

		Overall N= 2,427	DTG N= 811	EVG/ c N= 1,058	DTG vs. EVG p-value	RAL N= 31	DTG vs. RAL p-value	DRV(/r/ c) N= 166	DTG vs. DRV(/r/ c) p-value	RPV N= 361	DTG vs. RPV p-value
Change in weight from baseline, %	Median (IQR)	4.6 (0.0, 10.4)	5.7 (0.0, 12.1)	4.5 (0.0, 10.3)	0.0194	2.7 (-2.2, 6.4)	0.0267	4.7 (-0.0, 14.3)	0.9674	3.1 (-2.2, 8.3)	<.0001
	Mean (SD)	6.1 (11.4)	7.3 (12.4)	5.9 (10.9)	.	2.3 (10.9)	.	7.5 (13.3)	.	3.7 (8.6)	.
	No change ( $\pm$ <5%)	1022 (42.1%)	307 (37.9%)	466 (44.0%)	0.0253	13 (41.9%)	0.1010	65 (39.2%)	0.5525	171 (47.4%)	<.0001
	Weight increase $\geq$ 5%	1165 (48.0%)	430 (53.0%)	501 (47.4%)	.	12 (38.7%)	.	82 (49.4%)	.	140 (38.8%)	.
	Weight decrease $\geq$ 5%	240 (9.9%)	74 (9.1%)	91 (8.6%)	.	6 (19.4%)	.	19 (11.4%)	.	50 (13.9%)	.
BMI	Median (IQR)	26.4 (23.4, 30.5)	26.5 (23.5, 31.1)	25.9 (23.2, 29.7)	0.0028	28.9 (24.3, 34.7)	0.1364	25.7 (23.1, 30.2)	0.0493	27.5 (23.7, 31.3)	0.2959
Change in BMI from baseline	Median (IQR)	1.2 (-0.2, 2.7)	1.4 (0.0, 3.0)	1.2 (-0.1, 2.6)	0.0627	0.7 (-0.6, 1.9)	0.0673	1.1 (-0.1, 3.1)	0.8676	0.8 (-0.7, 2.1)	<.0001
	Mean (SD)	1.4 (3.3)	1.7 (3.4)	1.4 (2.8)	.	0.6 (3.2)	.	1.8 (3.9)	.	1.0 (4.1)	.
Number of patients without lipodystrophy at baseline	Yes	2425 (99.9%)	810 (99.9%)	1057 (99.9%)	1.0000	31 (100.0%)	1.0000	166 (100.0%)	1.0000	361 (100.0%)	1.0000
Number of incident cases of lipodystrophy	Yes	8 (0.3%)	3 (0.4%)	4 (0.4%)	1.0000	0 (0.0%)	1.0000	1 (0.6%)	0.5262	0 (0.0%)	0.5569

		Overall N= 2,427	DTG N= 811	EVG/ c N= 1,058	DTG vs. EVG p-value	RAL N= 31	DTG vs. RAL p-value	DRV(/r/ c) N= 166	DTG vs. DRV(/r/ c) p-value	RPV N= 361	DTG vs. RPV p-value
Incident lipodystrophy	% (95% CI)	0.33 (0.14, 0.65)	0.37 (0.08, 1.08)	0.38 (0.10, 0.97)	.		.	0.60 (0.02, 3.31)	.		.

Table 67. Changes in BMI category at 24-months follow-up in ART-naïve patients

		Overall N= 2,427	DTG N= 811	EVG/ c N= 1,058	DTG vs. EVG p-value	RAL N= 31	DTG vs. RAL p-value	DRV(/r/ c) N= 166	DTG vs. DRV(/r/ c) p-value	RPV N= 361	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	84 (3.5%)	29 (3.6%)	34 (3.2%)	0.69 91	1 (3.2%)	1.00 00	13 (7.8%)	0.0200	7 (1.9%)	0.14 65
	Underweight (BMI: <18.5)	30 (35.7%)	8 (27.6%)	13 (38.2%)	0.29 37	1 (100.0%)	0.36 67	5 (38.5%)	0.7636	3 (42.9%)	0.77 83
	Normal (BMI: 18.5 – 24.9)	50 (59.5%)	19 (65.5%)	20 (58.8%)	.	0 (0.0%)	.	7 (53.8%)	.	4 (57.1%)	.
	Overweight (BMI: 25.0-29.9)	3 (3.6%)	2 (6.9%)	0 (0.0%)	.	0 (0.0%)	.	1 (7.7%)	.	0 (0.0%)	.
	Obese (BMI: ≥30)	1 (1.2%)	0 (0.0%)	1 (2.9%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	1110 (45.7%)	358 (44.1%)	525 (49.6%)	0.01 87	7 (22.6%)	0.01 74	80 (48.2%)	0.3391	140 (38.8%)	0.08 65

		Overall N= 2,427	DTG N= 811	EVG/ c N= 1,058	DTG vs. EVG p-value	RAL N= 31	DTG vs. RAL p-value	DRV(/r /c) N= 166	DTG vs. DRV(/r /c) p-value	RPV N= 361	DTG vs. RPV p-value
	Underweight (BMI: <18.5)	19 (1.7%)	4 (1.1%)	7 (1.3%)	0.39 03	0 (0.0%)	0.79 75	5 (6.3%)	0.0424	3 (2.1%)	0.16 47
	Normal (BMI: 18.5 – 24.9)	761 (68.6%)	244 (68.2%)	361 (68.8%)	.	6 (85.7%)	.	49 (61.3%)	.	101 (72.1%)	.
	Overweight (BMI: 25.0-29.9)	290 (26.1%)	91 (25.4%)	141 (26.9%)	.	1 (14.3%)	.	23 (28.8%)	.	34 (24.3%)	.
	Obese (BMI: >=30)	40 (3.6%)	19 (5.3%)	16 (3.0%)	.	0 (0.0%)	.	3 (3.8%)	.	2 (1.4%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	749 (30.9%)	244 (30.1%)	334 (31.6%)	0.49 19	12 (38.7%)	0.30 57	48 (28.9%)	0.7640	111 (30.7%)	0.82 00
	Underweight (BMI: <18.5)	3 (0.4%)	1 (0.4%)	2 (0.6%)	0.83 05	0 (0.0%)	0.69 14	0 (0.0%)	0.2983	0 (0.0%)	0.46 18
	Normal (BMI: 18.5 – 24.9)	76 (10.1%)	28 (11.5%)	32 (9.6%)	.	2 (16.7%)	.	5 (10.4%)	.	9 (8.1%)	.
	Overweight (BMI: 25.0-29.9)	478 (63.8%)	151 (61.9%)	217 (65.0%)	.	8 (66.7%)	.	24 (50.0%)	.	78 (70.3%)	.
	Obese (BMI: >=30)	192 (25.6%)	64 (26.2%)	83 (24.9%)	.	2 (16.7%)	.	19 (39.6%)	.	24 (21.6%)	.
Change in BMI Category: Baseline Obese (BMI: >= 30)	Overall	484 (19.9%)	180 (22.2%)	165 (15.6%)	0.00 03	11 (35.5%)	0.08 29	25 (15.1%)	0.0397	103 (28.5%)	0.01 93

		Overall N= 2,427	DTG N= 811	EVG/ c N= 1,058	DTG vs. EVG p-value	RAL N= 31	DTG vs. RAL p-value	DRV(/r /c) N= 166	DTG vs. DRV(/r /c) p-value	RPV N= 361	DTG vs. RPV p-value
	Underweight (BMI: <18.5)	2 (0.4%)	1 (0.6%)	1 (0.6%)	0.62 25	0 (0.0%)	0.07 99	0 (0.0%)	0.7608	0 (0.0%)	0.64 13
	Normal (BMI: 18.5 – 24.9)	2 (0.4%)	0 (0.0%)	1 (0.6%)	.	1 (9.1%)	.	0 (0.0%)	.	0 (0.0%)	.
	Overweight (BMI: 25.0-29.9)	46 (9.5%)	18 (10.0%)	11 (6.7%)	.	0 (0.0%)	.	3 (12.0%)	.	14 (13.6%)	.
	Obese (BMI: >=30)	434 (89.7%)	161 (89.4%)	152 (92.1%)	.	10 (90.9%)	.	22 (88.0%)	.	89 (86.4%)	.

Table 68. Changes in backbone agent at 24-months follow-up in ART-naïve patients

		Overall N= 2,427	DTG N= 811	EVG/c N= 1,058	DTG vs. EVG p- value	RAL N= 31	DTG vs. RAL p- value	DRV(/r/ c) N= 166	DTG vs. DRV(/r/ c) p-value	RPV N= 361	DTG vs. RPV p- value
Change in Backbone Agent (concurrent TAF use at 24 months) : Baseline TAF	Over all	351 (14.5%)	23 (2.8%)	277 (26.2%)	<.0001	0 (0.0%)	1.0000	11 (6.6%)	0.0324	40 (11.1%)	<.0001
	TAF at 24 months	343 (97.7%)	20 (87.0%)	274 (98.9%)	0.0068	0	.	10 (90.9%)	1.0000	39 (97.5%)	0.1338
	No TAF at 24 months	8 (2.3%)	3 (13.0%)	3 (1.1%)	.	0	.	1 (9.1%)	.	1 (2.5%)	.
Change in Backbone Agent (concurrent TAF use at 24 months) : No Baseline TAF	Over all	2076 (85.5%)	788 (97.2%)	781 (73.8%)	<.0001	31 (100.0%)	1.0000	155 (93.4%)	0.0324	321 (88.9%)	<.0001
	TAF at 24 months	472 (22.7%)	42 (5.3%)	324 (41.5%)	<.0001	3 (9.7%)	0.2394	34 (21.9%)	<.0001	69 (21.5%)	<.0001
	No TAF at 24 months	1604 (77.3%)	746 (94.7%)	457 (58.5%)	.	28 (90.3%)	.	121 (78.1%)	.	252 (78.5%)	.
Change in Backbone Agent (TAF)	TAF during follow-up	351 (100.0%)	23 (100.0%)	277 (100.0%)	.	0	.	11 (100.0%)	.	40 (100.0%)	.

		Overall N= 2,427	DTG N= 811	EVG/c N= 1,058	DTG vs. EVG p-value	RAL N= 31	DTG vs. RAL p-value	DRV(/r/ c) N= 166	DTG vs. DRV(/r/ c) p-value	RPV N= 361	DTG vs. RPV p-value
use at any point during follow-up) : Baseline TAF											
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	491 (23.7%)	44 (5.6%)	334 (42.8%)	<.0001	3 (9.7%)	0.4149	35 (22.6%)	<.0001	75 (23.4%)	<.0001
	No TAF during follow-up	1585 (76.3%)	744 (94.4%)	447 (57.2%)	.	28 (90.3%)	.	120 (77.4%)	.	246 (76.6%)	.

*Table 69. Weight, BMI, lipids, and incident lipodystrophy at 24-months follow-up in ART-naïve patients with at least one lipid test available*

		Overall N= 1,384	DTG N= 452	EVG/c N= 618	DTG vs. EVG p-value	RAL N= 12	DTG vs. RAL p-value	DRV(/r/ c) N= 86	DTG vs. DRV(/r/ c) p-value	RPV N= 216	DTG vs. RPV p-value
Weight, kg	Median (IQR)	79.9 (69.7, 93.4)	80.5 (70.3, 95.1)	78.5 (68.7, 90.7)	0.0256	95.3 (80.5, 109.9)	0.0562	83.3 (67.7, 96.3)	0.9138	82.4 (72.1, 98.9)	0.3708
Change in weight from baseline, kg	Median (IQR)	3.6 (0.0, 8.2)	4.1 (0.6, 9.5)	3.3 (0.0, 7.7)	0.0216	4.1 (0.6, 8.9)	0.9261	4.4 (-0.2, 12.6)	0.8019	2.8 (-0.9, 6.9)	0.0049

		Overall N=1,384	DTG N=452	EVG/ c N=618	DTG vs. EVG p-value	RAL N=12	DTG vs. RAL p-value	DRV(/r /c) N=86	DTG vs. DRV(/r /c) p-value	RPV N=216	DTG vs. RPV p-value
	Mean (SD)	4.6 (8.2)	5.4 (8.7)	4.1 (7.7)	.	5.5 (8.6)	.	6.4 (10.4)	.	3.4 (7.0)	.
	No change ( $\pm$ <3 kg)	464 (33.5 %)	138 (30.5 %)	222 (35.9 %)	0.24 52	3 (25.0 %)	0.97 45	27 (31.4% )	0.2175	74 (34.3 %)	0.10 99
	Weight increase 3 to <5 kg	200 (14.5 %)	75 (16.6 %)	89 (14.4 %)	.	2 (16.7 %)	.	7 (8.1%)	.	27 (12.5 %)	.
	Weight increase ≥5 kg	550 (39.7 %)	190 (42.0 %)	235 (38.0 %)	.	5 (41.7 %)	.	41 (47.7% )	.	79 (36.6 %)	.
	Weight decrease 3 to <5 kg	87 (6.3% )	23 (5.1%)	41 (6.6% )	.	1 (8.3%)	.	3 (3.5%)	.	19 (8.8%)	.
	Weight decrease ≥5 kg	83 (6.0% )	26 (5.8%)	31 (5.0% )	.	1 (8.3%)	.	8 (9.3%)	.	17 (7.9%)	.
Change in weight from baseline, %	Median (IQR)	4.7 (0.0, 10.5)	5.6 (0.9, 11.6)	4.5 (0.0, 10.2)	0.01 86	4.9 (0.5, 8.3)	0.77 76	5.7 (- 0.4, 17.6)	0.7403	3.8 (- 1.3, 8.7)	0.00 12
	Mean (SD)	6.2 (11.1)	7.3 (11.5)	5.7 (11.2)	.	6.9 (10.9)	.	8.5 (13.4)	.	4.3 (8.4)	.
	No change ( $\pm$ <5%)	590 (42.6 %)	170 (37.6 %)	282 (45.6 %)	0.02 66	4 (33.3 %)	0.60 15	31 (36.0% )	0.6299	103 (47.7 %)	0.00 84
	Weight increase ≥5%	669 (48.3 %)	244 (54.0 %)	285 (46.1 %)	.	6 (50.0 %)	.	45 (52.3% )	.	89 (41.2 %)	.
	Weight decrease ≥5%	125 (9.0% )	38 (8.4%)	51 (8.3% )	.	2 (16.7 %)	.	10 (11.6% )	.	24 (11.1 %)	.
BMI	Median (IQR)	26.7 (23.5, 30.6)	26.8 (23.8, 31.3)	26.0 (23.2, 29.9)	0.00 24	31.0 (27.7, 34.0)	0.08 23	26.7 (23.3, 32.8)	0.6490	27.6 (24.0, 31.4)	0.46 31
Change in BMI from baseline	Median (IQR)	1.2 (- 0.0, 2.7)	1.3 (0.1, 3.1)	1.2 (- 0.1, 2.6)	0.06 36	1.2 (0.1, 2.4)	0.96 43	1.5 (- 0.1, 4.3)	0.6817	1.0 (- 0.4, 2.3)	0.01 97



		Overall N= 1,384	DTG N= 452	EVG/ c N= 618	DTG vs. EVG p- valu e	RAL N= 12	DTG vs. RAL p- valu e	DRV(/r /c) N= 86	DTG vs. DRV(/r /c) p-value	RPV N= 216	DTG vs. RPV p- valu e
	Mean (SD)	1.4 (3.0)	1.7 (3.3)	1.3 (2.8)	.	1.9 (3.1)	.	2.1 (3.4)	.	1.1 (2.4)	.
Number of patients without lipodystro phy at baseline	Yes	1383 (99.9 %)	452 (100.0 %)	617 (99.8 %)	1.00 00	12 (100.0 %)	.	86 (100.0 %)	.	216 (100.0 %)	.
Number of incident cases of lipodystro phy	Yes	6 (0.4% )	2 (0.4% )	3 (0.5% )	1.00 00	0 (0.0% )	1.00 00	1 (1.2% )	0.4076	0 (0.0% )	1.00 00
Incident lipodystro phy	% (95% CI)	0.43 (0.16, 0.94)	0.44 (0.05, 1.59)	0.49 (0.10, 1.41)	.		.	1.16 (0.03, 6.31)	.		.
Total Cholesterol, mg/dL	Median (IQR)	170.0 (149.0, 196.0 )	167.0 (148.0, 192.0)	176.0 (151.0, 199.0 )	0.00 50	168.5 (125.5, 196.5)	0.46 03	181.5 (150.5, 209.5)	0.0390	165.0 (143.5, 184.0)	0.20 00
	Normal (<200 mg/dl)	1074 (77.6 %)	357 (79.0 %)	470 (76.1 %)	0.65 75	10 (83.3 %)	1.00 00	57 (66.3% )	0.0044	180 (83.3 %)	0.18 31
	Borderlin e Abnormal (>=200 to <240 mg/dl)	237 (17.1 %)	71 (15.7 %)	115 (18.6 %)	.	2 (16.7 %)	.	17 (19.8% )	.	32 (14.8 %)	.
	Dyslipide mia (>=240 to <280 mg/dl)	60 (4.3% )	20 (4.4% )	28 (4.5% )	.	0 (0.0% )	.	9 (10.5% )	.	3 (1.4% )	.
	Severe Dyslipide mia (>=280 mg/dl)	11 (0.8% )	4 (0.9% )	5 (0.8% )	.	0 (0.0% )	.	1 (1.2% )	.	1 (0.5% )	.

		Overall N= 1,384	DTG N= 452	EVG/ c N= 618	DTG vs. EVG p-value	RAL N= 12	DTG vs. RAL p-value	DRV(/r /c) N= 86	DTG vs. DRV(/r /c) p-value	RPV N= 216	DTG vs. RPV p-value
	Missing	2 (0.1%)	0 (0.0%)	0 (0.0%)	.	0 (0.0%)	.	2 (2.3%)	.	0 (0.0%)	.
LDL, mg/dL	Median (IQR)	95.1 (76.2, 116.8)	92.0 (75.0, 113.0)	98.0 (78.0, 119.0)	0.01 63	76.2 (58.5, 99.5)	0.11 50	103.8 (79.0, 134.6)	0.0167	93.0 (76.0, 109.8)	0.93 81
	Normal (<100 mg/dl)	749 (54.1 %)	261 (57.7 %)	314 (50.8 %)	0.38 62	9 (75.0 %)	0.64 20	35 (40.7% )	0.0063	130 (60.2 %)	0.16 01
	Borderlin e Abnormal (≥100 to <130 mg/dl)	388 (28.0 %)	117 (25.9 %)	182 (29.4 %)	.	1 (8.3%)	.	23 (26.7% )	.	65 (30.1 %)	.
	Dyslipide mia (≥130 to <160 mg/dl)	151 (10.9 %)	44 (9.7%)	70 (11.3 %)	.	2 (16.7 %)	.	20 (23.3% )	.	15 (6.9%)	.
	Severe Dyslipide mia (≥160 to <190 mg/dl)	37 (2.7% )	11 (2.4%)	20 (3.2% )	.	0 (0.0%)	.	2 (2.3%)	.	4 (1.9%)	.
	Very Severe Dyslipide mia (≥190 mg/dl)	13 (0.9% )	4 (0.9%)	7 (1.1% )	.	0 (0.0%)	.	1 (1.2%)	.	1 (0.5%)	.
	Missing	46 (3.3% )	15 (3.3%)	25 (4.0% )	.	0 (0.0%)	.	5 (5.8%)	.	1 (0.5%)	.
HDL, mg/dL	Median (IQR)	45.0 (37.0, 55.0)	45.0 (37.0, 55.0)	45.0 (38.0, 55.0)	0.97 10	44.0 (33.0, 60.5)	0.79 98	45.0 (36.0, 56.0)	0.7535	45.0 (36.0, 54.0)	0.29 95
	Normal (≥60 mg/dl)	226 (16.3 %)	76 (16.8 %)	102 (16.5 %)	0.69 61	3 (25.0 %)	0.63 46	15 (17.4% )	0.0383	30 (13.9 %)	0.72 18

		Overall N=1,384	DTG N=452	EVG/ c N=618	DTG vs. EVG p-value	RAL N=12	DTG vs. RAL p-value	DRV(/r /c) N=86	DTG vs. DRV(/r /c) p-value	RPV N=216	DTG vs. RPV p-value
	Borderline Abnormal (>=40 to <60 mg/dl)	713 (51.5%)	228 (50.4%)	332 (53.7%)	.	5 (41.7%)	.	38 (44.2%)	.	110 (50.9%)	.
	Dyslipidemia (<40 mg/dl)	439 (31.7%)	147 (32.5%)	182 (29.4%)	.	4 (33.3%)	.	30 (34.9%)	.	76 (35.2%)	.
	Missing	6 (0.4%)	1 (0.2%)	2 (0.3%)	.	0 (0.0%)	.	3 (3.5%)	.	0 (0.0%)	.
Triglycerides, mg/dL	Median (IQR)	121.0 (81.0, 180.0)	117.0 (80.0, 179.0)	127.0 (84.0, 185.0)	0.1326	115.5 (57.0, 229.0)	0.6891	130.0 (86.0, 209.0)	0.1482	112.5 (71.0, 169.0)	0.1501
	Normal (<150 mg/dl)	877 (63.4%)	291 (64.4%)	384 (62.1%)	0.8574	7 (58.3%)	0.5510	52 (60.5%)	0.5098	143 (66.2%)	0.5447
	Borderline Abnormal (>=150 to <200 mg/dl)	220 (15.9%)	71 (15.7%)	102 (16.5%)	.	1 (8.3%)	.	11 (12.8%)	.	35 (16.2%)	.
	Dyslipidemia (>=200 to <500 mg/dl)	264 (19.1%)	83 (18.4%)	118 (19.1%)	.	4 (33.3%)	.	21 (24.4%)	.	38 (17.6%)	.
	Severe Dyslipidemia (>=500 mg/dl)	21 (1.5%)	6 (1.3%)	13 (2.1%)	.	0 (0.0%)	.	2 (2.3%)	.	0 (0.0%)	.
	Missing	2 (0.1%)	1 (0.2%)	1 (0.2%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.

*Table 70. Changes in BMI category at 24-months follow-up in ART-naïve patients with at least one lipid test available*

		Overall N= 1,384	DTG N= 452	EVG/ c N= 618	DTG vs. EVG p-value	RAL N= 12	DTG vs. RAL p-value	DRV(/r /c) N= 86	DTG vs. DRV(/r /c) p-value	RPV N= 216	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	40 (2.9%)	14 (3.1%)	16 (2.6%)	0.7085	1 (8.3%)	0.3291	5 (5.8%)	0.2065	4 (1.9%)	0.4493
	Underweight (BMI: <18.5)	14 (35.0%)	2 (14.3%)	8 (50.0%)	0.0343	1 (100.0%)	0.2000	1 (20.0%)	1.0000	2 (50.0%)	0.1971
	Normal (BMI: 18.5 – 24.9)	25 (62.5%)	12 (85.7%)	7 (43.8%)	.	0 (0.0%)	.	4 (80.0%)	.	2 (50.0%)	.
	Obese (BMI: ≥30)	1 (2.5%)	0 (0.0%)	1 (6.3%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	614 (44.4%)	188 (41.6%)	306 (49.5%)	0.0109	1 (8.3%)	0.0326	37 (43.0%)	0.8125	82 (38.0%)	0.3997
	Underweight (BMI: <18.5)	10 (1.6%)	2 (1.1%)	4 (1.3%)	0.4261	0 (0.0%)	1.0000	4 (10.8%)	0.0284	0 (0.0%)	0.0972
	Normal (BMI: 18.5 – 24.9)	421 (68.6%)	122 (64.9%)	215 (70.3%)	.	1 (100.0%)	.	23 (62.2%)	.	60 (73.2%)	.
	Overweight (BMI: 25.0-29.9)	163 (26.5%)	54 (28.7%)	78 (25.5%)	.	0 (0.0%)	.	9 (24.3%)	.	22 (26.8%)	.
	Obese (BMI: ≥30)	20 (3.3%)	10 (5.3%)	9 (2.9%)	.	0 (0.0%)	.	1 (2.7%)	.	0 (0.0%)	.

		Overall N= 1,384	DTG N= 452	EVG/ c N= 618	DTG vs. EVG p-value	RAL N= 12	DTG vs. RAL p-value	DRV(/r /c) N= 86	DTG vs. DRV(/r /c) p-value	RPV N= 216	DTG vs. RPV p-value
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	440 (31.8 %)	137 (30.3 %)	201 (32.5 %)	0.4643	5 (41.7%)	0.5257	27 (31.4%)	0.8984	70 (32.4 %)	0.5924
	Underweight (BMI: <18.5)	1 (0.2%)	0 (0.0%)	1 (0.5%)	0.9070	0 (0.0%)	0.7719	0 (0.0%)	0.0195	0 (0.0%)	0.5722
	Normal (BMI: 18.5 – 24.9)	38 (8.6%)	14 (10.2 %)	18 (9.0%)	.	0 (0.0%)	.	2 (7.4%)	.	4 (5.7%)	.
	Overweight (BMI: 25.0-29.9)	280 (63.6 %)	90 (65.7 %)	129 (64.2 %)	.	3 (60.0%)	.	11 (40.7%)	.	47 (67.1 %)	.
	Obese (BMI: ≥30)	121 (27.5 %)	33 (24.1 %)	53 (26.4 %)	.	2 (40.0%)	.	14 (51.9%)	.	19 (27.1 %)	.
Change in BMI Category: Baseline Obese (BMI: ≥30)	Overall	290 (21.0 %)	113 (25.0 %)	95 (15.4 %)	0.0001	5 (41.7%)	0.1920	17 (19.8%)	0.3379	60 (27.8 %)	0.4512
	Underweight (BMI: <18.5)	2 (0.7%)	1 (0.9%)	1 (1.1%)	0.3622	0 (0.0%)	1.0000	0 (0.0%)	1.0000	0 (0.0%)	1.0000
	Overweight (BMI: 25.0-29.9)	26 (9.0%)	12 (10.6 %)	5 (5.3%)	.	0 (0.0%)	.	2 (11.8%)	.	7 (11.7 %)	.
	Obese (BMI: ≥30)	262 (90.3 %)	100 (88.5 %)	89 (93.7 %)	.	5 (100.0 %)	.	15 (88.2%)	.	53 (88.3 %)	.

*Table 71. Changes in backbone agent at 24-months follow-up in ART-naïve patients with at least one lipid test available*

		Overall N= 1,384	DTG N= 452	EVG/c N= 618	DTG vs. EVG p- value	RAL N= 12	DTG vs. RAL p- value	DRV(/r/ c) N= 86	DTG vs. DRV(/r/ c) p-value	RPV N= 216	DTG vs. RPV p- value
Change in Backbone Agent (concurrent TAF use at 24 months) : Baseline TAF	Overall	202 (14.6%)	13 (2.9%)	163 (26.4%)	<.0001	0 (0.0%)	1.0000	7 (8.1%)	0.0276	19 (8.8%)	0.0015
	TAF at 24 months	201 (99.5%)	13 (100.0%)	163 (100.0%)	.	0	.	6 (85.7%)	0.3500	19 (100.0%)	.
	No TAF at 24 months	1 (0.5%)	0 (0.0%)	0 (0.0%)	.	0	.	1 (14.3%)	.	0 (0.0%)	.
Change in Backbone Agent (concurrent TAF use at 24 months) : No Baseline TAF	Overall	1182 (85.4%)	439 (97.1%)	455 (73.6%)	<.0001	12 (100.0%)	1.0000	79 (91.9%)	0.0276	197 (91.2%)	0.0015
	TAF at 24 months	290 (24.5%)	24 (5.5%)	198 (43.5%)	<.0001	1 (8.3%)	0.5000	20 (25.3%)	<.0001	47 (23.9%)	<.0001
	No TAF at 24 months	892 (75.5%)	415 (94.5%)	257 (56.5%)	.	11 (91.7%)	.	59 (74.7%)	.	150 (76.1%)	.
Change in Backbone Agent	TAF during	202 (100.0%)	13 (100.0%)	163 (100.0%)	.	0	.	7 (100.0%)	.	19 (100.0%)	.

		Overall N= 1,384	DTG N= 452	EVG/c N= 618	DTG vs. EVG p- value	RAL N= 12	DTG vs. RAL p- value	DRV(/r/ c) N= 86	DTG vs. DRV(/r/ c) p-value	RPV N= 216	DTG vs. RPV p- value
(TAF use at any point during follow- up) : Baseline TAF	follo w-up										
Change in Backbon e Agent (TAF use at any point during follow- up) : No Baseline TAF	TAF durin g follo w-up	302 (25.5% )	24 (5.5%)	205 (45.1% )	<.00 01	1 (8.3%)	0.50 00	20 (25.3%)	<.0001	52 (26.4% )	<.00 01
	No TAF durin g follo w-up	880 (74.5% )	415 (94.5% )	250 (54.9% )	.	11 (91.7% )	.	59 (74.7%)	.	145 (73.6% )	.

### 1.5.2.2. Treatment-experienced patients

Table 72. Weight, BMI, and incident lipodystrophy at 24-months follow-up in ART-experienced patients

		Overa ll N= 6,213	DTG N= 2,175	EVG/ c N= 2,214	DTG vs. EVG p- value	RAL N= 261	DTG vs. RAL p- value	DRV(/r/ c) N= 554	DTG vs. DRV(/r/ c) p-value	RPV N= 1,009	DTG vs. RPV p- value
Weight, kg	Media n (IQR)	81.2 (70.8, 92.5)	80.9 (70.4, 92.1)	80.9 (70.8, 92.1)	0.743 8	82.6 (71.7, 96.1)	0.075 4	81.8 (70.8, 94.3)	0.3054	81.6 (71.0, 93.4)	0.370 3

		Overall N=6,213	DTG N=2,175	EVG/ c N=2,214	DTG vs. EVG p-value	RAL N=261	DTG vs. RAL p-value	DRV(/r/ c) N=554	DTG vs. DRV(/r/ c) p-value	RPV N=1,009	DTG vs. RPV p-value
Change in weight from baseline, kg	Median (IQR)	1.8 (-1.4, 5.9)	1.8 (-1.4, 5.9)	2.0 (-0.9, 5.9)	0.4120	0.9 (-2.7, 5.4)	0.0093	1.4 (-1.8, 5.9)	0.1030	2.0 (-0.9, 5.7)	0.4905
	Mean (SD)	2.4 (7.4)	2.4 (7.7)	2.6 (7.1)	.	1.4 (8.1)	.	2.1 (7.4)	.	2.5 (6.7)	.
	No change ( $\pm <3$ kg)	2665 (42.9 %)	912 (41.9 %)	967 (43.7 %)	0.4819	111 (42.5 %)	0.0895	245 (44.2 %)	0.3347	430 (42.6 %)	0.5852
	Weight increase 3 to <5 kg	815 (13.1 %)	288 (13.2 %)	301 (13.6 %)	.	24 (9.2 %)	.	56 (10.1 %)	.	146 (14.5 %)	.
	Weight increase $\geq 5$ kg	1746 (28.1 %)	617 (28.4 %)	622 (28.1 %)	.	68 (26.1 %)	.	154 (27.8 %)	.	285 (28.2 %)	.
	Weight decrease 3 to <5 kg	426 (6.9 %)	154 (7.1 %)	145 (6.5 %)	.	26 (10.0 %)	.	43 (7.8 %)	.	58 (5.7 %)	.
	Weight decrease $\geq 5$ kg	561 (9.0 %)	204 (9.4 %)	179 (8.1 %)	.	32 (12.3 %)	.	56 (10.1 %)	.	90 (8.9 %)	.
Change in weight from baseline, %	Median (IQR)	2.4 (-1.6, 7.2)	2.4 (-1.6, 7.3)	2.6 (-1.3, 7.4)	0.4785	1.0 (-3.3, 6.6)	0.0058	1.8 (-2.4, 7.2)	0.0618	2.7 (-1.2, 7.1)	0.6173
	Mean (SD)	3.3 (9.3)	3.4 (9.8)	3.4 (8.8)	.	2.2 (10.2)	.	2.9 (10.2)	.	3.4 (8.6)	.
	No change ( $\pm <5\%$ )	3278 (52.8 %)	1135 (52.2 %)	1173 (53.0 %)	0.4322	137 (52.5 %)	0.0703	304 (54.9 %)	0.1499	529 (52.4 %)	0.9132



		Overall N=6,213	DTG N=2,175	EVG/ c N=2,214	DTG vs. EVG p-value	RAL N=261	DTG vs. RAL p-value	DRV(/r/ c) N= 554	DTG vs. DRV(/r/ c) p-value	RPV N=1,009	DTG vs. RPV p-value
	Weight increase ≥5%	2182 (35.1%)	772 (35.5%)	796 (36.0%)	.	80 (30.7%)	.	173 (31.2%)	.	361 (35.8%)	.
	Weight decrease ≥5%	753 (12.1%)	268 (12.3%)	245 (11.1%)	.	44 (16.9%)	.	77 (13.9%)	.	119 (11.8%)	.
BMI	Median (IQR)	26.7 (23.7, 30.4)	26.6 (23.8, 30.3)	26.5 (23.6, 30.0)	0.3856	26.9 (23.6, 30.8)	0.4267	27.2 (24.0, 31.0)	0.0380	27.0 (23.8, 31.0)	0.1143
Change in BMI from baseline	Median (IQR)	0.6 (-0.5, 2.0)	0.6 (-0.5, 2.0)	0.6 (-0.4, 1.9)	0.5318	0.3 (-0.9, 1.9)	0.0301	0.4 (-0.7, 1.9)	0.0876	0.7 (-0.4, 2.0)	0.4295
	Mean (SD)	0.8 (3.2)	0.7 (2.9)	0.8 (3.7)	.	0.4 (2.8)	.	0.6 (2.8)	.	0.8 (2.5)	.
Number of patients without lipodystrophy at baseline	Yes	6134 (98.7%)	2142 (98.5%)	2197 (99.2%)	0.0193	249 (95.4%)	0.0005	547 (98.7%)	0.6573	999 (99.0%)	0.2314
Number of incident cases of lipodystrophy	Yes	40 (0.7%)	14 (0.7%)	15 (0.7%)	1.0000	2 (0.8%)	0.6795	5 (0.9%)	0.5654	4 (0.4%)	0.4565
Incident lipodystrophy	% (95% CI)	0.65 (0.47, 0.89)	0.65 (0.36, 1.09)	0.68 (0.38, 1.12)	.	0.80 (0.10, 2.87)	.	0.91 (0.30, 2.12)	.	0.40 (0.11, 1.02)	.

Table 73. Changes in BMI category at 24-months follow-up in ART-experienced patients

		Overall N=6,213	DTG N=2,175	EVG/ c N=2,214	DTG vs. EVG p-value	RAL N=261	DTG vs. RAL p-value	DRV(/r /c) N=554	DTG vs. DRV(/r /c) p-value	RPV N=1,009	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	134 (2.2%)	49 (2.3%)	45 (2.0%)	0.6769	5 (1.9%)	1.0000	10 (1.8%)	0.6244	25 (2.5%)	0.7053
	Underweight (BMI: <18.5)	60 (44.8%)	18 (36.7%)	25 (55.6%)	0.0619	1 (20.0%)	0.1189	5 (50.0%)	0.4539	11 (44.0%)	0.5461
	Normal (BMI: 18.5 – 24.9)	67 (50.0%)	28 (57.1%)	20 (44.4%)	.	3 (60.0%)	.	4 (40.0%)	.	12 (48.0%)	.
	Overweight (BMI: 25.0-29.9)	5 (3.7%)	3 (6.1%)	0 (0.0%)	.	0 (0.0%)	.	1 (10.0%)	.	1 (4.0%)	.
	Obese (BMI: ≥30)	2 (1.5%)	0 (0.0%)	0 (0.0%)	.	1 (20.0%)	.	0 (0.0%)	.	1 (4.0%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	2411 (38.8%)	845 (38.9%)	908 (41.0%)	0.1439	91 (34.9%)	0.2111	189 (34.1%)	0.0403	378 (37.5%)	0.4538
	Underweight (BMI: <18.5)	35 (1.5%)	11 (1.3%)	13 (1.4%)	0.0881	3 (3.3%)	0.1205	4 (2.1%)	0.5496	4 (1.1%)	0.1901
	Normal (BMI: 18.5 – 24.9)	1767 (73.3%)	598 (70.8%)	675 (74.3%)	.	71 (78.0%)	.	134 (70.9%)	.	289 (76.5%)	.
	Overweight (BMI: 25.0-29.9)	570 (23.6%)	215 (25.4%)	210 (23.1%)	.	16 (17.6%)	.	49 (25.9%)	.	80 (21.2%)	.
	Obese (BMI: ≥30)	39 (1.6%)	21 (2.5%)	10 (1.1%)	.	1 (1.1%)	.	2 (1.1%)	.	5 (1.3%)	.

		Overall N= 6,213	DTG N= 2,175	EVG/ c N= 2,214	DTG vs. EVG p-value	RAL N= 261	DTG vs. RAL p-value	DRV(/r /c) N= 554	DTG vs. DRV(/r /c) p-value	RPV N= 1,009	DTG vs. RPV p-value
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	2291 (36.9 %)	819 (37.7 %)	794 (35.9 %)	0.21 81	101 (38.7 %)	0.74 28	215 (38.8%)	0.6173	362 (35.9 %)	0.33 39
	Underweight (BMI: <18.5)	3 (0.1%)	1 (0.1%)	2 (0.3%)	0.47 56	0 (0.0%)	0.41 35	0 (0.0%)	0.6819	0 (0.0%)	0.09 42
	Normal (BMI: 18.5 – 24.9)	222 (9.7%)	84 (10.3 %)	70 (8.8%)	.	14 (13.9 %)	.	27 (12.6%)	.	27 (7.5%)	.
	Overweight (BMI: 25.0-29.9)	1626 (71.0 %)	579 (70.7 %)	587 (73.9 %)	.	65 (64.4 %)	.	147 (68.4%)	.	248 (68.5 %)	.
	Obese (BMI: ≥30)	440 (19.2 %)	155 (18.9 %)	135 (17.0 %)	.	22 (21.8 %)	.	41 (19.1%)	.	87 (24.0 %)	.
Change in BMI Category: Baseline Obese (BMI: ≥30)	Overall	1377 (22.2 %)	462 (21.2 %)	467 (21.1 %)	0.90 43	64 (24.5 %)	0.22 37	140 (25.3%)	0.0412	244 (24.2 %)	0.06 31
	Underweight (BMI: <18.5)	2 (0.1%)	2 (0.4%)	0 (0.0%)	0.61 65	0 (0.0%)	0.94 96	0 (0.0%)	0.9784	0 (0.0%)	0.74 54
	Normal (BMI: 18.5 – 24.9)	21 (1.5%)	7 (1.5%)	9 (1.9%)	.	1 (1.6%)	.	2 (1.4%)	.	2 (0.8%)	.
	Overweight (BMI: 25.0-29.9)	154 (11.2 %)	53 (11.5 %)	50 (10.7 %)	.	8 (12.5 %)	.	17 (12.1%)	.	26 (10.7 %)	.
	Obese (BMI: ≥30)	1200 (87.1 %)	400 (86.6 %)	408 (87.4 %)	.	55 (85.9 %)	.	121 (86.4%)	.	216 (88.5 %)	.

Table 74. Changes in backbone agent at 24-months follow-up in ART-experienced patients

		Overall N= 6,213	DTG N= 2,175	EVG/c N= 2,214	DTG vs. EVG p- value	RAL N= 261	DTG vs. RAL p- value	DRV(/r/ c) N= 554	DTG vs. DRV(/r/ c) p-value	RPV N= 1,009	DTG vs. RPV p- value
Change in Backbone Agent (concurrent TAF use at 24 months) : Baseline TAF	Overall	1242 (20.0%)	104 (4.8%)	860 (38.8%)	<.0001	2 (0.8%)	0.0010	26 (4.7%)	1.0000	250 (24.8%)	<.0001
	TAF at 24 months	1221 (98.3%)	100 (96.2%)	846 (98.4%)	0.1196	2 (100.0%)	1.0000	25 (96.2%)	1.0000	248 (99.2%)	0.0640
	No TAF at 24 months	21 (1.7%)	4 (3.8%)	14 (1.6%)	.	0 (0.0%)	.	1 (3.8%)	.	2 (0.8%)	.
Change in Backbone Agent (concurrent TAF use at 24 months) : No Baseline TAF	Overall	4971 (80.0%)	2071 (95.2%)	1354 (61.2%)	<.0001	259 (99.2%)	0.0010	528 (95.3%)	1.0000	759 (75.2%)	<.0001
	TAF at 24 months	1296 (26.1%)	215 (10.4%)	660 (48.7%)	<.0001	32 (12.4%)	0.3307	127 (24.1%)	<.0001	262 (34.5%)	<.0001
	No TAF at 24 months	3675 (73.9%)	1856 (89.6%)	694 (51.3%)	.	227 (87.6%)	.	401 (75.9%)	.	497 (65.5%)	.
Change in Backbone	TAF during	1242 (100.0%)	104 (100.0%)	860 (100.0%)	.	2 (100.0%)	.	26 (100.0%)	.	250 (100.0%)	.

		Overall N= 6,213	DTG N= 2,175	EVG/c N= 2,214	DTG vs. EVG p- value	RAL N= 261	DTG vs. RAL p- value	DRV(/r/ c) N= 554	DTG vs. DRV(/r/ c) p-value	RPV N= 1,009	DTG vs. RPV p- value
e Agent (TAF use at any point during follow- up) : Baseline TAF	follo w-up										
Change in Backbon e Agent (TAF use at any point during follow- up) : No Baseline TAF	TAF durin g follo w-up	1335 (26.9% )	220 (10.6% )	678 (50.1% )	<.00 01	34 (13.1% )	0.22 27	130 (24.6%)	<.0001	273 (36.0% )	<.00 01
	No TAF durin g follo w-up	3636 (73.1% )	1851 (89.4% )	676 (49.9% )	.	225 (86.9% )	.	398 (75.4%)	.	486 (64.0% )	.

*Table 75. Weight, BMI, lipids, and incident lipodystrophy at 24-months follow-up in ART-experienced patients with at least one lipid test available*

		Overall N= 3,823	DTG N= 1,283	EVG/ c N= 1,383	DTG vs. EVG p-value	RAL N= 174	DTG vs. RAL p-value	DRV(/r /c) N= 351	DTG vs. DRV(/r /c) p-value	RPV N= 632	DTG vs. RPV p-value
Weight, kg	Median (IQR)	81.7 (71.4, 93.4)	81.6 (71.2, 93.0)	81.6 (71.7, 92.5)	0.52 90	84.2 (72.6, 95.3)	0.21 31	82.7 (72.3, 94.3)	0.2993	82.0 (70.7, 94.3)	0.71 02
Change in weight from baseline, kg	Median (IQR)	1.9 (- 1.0, 5.6)	1.8 (- 1.1, 5.6)	2.3 (- 0.9, 5.9)	0.24 98	0.9 (- 2.7, 5.4)	0.02 60	1.4 (- 1.8, 5.6)	0.1857	1.8 (- 0.9, 5.4)	0.88 61
	Mean (SD)	2.4 (7.2)	2.5 (7.8)	2.7 (6.7)	.	1.2 (8.4)	.	2.1 (7.2)	.	2.3 (6.4)	.
	No change ( $\pm$ <3 kg)	1682 (44.0 %)	551 (42.9 %)	622 (45.0 %)	0.34 18	73 (42.0 %)	0.26 79	167 (47.6%)	0.2235	269 (42.6 %)	0.97 30
	Weight increase 3 to <5 kg	511 (13.4 %)	178 (13.9 %)	187 (13.5 %)	.	18 (10.3 %)	.	33 (9.4%)	.	95 (15.0 %)	.
	Weight increase ≥5 kg	1053 (27.5 %)	353 (27.5 %)	390 (28.2 %)	.	45 (25.9 %)	.	95 (27.1%)	.	170 (26.9 %)	.
	Weight decrease 3 to <5 kg	244 (6.4%)	82 (6.4%)	85 (6.1%)	.	16 (9.2%)	.	22 (6.3%)	.	39 (6.2%)	.
	Weight decrease ≥5 kg	333 (8.7%)	119 (9.3%)	99 (7.2%)	.	22 (12.6 %)	.	34 (9.7%)	.	59 (9.3%)	.
Change in weight from baseline, %	Median (IQR)	2.4 (- 1.4, 7.1)	2.5 (- 1.3, 7.2)	2.7 (- 1.1, 7.3)	0.30 77	1.2 (- 3.0, 6.6)	0.01 61	1.8 (- 2.0, 7.0)	0.1059	2.4 (- 1.3, 6.8)	0.67 75
	Mean (SD)	3.3 (9.1)	3.5 (10.0)	3.6 (8.4)	.	2.1 (10.7)	.	2.8 (9.6)	.	3.0 (8.0)	.
	No change ( $\pm$ <5%)	2064 (54.0 %)	694 (54.1 %)	745 (53.9 %)	0.45 85	92 (52.9 %)	0.06 81	197 (56.1%)	0.2877	336 (53.2 %)	0.71 55

		Overall N=3,823	DTG N=1,283	EVG/ c N=1,383	DTG vs. EVG p-value	RAL N=174	DTG vs. RAL p-value	DRV(/r /c) N=351	DTG vs. DRV(/r /c) p-value	RPV N=632	DTG vs. RPV p-value
	Weight increase ≥5%	1317 (34.4%)	443 (34.5%)	499 (36.1%)	.	52 (29.9%)	.	107 (30.5%)	.	216 (34.2%)	.
	Weight decrease ≥5%	442 (11.6%)	146 (11.4%)	139 (10.1%)	.	30 (17.2%)	.	47 (13.4%)	.	80 (12.7%)	.
BMI	Median (IQR)	26.9 (24.0, 30.5)	26.9 (23.9, 30.5)	26.7 (24.0, 29.9)	0.28 54	27.5 (23.7, 31.0)	0.51 12	27.5 (24.3, 31.3)	0.1214	27.0 (23.8, 31.2)	0.56 24
Change in BMI from baseline	Median (IQR)	0.6 (- 0.4, 1.9)	0.6 (- 0.4, 1.9)	0.7 (- 0.3, 1.9)	0.30 41	0.4 (- 0.8, 2.0)	0.13 28	0.4 (- 0.6, 1.9)	0.2385	0.6 (- 0.4, 1.9)	0.99 63
	Mean (SD)	0.8 (2.7)	0.7 (3.0)	0.8 (2.4)	.	0.4 (2.9)	.	0.7 (2.6)	.	0.7 (2.5)	.
Number of patients without lipodystro phy at baseline	Yes	3766 (98.5%)	1259 (98.1%)	1371 (99.1%)	0.02 87	164 (94.3%)	0.00 46	347 (98.9%)	0.4868	625 (98.9%)	0.25 15
Number of incident cases of lipodystro phy	Yes	29 (0.8%)	10 (0.8%)	12 (0.9%)	0.83 45	1 (0.6%)	1.00 00	4 (1.2%)	0.5174	2 (0.3%)	0.35 72
Incident lipodystro phy	% (95% CI)	0.77 (0.52, 1.10)	0.79 (0.38, 1.46)	0.88 (0.45, 1.52)	.	0.61 (0.02, 3.35)	.	1.15 (0.31, 2.93)	.	0.32 (0.04, 1.15)	.
Total Cholesterol, mg/dL	Median (IQR)	175.0 (151.0, 202.0)	172.0 (148.0, 199.0)	181.0 (156.0, 206.0)	<.00 01	162.0 (141.0, 193.0)	0.01 44	179.0 (158.0, 204.0)	0.0016	167.5 (146.0, 198.0)	0.18 02
	Normal (<200 mg/dl)	2788 (72.9%)	964 (75.1%)	956 (69.1%)	0.00 64	134 (77.0%)	0.01 73	252 (71.8%)	0.0008	482 (76.3%)	0.68 74
	Borderline Abnormal (≥200 to <240 mg/dl)	754 (19.7%)	234 (18.2%)	319 (23.1%)	.	24 (13.8%)	.	60 (17.1%)	.	117 (18.5%)	.

		Overall N=3,823	DTG N=1,283	EVG/ c N=1,383	DTG vs. EVG p-value	RAL N=174	DTG vs. RAL p-value	DRV(/r /c) N=351	DTG vs. DRV(/r /c) p-value	RPV N=632	DTG vs. RPV p-value
	Dyslipidemia (≥240 to <280 mg/dl)	220 (5.8%)	69 (5.4%)	83 (6.0%)	.	13 (7.5%)	.	27 (7.7%)	.	28 (4.4%)	.
	Severe Dyslipidemia (≥280 mg/dl)	53 (1.4%)	16 (1.2%)	24 (1.7%)	.	1 (0.6%)	.	7 (2.0%)	.	5 (0.8%)	.
	Missing	8 (0.2%)	0 (0.0%)	1 (0.1%)	.	2 (1.1%)	.	5 (1.4%)	.	0 (0.0%)	.
LDL, mg/dL	Median (IQR)	98.0 (78.0, 121.0)	95.3 (75.0, 117.8)	102.0 (81.0, 125.0)	<.00 01	88.0 (66.0, 111.0)	0.01 52	100.4 (80.0, 125.0)	0.0085	96.0 (76.0, 116.0)	0.86 83
	Normal (<100 mg/dl)	1918 (50.2%)	690 (53.8%)	624 (45.1%)	0.00 02	103 (59.2%)	0.00 80	165 (47.0%)	0.1198	336 (53.2%)	0.97 86
	Borderline Abnormal (≥100 to <130 mg/dl)	1103 (28.9%)	363 (28.3%)	428 (30.9%)	.	33 (19.0%)	.	101 (28.8%)	.	178 (28.2%)	.
	Dyslipidemia (≥130 to <160 mg/dl)	476 (12.5%)	132 (10.3%)	201 (14.5%)	.	24 (13.8%)	.	49 (14.0%)	.	70 (11.1%)	.
	Severe Dyslipidemia (≥160 to <190 mg/dl)	142 (3.7%)	46 (3.6%)	55 (4.0%)	.	3 (1.7%)	.	18 (5.1%)	.	20 (3.2%)	.
	Very Severe Dyslipidemia (≥190 mg/dl)	40 (1.0%)	13 (1.0%)	15 (1.1%)	.	0 (0.0%)	.	6 (1.7%)	.	6 (0.9%)	.



		Overall N= 3,823	DTG N= 1,283	EVG/ c N= 1,383	DTG vs. EVG p-value	RAL N= 174	DTG vs. RAL p-value	DRV(/r /c) N= 351	DTG vs. DRV(/r /c) p-value	RPV N= 632	DTG vs. RPV p-value
	Missing	144 (3.8%)	39 (3.0%)	60 (4.3%)	.	11 (6.3%)	.	12 (3.4%)	.	22 (3.5%)	.
HDL, mg/dL	Median (IQR)	45.0 (37.0, 55.0)	45.0 (37.0, 54.0)	46.0 (38.0, 57.0)	0.00 01	41.0 (33.0, 51.0)	0.00 07	45.0 (37.0, 57.0)	0.6466	44.0 (36.0, 53.0)	0.54 57
	Normal (≥60 mg/dl)	653 (17.1 %)	201 (15.7 %)	280 (20.2 %)	0.00 09	19 (10.9 %)	0.00 86	64 (18.2%)	0.3780	89 (14.1 %)	0.49 80
	Borderline Abnormal (≥40 to <60 mg/dl)	1911 (50.0 %)	646 (50.4 %)	705 (51.0 %)	.	74 (42.5 %)	.	165 (47.0%)	.	321 (50.8 %)	.
	Dyslipide mia (<40 mg/dl)	1231 (32.2 %)	423 (33.0 %)	393 (28.4 %)	.	80 (46.0 %)	.	116 (33.0%)	.	219 (34.7 %)	.
	Missing	28 (0.7%)	13 (1.0%)	5 (0.4%)	.	1 (0.6%)	.	6 (1.7%)	.	3 (0.5%)	.
Triglyceri des, mg/dL	Median (IQR)	129.0 (90.0, 193.0)	128.5 (89.0, 193.0)	131.0 (92.0, 195.0)	0.20 54	130.0 (90.0, 209.0)	0.31 04	138.0 (94.0, 197.0)	0.0979	121.5 (84.0, 180.0)	0.00 96
	Normal (<150 mg/dl)	2297 (60.1 %)	769 (59.9 %)	815 (58.9 %)	0.85 08	96 (55.2 %)	0.72 43	200 (57.0%)	0.7337	417 (66.0 %)	0.09 01
	Borderline Abnormal (≥150 to <200 mg/dl)	617 (16.1 %)	206 (16.1 %)	231 (16.7 %)	.	30 (17.2 %)	.	64 (18.2%)	.	86 (13.6 %)	.
	Dyslipide mia (≥200 to <500 mg/dl)	841 (22.0 %)	282 (22.0 %)	310 (22.4 %)	.	45 (25.9 %)	.	82 (23.4%)	.	122 (19.3 %)	.
	Severe Dyslipide mia (≥500 mg/dl)	64 (1.7%)	23 (1.8%)	26 (1.9%)	.	3 (1.7%)	.	5 (1.4%)	.	7 (1.1%)	.

		Overall N= 3,823	DTG N= 1,283	EVG/ c N= 1,383	DTG vs. EVG p-value	RAL N= 174	DTG vs. RAL p-value	DRV(/r /c) N= 351	DTG vs. DRV(/r /c) p-value	RPV N= 632	DTG vs. RPV p-value
	Missing	4 (0.1%)	3 (0.2%)	1 (0.1%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.

*Table 76. Changes in BMI category at 24-months follow-up in ART-experienced patients with at least one lipid test available*

		Overall N= 3,823	DTG N= 1,283	EVG/ c N= 1,383	DTG vs. EVG p-value	RAL N= 174	DTG vs. RAL p-value	DRV(/r /c) N= 351	DTG vs. DRV(/r /c) p-value	RPV N= 632	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	75 (2.0%)	28 (2.2%)	21 (1.5%)	0.24 82	5 (2.9%)	0.58 34	6 (1.7%)	0.6780	15 (2.4%)	0.86 99
	Underweight (BMI: <18.5)	34 (45.3%)	12 (42.9%)	11 (52.4%)	0.38 23	1 (20.0%)	0.21 58	3 (50.0%)	1.0000	7 (46.7%)	1.00 00
	Normal (BMI: 18.5 – 24.9)	36 (48.0%)	13 (46.4%)	10 (47.6%)	.	3 (60.0%)	.	3 (50.0%)	.	7 (46.7%)	.
	Overweight (BMI: 25.0-29.9)	4 (5.3%)	3 (10.7%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (6.7%)	.
	Obese (BMI: >=30)	1 (1.3%)	0 (0.0%)	0 (0.0%)	.	1 (20.0%)	.	0 (0.0%)	.	0 (0.0%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	1399 (36.6%)	462 (36.0%)	545 (39.4%)	0.07 06	56 (32.2%)	0.32 25	107 (30.5%)	0.0542	229 (36.2%)	0.92 33

		Overall N= 3,823	DTG N= 1,283	EVG/ c N= 1,383	DTG vs. EVG p-value	RAL N= 174	DTG vs. RAL p-value	DRV(/r /c) N= 351	DTG vs. DRV(/r /c) p-value	RPV N= 632	DTG vs. RPV p-value
	Underweight (BMI: <18.5)	18 (1.3%)	6 (1.3%)	7 (1.3%)	0.52 26	2 (3.6%)	0.37 28	0 (0.0%)	0.5953	3 (1.3%)	0.38 61
	Normal (BMI: 18.5 – 24.9)	1021 (73.0%)	326 (70.6%)	396 (72.7%)	.	42 (75.0%)	.	82 (76.6%)	.	175 (76.4%)	.
	Overweight (BMI: 25.0-29.9)	330 (23.6%)	116 (25.1%)	133 (24.4%)	.	11 (19.6%)	.	23 (21.5%)	.	47 (20.5%)	.
	Obese (BMI: >=30)	30 (2.1%)	14 (3.0%)	9 (1.7%)	.	1 (1.8%)	.	2 (1.9%)	.	4 (1.7%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	1470 (38.5%)	496 (38.7%)	537 (38.8%)	0.92 86	68 (39.1%)	0.91 48	145 (41.3%)	0.3674	224 (35.4%)	0.17 18
	Underweight (BMI: <18.5)	1 (0.1%)	1 (0.2%)	0 (0.0%)	0.22 52	0 (0.0%)	0.22 57	0 (0.0%)	0.9905	0 (0.0%)	0.84 71
	Normal (BMI: 18.5 – 24.9)	133 (9.0%)	46 (9.3%)	42 (7.8%)	.	10 (14.7%)	.	14 (9.7%)	.	21 (9.4%)	.
	Overweight (BMI: 25.0-29.9)	1062 (72.2%)	354 (71.4%)	409 (76.2%)	.	41 (60.3%)	.	103 (71.0%)	.	155 (69.2%)	.
	Obese (BMI: >=30)	274 (18.6%)	95 (19.2%)	86 (16.0%)	.	17 (25.0%)	.	28 (19.3%)	.	48 (21.4%)	.
Change in BMI Category: Baseline Obese (BMI: >= 30)	Overall	879 (23.0%)	297 (23.1%)	280 (20.2%)	0.06 90	45 (25.9%)	0.42 81	93 (26.5%)	0.1924	164 (25.9%)	0.17 77

		Overall N=3,823	DTG N=1,283	EVG/ c N=1,383	DTG vs. EVG p-value	RAL N=174	DTG vs. RAL p-value	DRV(/r /c) N= 351	DTG vs. DRV(/r /c) p-value	RPV N=632	DTG vs. RPV p-value
	Underweight (BMI: <18.5)	2 (0.2%)	2 (0.7%)	0 (0.0%)	0.5409	0 (0.0%)	0.6980	0 (0.0%)	0.8788	0 (0.0%)	0.4957
	Normal (BMI: 18.5 – 24.9)	12 (1.4%)	4 (1.3%)	6 (2.1%)	.	1 (2.2%)	.	1 (1.1%)	.	0 (0.0%)	.
	Overweight (BMI: 25.0-29.9)	106 (12.1%)	36 (12.1%)	30 (10.7%)	.	6 (13.3%)	.	14 (15.1%)	.	20 (12.2%)	.
	Obese (BMI: >=30)	759 (86.3%)	255 (85.9%)	244 (87.1%)	.	38 (84.4%)	.	78 (83.9%)	.	144 (87.8%)	.

*Table 77. Changes in backbone agent at 24-months follow-up in ART-experienced patients with at least one lipid test available*

		Overall N= 3,823	DTG N= 1,283	EVG/c N= 1,383	DTG vs. EVG p- value	RAL N= 174	DTG vs. RAL p- value	DRV(/r/ c) N= 351	DTG vs. DRV(/r/ c) p-value	RPV N= 632	DTG vs. RPV p- value
Change in Backbone Agent (concurrent TAF use at 24 months) : Baseline TAF	Overall	771 (20.2%)	57 (4.4%)	546 (39.5%)	<.0001	1 (0.6%)	0.0111	16 (4.6%)	0.8849	151 (23.9%)	<.0001
	TAF at 24 months	757 (98.2%)	53 (93.0%)	537 (98.4%)	0.0269	1 (100.0%)	1.0000	15 (93.8%)	1.0000	151 (100.0%)	0.0052
	No TAF at 24 months	14 (1.8%)	4 (7.0%)	9 (1.6%)	.	0 (0.0%)	.	1 (6.3%)	.	0 (0.0%)	.
Change in Backbone Agent (concurrent TAF use at 24 months) : No Baseline TAF	Overall	3052 (79.8%)	1226 (95.6%)	837 (60.5%)	<.0001	173 (99.4%)	0.0111	335 (95.4%)	0.8849	481 (76.1%)	<.0001
	TAF at 24 months	866 (28.4%)	142 (11.6%)	434 (51.9%)	<.0001	26 (15.0%)	0.1917	84 (25.1%)	<.0001	180 (37.4%)	<.0001
	No TAF at 24 months	2186 (71.6%)	1084 (88.4%)	403 (48.1%)	.	147 (85.0%)	.	251 (74.9%)	.	301 (62.6%)	.
Change in Backbone Agent	TAF during	771 (100.0%)	57 (100.0%)	546 (100.0%)	.	1 (100.0%)	.	16 (100.0%)	.	151 (100.0%)	.

		Overall N= 3,823	DTG N= 1,283	EVG/c N= 1,383	DTG vs. EVG p-value	RAL N= 174	DTG vs. RAL p-value	DRV(/r/ c) N= 351	DTG vs. DRV(/r/ c) p-value	RPV N= 632	DTG vs. RPV p-value
(TAF use at any point during follow-up) : Baseline TAF	follow-up										
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	894 (29.3%)	146 (11.9%)	446 (53.3%)	<.0001	27 (15.6%)	0.1666	87 (26.0%)	<.0001	188 (39.1%)	<.0001
	No TAF during follow-up	2158 (70.7%)	1080 (88.1%)	391 (46.7%)	.	146 (84.4%)	.	248 (74.0%)	.	293 (60.9%)	.

### 1.5.2.3. Treatment-experienced, suppressed patients

Table 78. Weight, BMI, and incident lipodystrophy at 24-months follow-up in ART-experienced, suppressed patients

		Overall N= 4,436	DTG N= 1,548	EVG/c N= 1,506	DTG vs. EVG p-value	RAL N= 217	DTG vs. RAL p-value	DRV(/r/ c) N= 370	DTG vs. DRV(/r/ c) p-value	RPV N= 795	DTG vs. RPV p-value
Weight, kg	Median (IQR)	81.3 (71.2, 93.0)	81.2 (71.0, 92.1)	81.2 (71.2, 92.2)	0.6771	82.9 (72.1, 95.3)	0.1830	81.8 (70.8, 94.8)	0.4178	81.4 (71.2, 93.0)	0.7508
Change in weight from	Median (IQR)	1.8 (-1.4, 5.4)	1.8 (-1.4, 5.2)	1.8 (-1.1, 5.4)	0.2308	0.8 (-2.4, 4.5)	0.0370	0.8 (-2.1, 4.5)	0.0177	2.0 (-0.9, 5.6)	0.0264

		Overall N=4,436	DTG N=1,548	EVG/ c N=1,506	DTG vs. EVG p-value	RAL N=217	DTG vs. RAL p-value	DRV(/r/ c) N=370	DTG vs. DRV(/r/ c) p-value	RPV N=795	DTG vs. RPV p-value
baseline, kg											
	Mean (SD)	2.0 (6.8)	2.0 (7.2)	2.2 (6.6)	.	1.1 (7.3)	.	1.2 (6.3)	.	2.5 (6.3)	.
	No change ( $\pm$ <3 kg)	1986 (44.8 %)	688 (44.4 %)	677 (45.0 %)	0.722 5	99 (45.6 %)	0.536 2	176 (47.6%)	0.3465	346 (43.5 %)	0.274 6
	Weight increase 3 to <5 kg	585 (13.2 %)	203 (13.1 %)	203 (13.5 %)	.	23 (10.6 %)	.	39 (10.5%)	.	117 (14.7 %)	.
	Weight increase $\geq$ 5 kg	1146 (25.8 %)	395 (25.5 %)	397 (26.4 %)	.	50 (23.0 %)	.	83 (22.4%)	.	221 (27.8 %)	.
	Weight decrease 3 to <5 kg	310 (7.0%) )	111 (7.2%) )	103 (6.8%) )	.	20 (9.2%) )	.	31 (8.4%)	.	45 (5.7%) )	.
	Weight decrease $\geq$ 5 kg	409 (9.2%) )	151 (9.8%) )	126 (8.4%) )	.	25 (11.5 %)	.	41 (11.1%)	.	66 (8.3%) )	.
Change in weight from baseline, %	Median (IQR)	2.2 (- 1.7, 6.7)	2.1 (- 1.7, 6.5)	2.3 (- 1.4, 6.9)	0.291 1	0.8 (- 2.9, 5.8)	0.027 0	0.9 (- 2.7, 5.4)	0.0081	2.8 (- 1.1, 7.0)	0.031 9
	Mean (SD)	2.7 (8.4)	2.7 (8.8)	2.8 (8.2)	.	1.8 (9.4)	.	1.6 (7.7)	.	3.4 (7.9)	.
	No change ( $\pm$ <5%)	2433 (54.8 %)	857 (55.4 %)	818 (54.3 %)	0.520 0	121 (55.8 %)	0.316 9	217 (58.6%)	0.0302	420 (52.8 %)	0.190 5
	Weight increase	1452 (32.7 %)	498 (32.2 %)	512 (34.0 %)	.	62 (28.6 %)	.	95 (25.7%)	.	285 (35.8 %)	.

		Overall N= 4,436	DTG N= 1,548	EVG/ c N= 1,506	DTG vs. EVG p-value	RAL N= 217	DTG vs. RAL p-value	DRV(/r/ c) N= 370	DTG vs. DRV(/r/ c) p-value	RPV N= 795	DTG vs. RPV p-value
	e ≥5%										
	Weight decrease ≥5%	551 (12.4 %)	193 (12.5 %)	176 (11.7 %)	.	34 (15.7 %)	.	58 (15.7%)	.	90 (11.3 %)	.
BMI	Median (IQR)	26.8 (23.9, 30.3)	26.7 (23.9, 30.2)	26.6 (23.8, 30.1)	0.547 3	26.9 (23.6, 30.5)	0.627 9	27.2 (24.2, 30.8)	0.0908	27.0 (23.9, 30.9)	0.263 6
Change in BMI from baseline	Median (IQR)	0.6 (- 0.5, 1.8)	0.6 (- 0.5, 1.8)	0.6 (- 0.4, 1.9)	0.381 7	0.3 (- 0.8, 1.8)	0.097 6	0.2 (- 0.8, 1.5)	0.0116	0.7 (- 0.4, 1.9)	0.032 5
	Mean (SD)	0.6 (3.2)	0.6 (2.8)	0.7 (4.0)	.	0.3 (2.6)	.	0.3 (2.5)	.	0.8 (2.4)	.
Number of patients without lipodystrophy at baseline	Yes	4363 (98.4 %)	1518 (98.1 %)	1490 (98.9 %)	0.047 0	205 (94.5 %)	0.001 1	364 (98.4%)	0.6871	786 (98.9 %)	0.148 8
Number of incident cases of lipodystrophy	Yes	38 (0.9%)	12 (0.8%)	15 (1.0%)	0.566 7	2 (1.0%)	0.678 6	5 (1.4%)	0.3492	4 (0.5%)	0.599 2
Incident lipodystrophy	% (95% CI)	0.87 (0.62, 1.19)	0.79 (0.41, 1.38)	1.01 (0.56, 1.65)	.	0.98 (0.12, 3.48)	.	1.37 (0.45, 3.18)	.	0.51 (0.14, 1.30)	.



Table 79. Changes in BMI category at 24-months follow-up in ART-experienced, suppressed patients

		Overall N= 4,436	DTG N= 1,548	EVG/ c N= 1,506	DTG vs. EVG p-value	RAL N= 217	DTG vs. RAL p-value	DRV(/r /c) N= 370	DTG vs. DRV(/r /c) p-value	RPV N= 795	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	81 (1.8%)	26 (1.7%)	26 (1.7%)	1.0000	5 (2.3%)	0.5766	5 (1.4%)	0.8198	19 (2.4%)	0.2659
	Underweight (BMI: <18.5)	37 (45.7%)	10 (38.5%)	15 (57.7%)	0.2394	1 (20.0%)	0.3176	3 (60.0%)	0.7429	8 (42.1%)	1.0000
	Normal (BMI: 18.5 – 24.9)	40 (49.4%)	14 (53.8%)	11 (42.3%)	.	3 (60.0%)	.	2 (40.0%)	.	10 (52.6%)	.
	Overweight (BMI: 25.0-29.9)	3 (3.7%)	2 (7.7%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (5.3%)	.
	Obese (BMI: ≥30)	1 (1.2%)	0 (0.0%)	0 (0.0%)	.	1 (20.0%)	.	0 (0.0%)	.	0 (0.0%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	1644 (37.1%)	564 (36.4%)	597 (39.6%)	0.0679	71 (32.7%)	0.2855	117 (31.6%)	0.0822	295 (37.1%)	0.7490
	Underweight (BMI: <18.5)	23 (1.4%)	8 (1.4%)	6 (1.0%)	0.3397	3 (4.2%)	0.0994	3 (2.6%)	0.5723	3 (1.0%)	0.4985
	Normal (BMI: 18.5 – 24.9)	1235 (75.1%)	410 (72.7%)	455 (76.2%)	.	57 (80.3%)	.	85 (72.6%)	.	228 (77.3%)	.
	Overweight (BMI: 25.0-29.9)	372 (22.6%)	139 (24.6%)	133 (22.3%)	.	11 (15.5%)	.	29 (24.8%)	.	60 (20.3%)	.
	Obese (BMI: ≥30)	14 (0.9%)	7 (1.2%)	3 (0.5%)	.	0 (0.0%)	.	0 (0.0%)	.	4 (1.4%)	.

		Overall N= 4,436	DTG N= 1,548	EVG/ c N= 1,506	DTG vs. EVG p-value	RAL N= 217	DTG vs. RAL p-value	DRV(/r /c) N= 370	DTG vs. DRV(/r /c) p-value	RPV N= 795	DTG vs. RPV p-value
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	1702 (38.4 %)	622 (40.2 %)	551 (36.6 %)	0.0412	89 (41.0 %)	0.8148	150 (40.5%)	0.8991	290 (36.5 %)	0.0818
	Underweight (BMI: <18.5)	3 (0.2%)	1 (0.2%)	2 (0.4%)	0.9522	0 (0.0%)	0.6537	0 (0.0%)	0.5447	0 (0.0%)	0.1332
	Normal (BMI: 18.5 – 24.9)	164 (9.6%)	60 (9.6%)	52 (9.4%)	.	11 (12.4 %)	.	17 (11.3%)	.	24 (8.3%)	.
	Overweight (BMI: 25.0-29.9)	1227 (72.1 %)	453 (72.8 %)	402 (73.0 %)	.	61 (68.5 %)	.	113 (75.3%)	.	198 (68.3 %)	.
	Obese (BMI: ≥30)	308 (18.1 %)	108 (17.4 %)	95 (17.2 %)	.	17 (19.1 %)	.	20 (13.3%)	.	68 (23.4 %)	.
Change in BMI Category: Baseline Obese (BMI: ≥30)	Overall	1009 (22.7 %)	336 (21.7 %)	332 (22.0 %)	0.8204	52 (24.0 %)	0.4520	98 (26.5%)	0.0483	191 (24.0 %)	0.2029
	Underweight (BMI: <18.5)	2 (0.2%)	2 (0.6%)	0 (0.0%)	0.4696	0 (0.0%)	0.8922	0 (0.0%)	1.0000	0 (0.0%)	0.6079
	Normal (BMI: 18.5 – 24.9)	14 (1.4%)	5 (1.5%)	6 (1.8%)	.	1 (1.9%)	.	1 (1.0%)	.	1 (0.5%)	.
	Overweight (BMI: 25.0-29.9)	119 (11.8 %)	43 (12.8 %)	35 (10.5 %)	.	6 (11.5 %)	.	13 (13.3%)	.	22 (11.5 %)	.
	Obese (BMI: ≥30)	874 (86.6 %)	286 (85.1 %)	291 (87.7 %)	.	45 (86.5 %)	.	84 (85.7%)	.	168 (88.0 %)	.

Table 80. Changes in backbone agent at 24-months follow-up in ART-experienced, suppressed patients

		Overall N= 4,436	DTG N= 1,548	EVG/c N= 1,506	DTG vs. EVG p-value	RAL N= 217	DTG vs. RAL p-value	DRV(/r/ c) N= 370	DTG vs. DRV(/r/ c) p-value	RPV N= 795	DTG vs. RPV p-value
Change in Backbone Agent (concurrent TAF use at 24 months) : Baseline TAF	Overall	961 (21.7%)	78 (5.0%)	647 (43.0%)	<.0001	2 (0.9%)	0.0028	15 (4.1%)	0.5014	219 (27.5%)	<.0001
	TAF at 24 months	948 (98.6%)	76 (97.4%)	638 (98.6%)	0.3352	2 (100.0%)	1.0000	15 (100.0%)	1.0000	217 (99.1%)	0.2826
	No TAF at 24 months	13 (1.4%)	2 (2.6%)	9 (1.4%)	.	0 (0.0%)	.	0 (0.0%)	.	2 (0.9%)	.
Change in Backbone Agent (concurrent TAF use at 24 months) : No Baseline TAF	Overall	3475 (78.3%)	1470 (95.0%)	859 (57.0%)	<.0001	215 (99.1%)	0.0028	355 (95.9%)	0.5014	576 (72.5%)	<.0001
	TAF at 24 months	937 (27.0%)	166 (11.3%)	435 (50.6%)	<.0001	26 (12.1%)	0.7301	93 (26.2%)	<.0001	217 (37.7%)	<.0001
	No TAF at 24 months	2538 (73.0%)	1304 (88.7%)	424 (49.4%)	.	189 (87.9%)	.	262 (73.8%)	.	359 (62.3%)	.
Change in Backbone Agent (TAF)	TAF during follow-up	961 (100.0%)	78 (100.0%)	647 (100.0%)	.	2 (100.0%)	.	15 (100.0%)	.	219 (100.0%)	.

		Overall N= 4,436	DTG N= 1,548	EVG/c N= 1,506	DTG vs. EVG p-value	RAL N= 217	DTG vs. RAL p-value	DRV(/r/ c) N= 370	DTG vs. DRV(/r/ c) p-value	RPV N= 795	DTG vs. RPV p-value
use at any point during follow-up) : Baseline TAF											
Change in Backbone Agent (TAF use at any point during follow-up) : No Baseline TAF	TAF during follow-up	964 (27.7%)	168 (11.4%)	446 (51.9%)	<.0001	28 (13.0%)	0.4957	96 (27.0%)	<.0001	226 (39.2%)	<.0001
	No TAF during follow-up	2511 (72.3%)	1302 (88.6%)	413 (48.1%)	.	187 (87.0%)	.	259 (73.0%)	.	350 (60.8%)	.

*Table 81. Weight, BMI, lipids, and incident lipodystrophy at 24-months follow-up in ART-experienced, suppressed patients with at least one lipid test available*

		Overall N= 2,810	DTG N= 935	EVG/c N= 962	DTG vs. EVG p-value	RAL N= 152	DTG vs. RAL p-value	DRV(/r/ c) N= 248	DTG vs. DRV(/r/ c) p-value	RPV N= 513	DTG vs. RPV p-value
Weight, kg	Median (IQR)	81.6 (72.0, 93.4)	81.6 (72.0, 93.3)	81.6 (72.1, 92.7)	0.7400	84.5 (72.9, 95.3)	0.2609	82.3 (73.0, 94.3)	0.3996	81.6 (71.2, 93.4)	0.9411
Change in weight from baseline, kg	Median (IQR)	1.8 (-1.3, 5.0)	1.8 (-1.3, 5.0)	1.8 (-1.0, 5.4)	0.2884	0.9 (-2.4, 4.7)	0.1013	0.9 (-2.0, 4.0)	0.0464	1.9 (-0.9, 5.4)	0.1199

		Overall N= 2,810	DTG N= 935	EVG/ c N= 962	DTG vs. EVG p-value	RAL N= 152	DTG vs. RAL p-value	DRV(/r /c) N= 248	DTG vs. DRV(/r /c) p-value	RPV N= 513	DTG vs. RPV p-value
	Mean (SD)	2.1 (6.7)	2.0 (7.1)	2.3 (6.4)	.	1.1 (7.7)	.	1.3 (6.0)	.	2.5 (6.2)	.
	No change ( $\pm$ <3 kg)	1300 (46.3 %)	431 (46.1 %)	451 (46.9 %)	0.72 16	68 (44.7 %)	0.62 76	127 (51.2%)	0.3586	223 (43.5 %)	0.58 01
	Weight increase 3 to <5 kg	379 (13.5 %)	129 (13.8 %)	127 (13.2 %)	.	17 (11.2 %)	.	25 (10.1%)	.	81 (15.8 %)	.
	Weight increase ≥5 kg	706 (25.1 %)	229 (24.5 %)	250 (26.0 %)	.	36 (23.7 %)	.	53 (21.4%)	.	138 (26.9 %)	.
	Weight decrease 3 to <5 kg	180 (6.4%) )	60 (6.4%) )	61 (6.3%) )	.	13 (8.6%) )	.	17 (6.9%) )	.	29 (5.7%) )	.
	Weight decrease ≥5 kg	245 (8.7%) )	86 (9.2%) )	73 (7.6%) )	.	18 (11.8 %)	.	26 (10.5%) )	.	42 (8.2%) )	.
Change in weight from baseline, %	Median (IQR)	2.1 (- 1.5, 6.5)	2.1 (- 1.5, 6.3)	2.4 (- 1.4, 6.7)	0.36 56	1.1 (- 2.9, 5.8)	0.06 90	1.0 (- 2.4, 4.9)	0.0215	2.6 (- 1.0, 6.7)	0.17 15
	Mean (SD)	2.8 (8.2)	2.8 (8.7)	2.9 (7.8)	.	1.9 (9.9)	.	1.6 (7.3)	.	3.3 (7.9)	.
	No change ( $\pm$ <5%)	1583 (56.3 %)	540 (57.8 %)	534 (55.5 %)	0.49 02	85 (55.9 %)	0.26 13	151 (60.9%)	0.0597	273 (53.2 %)	0.22 65
	Weight increase ≥5%	896 (31.9 %)	290 (31.0 %)	323 (33.6 %)	.	43 (28.3 %)	.	60 (24.2%)	.	180 (35.1 %)	.
	Weight decrease ≥5%	331 (11.8 %)	105 (11.2 %)	105 (10.9 %)	.	24 (15.8 %)	.	37 (14.9%)	.	60 (11.7 %)	.
BMI	Median (IQR)	26.9 (24.1, 30.5)	26.9 (24.2, 30.4)	26.7 (24.0, 30.0)	0.27 12	27.5 (23.8, 31.0)	0.56 05	27.2 (24.8, 31.0)	0.1971	27.1 (23.9, 31.3)	0.64 57
Change in BMI from baseline	Median (IQR)	0.6 (- 0.4, 1.8)	0.6 (- 0.4, 1.7)	0.6 (- 0.4, 1.8)	0.44 06	0.3 (- 0.8, 1.9)	0.33 17	0.3 (- 0.7, 1.4)	0.0467	0.7 (- 0.3, 1.8)	0.11 92

		Overall N= 2,810	DTG N= 935	EVG/ c N= 962	DTG vs. EVG p-value	RAL N= 152	DTG vs. RAL p-value	DRV(/r /c) N= 248	DTG vs. DRV(/r /c) p-value	RPV N= 513	DTG vs. RPV p-value
	Mean (SD)	0.6 (2.5)	0.6 (2.9)	0.7 (2.3)	.	0.4 (2.6)	.	0.4 (2.2)	.	0.8 (2.4)	.
Number of patients without lipodystrophy at baseline	Yes	2757 (98.1 %)	914 (97.8 %)	950 (98.8 %)	0.11 42	142 (93.4 %)	0.00 68	245 (98.8%)	0.4472	506 (98.6 %)	0.31 92
Number of incident cases of lipodystrophy	Yes	28 (1.0%)	9 (1.0%)	12 (1.3%)	0.66 31	1 (0.7%)	1.00 00	4 (1.6%)	0.4907	2 (0.4%)	0.34 58
Incident lipodystrophy	% (95% CI)	1.02 (0.68, 1.46)	0.98 (0.45, 1.86)	1.26 (0.65, 2.20)	.	0.70 (0.02, 3.86)	.	1.63 (0.45, 4.13)	.	0.40 (0.05, 1.42)	.
Total Cholesterol, mg/dL	Median (IQR)	176.0 (151.0 , 203.0)	173.0 (148.0 , 201.0)	182.0 (157.0 , 207.0)	<.00 01	161.0 (141.0 , 193.0)	0.00 77	181.0 (159.0, 208.0)	0.0034	169.0 (148.0 , 200.0)	0.37 50
	Normal (<200 mg/dl)	2027 (72.1 %)	693 (74.1 %)	656 (68.2 %)	0.02 04	119 (78.3 %)	0.38 14	175 (70.6%)	0.0296	384 (74.9 %)	0.63 78
	Borderline Abnormal (>=200 to <240 mg/dl)	576 (20.5 %)	177 (18.9 %)	234 (24.3 %)	.	21 (13.8 %)	.	44 (17.7%)	.	100 (19.5 %)	.
	Dyslipidemia (>=240 to <280 mg/dl)	166 (5.9%)	53 (5.7%)	53 (5.5%)	.	11 (7.2%)	.	23 (9.3%)	.	26 (5.1%)	.
	Severe Dyslipidemia (>=280 mg/dl)	38 (1.4%)	12 (1.3%)	18 (1.9%)	.	1 (0.7%)	.	4 (1.6%)	.	3 (0.6%)	.
	Missing	3 (0.1%)	0 (0.0%)	1 (0.1%)	.	0 (0.0%)	.	2 (0.8%)	.	0 (0.0%)	.

		Overall N= 2,810	DTG N= 935	EVG/ c N= 962	DTG vs. EVG p-value	RAL N= 152	DTG vs. RAL p-value	DRV(/r /c) N= 248	DTG vs. DRV(/r /c) p-value	RPV N= 513	DTG vs. RPV p-value
LDL, mg/dL	Median (IQR)	99.0 (78.0, 122.4)	95.6 (76.0, 119.0)	103.2 (82.6, 126.0)	<.00 01	88.0 (66.0, 113.0)	0.02 08	103.0 (81.0, 126.4)	0.0051	97.0 (77.0, 122.0)	0.52 97
	Normal (<100 mg/dl)	1384 (49.3 %)	499 (53.4 %)	421 (43.8 %)	0.00 14	91 (59.9 %)	0.05 91	108 (43.5%)	0.0312	265 (51.7 %)	0.91 79
	Borderline Abnormal (≥100 to <130 mg/dl)	811 (28.9 %)	255 (27.3 %)	310 (32.2 %)	.	28 (18.4 %)	.	77 (31.0%)	.	141 (27.5 %)	.
	Dyslipide mia (≥130 to <160 mg/dl)	370 (13.2 %)	104 (11.1 %)	144 (15.0 %)	.	23 (15.1 %)	.	34 (13.7%)	.	65 (12.7 %)	.
	Severe Dyslipide mia (≥160 to <190 mg/dl)	107 (3.8%)	35 (3.7%)	36 (3.7%)	.	2 (1.3%)	.	15 (6.0%)	.	19 (3.7%)	.
	Very Severe Dyslipide mia (≥190 mg/dl)	27 (1.0%)	6 (0.6%)	11 (1.1%)	.	0 (0.0%)	.	5 (2.0%)	.	5 (1.0%)	.
	Missing	111 (4.0%)	36 (3.9%)	40 (4.2%)	.	8 (5.3%)	.	9 (3.6%)	.	18 (3.5%)	.
HDL, mg/dL	Median (IQR)	45.0 (37.0, 55.0)	45.0 (37.0, 54.0)	47.0 (39.0, 58.0)	0.00 01	41.0 (33.0, 51.0)	0.00 75	44.0 (37.0, 57.0)	0.3682	45.0 (37.0, 53.0)	0.89 78
	Normal (≥60 mg/dl)	482 (17.2 %)	142 (15.2 %)	205 (21.3 %)	0.00 04	18 (11.8 %)	0.03 35	49 (19.8%)	0.3668	68 (13.3 %)	0.40 75
	Borderline Abnormal (≥40 to <60 mg/dl)	1397 (49.7 %)	465 (49.7 %)	482 (50.1 %)	.	65 (42.8 %)	.	114 (46.0%)	.	271 (52.8 %)	.

		Overall N= 2,810	DTG N= 935	EVG/ c N= 962	DTG vs. EVG p-value	RAL N= 152	DTG vs. RAL p-value	DRV(/r /c) N= 248	DTG vs. DRV(/r /c) p-value	RPV N= 513	DTG vs. RPV p-value
	Dyslipidemia (<40 mg/dl)	908 (32.3 %)	316 (33.8 %)	270 (28.1 %)	.	69 (45.4 %)	.	82 (33.1%)	.	171 (33.3 %)	.
	Missing	23 (0.8% )	12 (1.3% )	5 (0.5% )	.	0 (0.0% )	.	3 (1.2%)	.	3 (0.6% )	.
Triglycerides, mg/dL	Median (IQR)	131.0 (91.0, 196.0)	134.0 (95.0, 201.5)	133.0 (94.0, 196.0)	0.83 15	126.5 (88.0, 205.5)	0.75 38	137.0 (91.0, 199.0)	0.9506	122.0 (87.0, 180.0)	0.00 35
	Normal (<150 mg/dl)	1673 (59.5 %)	538 (57.5 %)	566 (58.8 %)	0.72 45	86 (56.6 %)	0.98 85	146 (58.9%)	0.9851	337 (65.7 %)	0.02 15
	Borderline Abnormal (>=150 to <200 mg/dl)	448 (15.9 %)	152 (16.3 %)	159 (16.5 %)	.	25 (16.4 %)	.	40 (16.1%)	.	72 (14.0 %)	.
	Dyslipidemia (>=200 to <500 mg/dl)	635 (22.6 %)	221 (23.6 %)	220 (22.9 %)	.	38 (25.0 %)	.	58 (23.4%)	.	98 (19.1 %)	.
	Severe Dyslipidemia (>=500 mg/dl)	50 (1.8% )	21 (2.2% )	16 (1.7% )	.	3 (2.0% )	.	4 (1.6%)	.	6 (1.2% )	.
	Missing	4 (0.1% )	3 (0.3% )	1 (0.1% )	.	0 (0.0% )	.	0 (0.0%)	.	0 (0.0% )	.



*Table 82. Changes in BMI category at 24-months follow-up in ART-experienced, suppressed patients with at least one lipid test available*

		Overall N=2,810	DTG N=935	EVG/ c N=962	DTG vs. EVG p-value	RAL N=152	DTG vs. RAL p-value	DRV(/r /c) N=248	DTG vs. DRV(/r /c) p-value	RPV N=513	DTG vs. RPV p-value
Change in BMI Category: Baseline Underweight (BMI: < 18.5)	Overall	48 (1.7%)	16 (1.7%)	12 (1.2%)	0.44 97	5 (3.3%)	0.19 92	4 (1.6%)	1.0000	11 (2.1%)	0.54 90
	Underweight (BMI: <18.5)	20 (41.7%)	7 (43.8%)	6 (50.0%)	0.70 96	1 (20.0%)	0.29 33	2 (50.0%)	1.0000	4 (36.4%)	0.86 32
	Normal (BMI: 18.5 – 24.9)	24 (50.0%)	7 (43.8%)	6 (50.0%)	.	3 (60.0%)	.	2 (50.0%)	.	6 (54.5%)	.
	Overweight (BMI: 25.0-29.9)	3 (6.3%)	2 (12.5%)	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.	1 (9.1%)	.
	Obese (BMI: ≥30)	1 (2.1%)	0 (0.0%)	0 (0.0%)	.	1 (20.0%)	.	0 (0.0%)	.	0 (0.0%)	.
Change in BMI Category: Baseline Normal (BMI: 18.5 – 24.9)	Overall	989 (35.2%)	318 (34.0%)	368 (38.3%)	0.05 45	46 (30.3%)	0.36 39	69 (27.8%)	0.0648	188 (36.6%)	0.31 42
	Underweight (BMI: <18.5)	12 (1.2%)	3 (0.9%)	5 (1.4%)	0.21 94	2 (4.3%)	0.14 96	0 (0.0%)	0.6253	2 (1.1%)	0.47 32
	Normal (BMI: 18.5 – 24.9)	741 (74.9%)	228 (71.7%)	277 (75.3%)	.	36 (78.3%)	.	54 (78.3%)	.	146 (77.7%)	.
	Overweight (BMI: 25.0-29.9)	223 (22.5%)	80 (25.2%)	84 (22.8%)	.	8 (17.4%)	.	15 (21.7%)	.	36 (19.1%)	.

		Overall N=2,810	DTG N=935	EVG/ c N=962	DTG vs. EVG p-value	RAL N=152	DTG vs. RAL p-value	DRV(/r /c) N=248	DTG vs. DRV(/r /c) p-value	RPV N=513	DTG vs. RPV p-value
	Obese (BMI: ≥30)	13 (1.3%)	7 (2.2%)	2 (0.5%)	.	0 (0.0%)	.	0 (0.0%)	.	4 (2.1%)	.
Change in BMI Category: Baseline Overweight (BMI: 25.0 – 29.9)	Overall	1102 (39.2%)	379 (40.5%)	377 (39.2%)	0.54 95	61 (40.1%)	0.92 52	105 (42.3%)	0.6075	180 (35.1%)	0.04 17
	Underweight (BMI: <18.5)	1 (0.1%)	1 (0.3%)	0 (0.0%)	0.92 92	0 (0.0%)	0.30 23	0 (0.0%)	0.7251	0 (0.0%)	0.43 49
	Normal (BMI: 18.5 – 24.9)	100 (9.1%)	32 (8.4%)	32 (8.5%)	.	8 (13.1%)	.	9 (8.6%)	.	19 (10.6%)	.
	Overweight (BMI: 25.0-29.9)	809 (73.4%)	281 (74.1%)	284 (75.3%)	.	39 (63.9%)	.	82 (78.1%)	.	123 (68.3%)	.
	Obese (BMI: ≥30)	192 (17.4%)	65 (17.2%)	61 (16.2%)	.	14 (23.0%)	.	14 (13.3%)	.	38 (21.1%)	.
Change in BMI Category: Baseline Obese (BMI: ≥30)	Overall	671 (23.9%)	222 (23.7%)	205 (21.3%)	0.20 45	40 (26.3%)	0.49 16	70 (28.2%)	0.1455	134 (26.1%)	0.31 49
	Underweight (BMI: <18.5)	2 (0.3%)	2 (0.9%)	0 (0.0%)	0.43 77	0 (0.0%)	0.73 82	0 (0.0%)	0.7168	0 (0.0%)	0.50 83
	Normal (BMI: 18.5 – 24.9)	9 (1.3%)	3 (1.4%)	5 (2.4%)	.	1 (2.5%)	.	0 (0.0%)	.	0 (0.0%)	.
	Overweight (BMI: 25.0-29.9)	81 (12.1%)	28 (12.6%)	21 (10.2%)	.	4 (10.0%)	.	12 (17.1%)	.	16 (11.9%)	.

		Overall N= 2,810	DTG N= 935	EVG/ c N= 962	DTG vs. EVG p- value	RAL N= 152	DTG vs. RAL p- value	DRV(/r /c) N= 248	DTG vs. DRV(/r /c) p-value	RPV N= 513	DTG vs. RPV p- value
	Obese (BMI: ≥30)	579 (86.3 %)	189 (85.1 %)	179 (87.3 %)	.	35 (87.5 %)	.	58 (82.9%)	.	118 (88.1 %)	.

*Table 83. Changes in backbone agent at 24-months follow-up in ART-experienced, suppressed patients with at least one lipid test available*

		Overall N= 2,810	DTG N= 935	EVG/c N= 962	DTG vs. EVG p- value	RAL N= 152	DTG vs. RAL p- value	DRV(/r/ c) N= 248	DTG vs. DRV(/r/ c) p-value	RPV N= 513	DTG vs. RPV p- value
Change in Backbone Agent (concurrent TAF use at 24 months) : Baseline TAF	Over all	606 (21.6% )	44 (4.7%)	417 (43.3% )	<.00 01	1 (0.7%)	0.01 45	10 (4.0%)	0.7347	134 (26.1% )	<.00 01
	TAF at 24 months	597 (98.5% )	42 (95.5% )	410 (98.3% )	0.208 7	1 (100.0 %)	1.00 00	10 (100.0 %)	1.0000	134 (100.0 %)	0.060 1
	No TAF at 24 months	9 (1.5%)	2 (4.5%)	7 (1.7%)	.	0 (0.0%)	.	0 (0.0%)	.	0 (0.0%)	.
Change in Backbone Agent (concurrent TAF use at 24 months) : No Baseline TAF	Over all	2204 (78.4% )	891 (95.3% )	545 (56.7% )	<.00 01	151 (99.3% )	0.01 45	238 (96.0%)	0.7347	379 (73.9% )	<.00 01
	TAF at 24 months	638 (28.9% )	112 (12.6% )	292 (53.6% )	<.00 01	21 (13.9% )	0.64 89	65 (27.3%)	<.0001	148 (39.1% )	<.00 01
	No TAF at 24 months	1566 (71.1% )	779 (87.4% )	253 (46.4% )	.	130 (86.1% )	.	173 (72.7%)	.	231 (60.9% )	.
Change in Backbone Agent	TAF durin g	606 (100.0 %)	44 (100.0 %)	417 (100.0 %)	.	1 (100.0 %)	.	10 (100.0 %)	.	134 (100.0 %)	.

		Overall N= 2,810	DTG N= 935	EVG/c N= 962	DTG vs. EVG p- value	RAL N= 152	DTG vs. RAL p- value	DRV(/r/ c) N= 248	DTG vs. DRV(/r/ c) p-value	RPV N= 513	DTG vs. RPV p- value
(TAF use at any point during follow- up) : Baseline TAF	follo w-up										
Change in Backbon e Agent (TAF use at any point during follow- up) : No Baseline TAF	TAF durin g follo w-up	659 (29.9% )	114 (12.8% )	301 (55.2% )	<.00 01	22 (14.6% )	0.54 94	68 (28.6%)	<.0001	154 (40.6% )	<.00 01
	No TAF durin g follo w-up	1545 (70.1% )	777 (87.2% )	244 (44.8% )	.	129 (85.4% )	.	170 (71.4%)	.	225 (59.4% )	.

## 1.6. Association between core agent group and changes in BMI (among treatment-experienced patients only)

### 1.6.1. Differences in mean BMI at 6-months

#### 1.6.1.1. Overall: Unadjusted and adjusted differences in mean BMI at 6 months (with and without TAF use)

Table 84. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced patients (n=13731)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	B: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>b</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=4592)	27.11 (26.95, 27.27)	0.00 (Ref)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=4975)	27.07 (26.91, 27.22)	-0.06 (-0.14, 0.02)	-0.05 (-0.13, 0.03)	-0.16 (-0.25, -0.07)
RAL (n=599)	27.28 (26.83, 27.72)	-0.24 (-0.42, -0.07)	-0.24 (-0.42, -0.07)	-0.23 (-0.40, -0.05)
RPV (n=2226)	27.55 (27.32, 27.78)	-0.02 (0.12, 0.09)	0.02 (-0.08, 0.13)	-0.05 (-0.16, 0.06)
DRV/c, DRV/r (n=1339)	27.30 (27.00, 27.60)	-0.17 (-0.30, -0.05)	-0.20 (-0.33, -0.07)	-0.22 (-0.34, -0.09)
Female	-	-	0.06 (-0.04, 0.16)	0.06 (-0.04, 0.16)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.08 (-0.01, 0.17)	0.07 (-0.01, 0.16)
Race/ethnicity: Other non-Hispanic	-	-	-0.24 (-0.46, -0.03)	-0.25 (-0.47, -0.03)
Race/ethnicity: Hispanic	-	-	0.20 (0.11, 0.30)	0.20 (0.10, 0.29)
Lipodystrophy	-	-	-0.02 (-0.38, 0.34)	0.01 (-0.35, 0.37)
Endocrine disorders	-	-	0.04 (-0.05, 0.12)	0.04 (-0.05, 0.12)
Hypertension	-	-	0.07 (-0.02, 0.16)	0.06 (-0.03, 0.15)
Substance abuse	-	-	-0.08 (-0.18, 0.02)	-0.08 (-0.19, 0.02)
Medications associated with weight gain	-	-	0.09 (0.01, 0.17)	0.09 (0.00, 0.18)
Medications associated with weight loss	-	-	-0.09 (-0.19, 0.02)	-0.09 (-0.19, 0.02)
BMI <sup>†</sup>	-	N/A	N/A	N/A
Age <sup>†</sup>	-	-	N/A	N/A
CD4 count <sup>†</sup>	-	-	N/A	N/A
Viral load <sup>†</sup>	-	-	N/A	N/A
TAF use	-	-	-	0.27 (0.18, 0.35)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>b</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), and substance abuse (yes, no)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

**Example of interpretation of Table 83 (Adjustment B, EVG/c vs. DTG):** On average, after 6 months on the core agent, BMI increased by 0.16 kg/m<sup>2</sup> less with EVG/c than with DTG.

#### 1.6.1.2. Overall: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)

Table 85. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced patients (n=13731) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=4592)	27.36 (27.21, 27.52)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=4975)	27.42 (27.26, 27.58)	-0.03 (-0.11, 0.06)	-0.13 (-0.23, -0.04)
RAL (n=599)	27.46 (27.01, 27.92)	-0.23 (-0.41, -0.06)	-0.20 (-0.38, -0.03)
RPV (n=2226)	27.79 (27.55, 28.03)	0.02 (-0.09, 0.12)	-0.02 (-0.13, 0.08)
DRV/c, DRV/r (n=1339)	27.61 (27.28, 27.94)	-0.18 (-0.31, -0.05)	-0.22 (-0.35, -0.08)
Female	-	-	0.04 (-0.06, 0.14)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.09 (0.00, 0.18)
Race/ethnicity: Other non-Hispanic	-	-	-0.28 (-0.49, -0.06)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
Race/ethnicity: Hispanic	-	-	0.19 (0.10, 0.28)
Lipodystrophy	-	-	0.05 (-0.31, 0.41)
Endocrine disorders	-	-	0.04 (-0.04, 0.12)
Hypertension	-	-	0.08 (0.00, 0.17)
Substance abuse	-	-	-0.07 (-0.19, 0.06)
Medications associated with weight gain	-	-	0.06 (-0.02, 0.15)
Medications associated with weight loss	-	-	-0.11 (-0.21, -0.01)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.26 (0.17, 0.34)

<sup>±</sup> Mean (range) = 1.13 (0.38 to 7.32)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.6.1.3. Underweight: Unadjusted and adjusted differences in mean BMI at 6 months

Table 86. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced patients who were underweight (n=344)



	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
<b>DTG (n=119)</b>	18.92 (18.43, 19.40)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=135)</b>	18.65 (18.20, 19.10)	-0.34 (-1.00, 0.31)	-0.28 (-1.01, 0.44)
<b>RAL (n=14)</b>	18.72 (17.31, 20.13)	-0.43 (-1.91, 1.05)	-0.53 (-2.04, 0.99)
<b>RPV (n=45)</b>	19.20 (18.42, 19.99)	0.18 (-0.73, 1.09)	0.36 (-0.61, 1.32)
<b>DRV/c, DRV/r (n=31)</b>	18.52 (17.57, 19.47)	-0.35 (-1.40, 0.70)	-0.47 (-1.53, 0.59)
<b>Female</b>	-	-	-0.39 (-1.10, 0.31)
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	0.03 (-0.68, 0.75)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	-0.08 (-1.69, 1.53)
<b>Race/ethnicity: Hispanic</b>	-	-	0.60 (-0.27, 1.47)
<b>Lipodystrophy</b>	-	-	-1.63 (-5.39, 2.12)
<b>Endocrine disorders</b>	-	-	0.17 (-0.73, 1.08)
<b>Hypertension</b>	-	-	0.85 (-0.15, 1.85)
<b>Substance abuse</b>	-	-	-0.52 (-1.36, 0.32)
<b>Medications associated with weight gain</b>	-	-	0.05 (-0.70, 0.80)
<b>Medications associated with weight loss</b>	-	-	-0.62 (-1.44, 0.19)
<b>BMI<sup>†</sup></b>	-	N/A	N/A
<b>Age<sup>†</sup></b>	-	-	N/A
<b>CD4 count<sup>†</sup></b>	-	-	N/A
<b>Viral load<sup>†</sup></b>	-	-	N/A
<b>TAF use</b>	-	-	-0.04 (-0.73, 0.65)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.1.4. Underweight: Unadjusted and adjusted differences in means BMI at 6-months (with IPC weights)

\*\*\*\*\* IPC weighting could not be performed due to large weights (Mean (range) = 2905934.15 (0.16 to 993288264))

#### 1.6.1.5. Normal weight: Unadjusted and adjusted differences in mean BMI at 6 months

Table 87. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced patients who were normal weight (n=5375)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=1833)	23.10 (23.00, 23.20)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=1985)	23.03 (22.94, 23.13)	-0.05 (-0.15, 0.05)	-0.18 (-0.28, -0.07)
RAL (n=214)	22.80 (22.51, 23.09)	-0.20 (-0.42, 0.02)	-0.20 (-0.41, 0.02)
RPV (n=840)	23.01 (22.86, 23.16)	-0.18 (-0.31, -0.06)	-0.21 (-0.34, -0.08)
DRV/c, DRV/r (n=503)	22.93 (22.74, 23.12)	-0.07 (-0.22, 0.08)	-0.16 (-0.31, -0.01)
Female	-	-	0.09 (-0.05, 0.22)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.07 (-0.04, 0.17)
Race/ethnicity: Other non-Hispanic	-	-	-0.20 (-0.42, 0.02)
Race/ethnicity: Hispanic	-	-	0.10 (-0.01, 0.21)
Lipodystrophy	-	-	-0.09 (-0.57, 0.38)
Endocrine disorders	-	-	0.01 (-0.10, 0.12)
Hypertension	-	-	0.05 (-0.07, 0.17)
Substance abuse	-	-	-0.09 (-0.20, 0.03)
Medications associated with weight gain	-	-	0.04 (-0.08, 0.15)
Medications associated with weight loss	-	-	-0.02 (-0.15, 0.12)
BMI <sup>†</sup>	-	N/A	N/A

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.38 (0.28, 0.48)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.1.6. Normal weight: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)

Table 88. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced patients who were normal weight (n=5375) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=1833)	23.19 (23.10, 23.28)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=1985)	23.17 (23.07, 23.28)	-0.02 (-0.12, 0.07)	-0.17 (-0.27, -0.06)
RAL (n=214)	22.98 (22.70, 23.25)	-0.26 (-0.47, -0.05)	-0.21 (-0.41, 0.00)
RPV (n=840)	23.18 (23.03, 23.32)	-0.15 (-0.27, -0.02)	-0.19 (-0.32, -0.07)
DRV/c, DRV/r (n=503)	22.94 (22.73, 23.16)	-0.13 (-0.30, 0.04)	-0.20 (-0.36, -0.03)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
Female	-	-	0.05 (-0.08, 0.17)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.10 (0.00, 0.21)
Race/ethnicity: Other non-Hispanic	-	-	-0.13 (-0.33, 0.06)
Race/ethnicity: Hispanic	-	-	0.10 (-0.01, 0.21)
Lipodystrophy	-	-	-0.17 (-0.62, 0.28)
Endocrine disorders	-	-	-0.01 (-0.11, 0.08)
Hypertension	-	-	0.05 (-0.05, 0.16)
Substance abuse	-	-	-0.14 (-0.28, 0.00)
Medications associated with weight gain	-	-	0.04 (-0.07, 0.15)
Medications associated with weight loss	-	-	0.01 (-0.12, 0.15)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.40 (0.31, 0.50)

<sup>±</sup> Mean (range) = 1.26 (0.33 to 18.32)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup> Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.1.7. Overweight: Unadjusted and adjusted differences in mean BMI at 6 months

Table 89. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced patients who were overweight (n=4975)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
<b>DTG (n=1653)</b>	27.59 (27.48, 27.69)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=1800)</b>	27.57 (27.47, 27.67)	-0.02 (-0.14, 0.08)	-0.12 (-0.25, 0.00)
<b>RAL (n=232)</b>	27.40 (27.12, 27.67)	-0.25 (-0.48, -0.02)	-0.21 (-0.44, 0.02)
<b>RPV (n=799)</b>	27.63 (27.49, 27.78)	-0.05 (-0.19, 0.10)	-0.08 (-0.23, 0.06)
<b>DRV/c, DRV/r (n=491)</b>	27.38 (27.19, 27.56)	-0.19 (-0.36, -0.02)	-0.22 (-0.39, -0.05)
<b>Female</b>	-	-	0.16 (0.01, 0.31)
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	0.18 (0.06, 0.31)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	-0.21 (-0.55, 0.12)
<b>Race/ethnicity: Hispanic</b>	-	-	0.15 (0.03, 0.26)
<b>Lipodystrophy</b>	-	-	0.21 (-0.22, 0.64)
<b>Endocrine disorders</b>	-	-	0.01 (-0.10, 0.12)
<b>Hypertension</b>	-	-	0.05 (-0.07, 0.16)
<b>Substance abuse</b>	-	-	-0.10 (-0.23, 0.04)
<b>Medications associated with weight gain</b>	-	-	0.16 (0.04, 0.29)
<b>Medications associated with weight loss</b>	-	-	0.04 (-0.10, 0.18)
<b>BMI<sup>†</sup></b>	-	N/A	N/A
<b>Age<sup>†</sup></b>	-	-	N/A
<b>CD4 count<sup>†</sup></b>	-	-	N/A
<b>Viral load<sup>†</sup></b>	-	-	N/A
<b>TAF use</b>	-	-	0.25 (0.13, 0.36)

<sup>a</sup> Model adjusted for baseline BMI (continuous)<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.1.8. Overweight: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)

Table 90. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced patients who were overweight (n=4975) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=1653)	27.66 (27.56, 27.76)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=1800)	27.64 (27.54, 27.73)	-0.02 (-0.13, 0.09)	-0.11 (-0.23, 0.01)
RAL (n=232)	27.43 (27.15, 27.71)	-0.29 (-0.52, -0.06)	-0.24 (-0.47, -0.01)
RPV (n=799)	27.68 (27.52, 27.84)	-0.06 (-0.21, 0.09)	-0.09 (-0.25, 0.06)
DRV/c, DRV/r (n=491)	27.46 (27.25, 27.66)	-0.16 (-0.34, 0.02)	-0.18 (-0.37, -0.01)
Female	-	-	0.16 (0.03, 0.30)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.18 (0.05, 0.30)
Race/ethnicity: Other non-Hispanic	-	-	-0.30 (-0.70, 0.09)
Race/ethnicity: Hispanic	-	-	0.12 (0.01, 0.24)
Lipodystrophy	-	-	0.28 (-0.15, 0.70)
Endocrine disorders	-	-	0.04 (-0.06, 0.15)
Hypertension	-	-	0.05 (-0.06, 0.15)
Substance abuse	-	-	-0.11 (-0.26, 0.04)
Medications associated with weight gain	-	-	0.15 (0.03, 0.27)
Medications associated with weight loss	-	-	0.04 (-0.10, 0.18)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.22 (0.11, 0.33)

<sup>±</sup> Mean (range) = 1.15 (0.21 to 3.93)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.6.1.9. Obese: Unadjusted and adjusted differences in mean BMI at 6 months

Table 91. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced patients who were obese (n=3037)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI change at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
<b>DTG (n=987)</b>	34.74 (34.43, 35.05)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=1055)</b>	34.87 (34.57, 35.16)	-0.06 (-0.28, 0.15)	-0.18 (-0.41, 0.06)
<b>RAL (n=139)</b>	34.83 (34.00, 35.65)	-0.22 (-0.67, 0.22)	-0.22 (-0.66, 0.21)
<b>RPV (n=542)</b>	35.16 (34.75, 35.58)	0.21 (-0.05, 0.47)	0.10 (-0.16, 0.37)
<b>DRV/c, DRV/r (n=314)</b>	35.05 (34.50, 35.60)	-0.18 (-0.50, 0.13)	-0.30 (-0.62, 0.01)
<b>Female</b>	-	-	0.39 (0.18, 0.60)
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	0.21 (-0.01, 0.43)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	-0.99 (-1.66, -0.33)
<b>Race/ethnicity: Hispanic</b>	-	-	0.05 (-0.20, 0.31)
<b>Lipodystrophy</b>	-	-	-0.32 (-1.22, 0.59)
<b>Endocrine disorders</b>	-	-	-0.19 (-0.39, 0.01)
<b>Hypertension</b>	-	-	-0.02 (-0.22, 0.17)
<b>Substance abuse</b>	-	-	-0.04 (-0.32, 0.25)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
Medications associated with weight gain	-	-	0.22 (0.00, 0.43)
Medications associated with weight loss	-	-	-0.10 (-0.34, 0.15)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.24 (0.03, 0.45)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.1.10. Obese: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)

Table 92. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced patients who were obese (n=3037) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=987)	35.22 (34.88, 35.56)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=1055)	35.80 (35.45, 36.15)	0.04 (-0.19, 0.26)	-0.13 (-0.38, 0.11)
RAL (n=139)	35.39 (34.40, 36.38)	-0.13 (-0.61, 0.35)	-0.12 (-0.59, 0.35)



	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
RPV (n=542)	35.90 (35.46, 36.35)	0.33 (0.07, 0.58)	0.19 (-0.08, 0.46)
DRV/c, DRV/r (n=314)	36.06 (35.44, 36.68)	-0.17 (-0.49, 0.16)	-0.29 (-0.61, 0.04)
Female	-	-	0.35 (0.14, 0.57)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.14 (-0.09, 0.37)
Race/ethnicity: Other non-Hispanic	-	-	-0.94 (-1.58, -0.30)
Race/ethnicity: Hispanic	-	-	-0.03 (-0.29, 0.22)
Lipodystrophy	-	-	-0.30 (-1.39, 0.78)
Endocrine disorders	-	-	-0.20 (-0.41, 0.00)
Hypertension	-	-	0.02 (-0.17, 0.23)
Substance abuse	-	-	0.10 (-0.24, 0.45)
Medications associated with weight gain	-	-	0.16 (-0.05, 0.37)
Medications associated with weight loss	-	-	-0.16 (-0.40, 0.07)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.32 (0.11, 0.53)

<sup>±</sup> Mean (range) = 1.17 (0.36 to 4.89)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

## 1.6.2. Differences in mean BMI at 12-months

## 1.6.2.1. Overall: Unadjusted and adjusted differences in mean BMI at 12 months (with and without TAF use)

Table 93. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced patients (n=11154)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	B: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>b</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=3812)	27.34 (27.16, 27.51)	0.00 (Ref)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=3991)	27.34 (27.16, 27.51)	0.07 (-0.04, 0.18)	0.07 (-0.05, 0.17)	-0.08 (-0.20, 0.04)
RAL (n=465)	27.42 (26.90, 27.93)	-0.27 (-0.51, -0.03)	-0.26 (-0.50, -0.02)	-0.24 (-0.48, 0.00)
RPV (n=1844)	27.69 (27.43, 27.94)	0.03 (-0.11, 0.17)	0.05 (-0.09, 0.19)	-0.04 (-0.18, 0.10)
DRV/c, DRV/r (n=1042)	27.58 (27.24, 27.92)	-0.04 (-0.21, 0.13)	-0.10 (-0.27, 0.07)	-0.12 (-0.29, 0.05)
Female	-	-	0.37 (0.24, 0.50)	0.37 (0.24, 0.51)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.12 (0.00, 0.23)	0.11 (-0.01, 0.23)
Race/ethnicity: Other non-Hispanic	-	-	-0.37 (-0.65, -0.08)	-0.38 (-0.66, -0.09)
Race/ethnicity: Hispanic	-	-	0.18 (0.05, 0.30)	0.17 (0.04, 0.29)
Lipodystrophy	-	-	-0.33 (-0.79, 0.13)	-0.28 (-0.75, 0.18)
Endocrine disorders	-	-	-0.05 (-0.16, 0.06)	-0.05 (-0.16, 0.06)
Hypertension	-	-	0.16 (0.05, 0.28)	0.16 (0.05, 0.28)
Substance abuse	-	-	-0.28 (-0.41, -0.14)	-0.28 (-0.42, -0.15)
Medications associated with weight gain	-	-	0.01 (-0.11, 0.13)	0.01 (-0.11, 0.13)
Medications associated with weight loss	-	-	-0.07 (-0.21, 0.07)	-0.06 (-0.20, 0.08)
BMI <sup>†</sup>	-	N/A	N/A	N/A
Age <sup>†</sup>	-	-	N/A	N/A
CD4 count <sup>†</sup>	-	-	N/A	N/A
Viral load <sup>†</sup>	-	-	N/A	N/A
TAF use	-	-	-	0.33 (0.22, 0.44)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>b</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), and substance abuse (yes, no)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.6.2.2. Overall: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights)

Table 94. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced patients (n=11154) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI change at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
<b>DTG (n=3812)</b>	27.53 (27.36, 27.70)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=3991)</b>	27.55 (27.37, 27.73)	0.08 (-0.03, 0.19)	-0.08 (-0.20, 0.03)
<b>RAL (n=465)</b>	27.52 (26.98, 28.07)	-0.27 (-0.52, -0.02)	-0.23 (-0.48, 0.02)
<b>RPV (n=1844)</b>	27.85 (27.60, 28.10)	0.05 (-0.08, 0.18)	-0.04 (-0.18, 0.09)
<b>DRV/c, DRV/r (n=1042)</b>	27.77 (27.40, 28.14)	-0.03 (-0.21, 0.14)	-0.12 (-0.29, 0.06)
<b>Female</b>	-	-	0.37 (0.24, 0.50)
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	0.12 (0.00, 0.23)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	-0.37 (-0.64, -0.09)
<b>Race/ethnicity: Hispanic</b>	-	-	0.14 (0.02, 0.26)
<b>Lipodystrophy</b>	-	-	-0.26 (-0.70, 0.18)
<b>Endocrine disorders</b>	-	-	-0.05 (-0.16, 0.06)
<b>Hypertension</b>	-	-	0.16 (0.05, 0.28)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
Substance abuse	-	-	-0.27 (-0.41, -0.13)
Medications associated with weight gain	-	-	0.02 (-0.09, 0.14)
Medications associated with weight loss	-	-	-0.07 (-0.21, 0.06)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.35 (0.24, 0.46)

<sup>±</sup> Mean (range) = 1.04 (0.46 to 1.83)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup> Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.6.2.3. Underweight: Unadjusted and adjusted differences in mean BMI at 12 months

Table 95. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced patients who were underweight (n=263)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=98)	19.22 (18.61, 19.83)	0.00 (Ref)	0.00 (Ref)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
<b>EVG/c (n=92)</b>	18.97 (18.33, 19.60)	-0.41 (-1.29, 0.47)	-0.29 (-1.24, 0.67)
<b>RAL (n=10)</b>	19.25 (17.34, 21.16)	-0.37 (-2.39, 1.64)	-0.33 (-2.36, 1.70)
<b>RPV (n=42)</b>	19.35 (18.42, 20.28)	-0.02 (-1.13, 1.09)	0.01 (-1.14, 1.16)
<b>DRV/c, DRV/r (n=21)</b>	18.75 (17.43, 20.07)	-0.48 (-1.91, 0.96)	-0.59 (-2.01, 0.82)
<b>Female</b>	-	-	-0.43 (-0.47, 1.33)
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	0.09 (-0.84, 1.02)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	-0.11 (-2.12, 1.89)
<b>Race/ethnicity: Hispanic</b>	-	-	1.04 (-0.08, 2.16)
<b>Lipodystrophy</b>	-	-	-3.61 (-9.57, 2.34)
<b>Endocrine disorders</b>	-	-	-0.30 (-1.45, 0.85)
<b>Hypertension</b>	-	-	1.84 (0.52, 3.15)
<b>Substance abuse</b>	-	-	-1.10 (-2.15, -0.05)
<b>Medications associated with weight gain</b>	-	-	0.35 (-0.62, 1.33)
<b>Medications associated with weight loss</b>	-	-	-1.10 (-2.25, 0.05)
<b>BMI<sup>†</sup></b>	-	N/A	N/A
<b>Age<sup>†</sup></b>	-	-	N/A
<b>CD4 count<sup>†</sup></b>	-	-	N/A
<b>Viral load<sup>†</sup></b>	-	-	N/A
<b>TAF use</b>	-	-	0.23 (-0.67, 1.13)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.2.4. Underweight: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights)

Table 96. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced patients who were underweight (n=263) with inverse probability-of-censoring (IPC) weights<sup>±</sup>

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI change at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=98)	19.11 (18.44, 19.78)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=92)	18.97 (18.17, 19.78)	-0.29 (-1.34, 0.76)	-0.29 (-1.42, 0.83)
RAL (n=10)	19.28 (17.07, 21.48)	-0.21 (-2.54, 2.12)	-0.26 (-2.59, 2.07)
RPV (n=42)	19.42 (18.59, 20.25)	0.16 (-0.91, 1.24)	-0.05 (-1.19, 1.09)
DRV/c, DRV/r (n=21)	18.46 (16.64, 20.28)	-0.65 (-2.58, 1.28)	-0.64 (-2.51, 1.23)
Female	-	-	0.34 (-0.68, 1.36)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.29 (-0.82, 1.39)
Race/ethnicity: Other non-Hispanic	-	-	0.14 (-1.76, 2.05)
Race/ethnicity: Hispanic	-	-	1.45 (0.19, 2.71)
Lipodystrophy	-	-	-3.70 (-13.80, 6.40)
Endocrine disorders	-	-	-0.48 (-1.75, 0.78)
Hypertension	-	-	2.33 (0.90, 3.76)
Substance abuse	-	-	-1.22 (-2.40, -0.04)
Medications associated with weight gain	-	-	0.30 (-0.78, 1.38)
Medications associated with weight loss	-	-	-1.25 (-2.72, 0.23)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.43 (-0.56, 1.42)

<sup>±</sup> Mean (range) = 1.19 (0.50 to 3.14)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.2.5. Normal weight: Unadjusted and adjusted differences in mean BMI at 12 months

Table 97. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced patients who were normal weight (n=4334)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
<b>DTG (n=1477)</b>	23.34 (23.22, 23.46)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=1611)</b>	23.23 (23.11, 23.34)	-0.07 (-0.20, 0.06)	<b>-0.23 (-0.37, -0.10)</b>
<b>RAL (n=161)</b>	22.89 (22.53, 23.26)	<b>-0.33 (-0.62, -0.03)</b>	-0.28 (-0.58, 0.01)
<b>RPV (n=690)</b>	23.29 (23.12, 23.47)	-0.10 (-0.26, 0.07)	-0.15 (-0.32, 0.02)
<b>DRV/c, DRV/r (n=395)</b>	23.25 (23.02, 23.49)	-0.09 (-0.29, 0.12)	<b>-0.20 (-0.41, 0.00)</b>
<b>Female</b>	-	-	<b>0.38 (0.20, 0.56)</b>
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	0.11 (-0.03, 0.25)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	<b>-0.35 (-0.64, -0.06)</b>
<b>Race/ethnicity: Hispanic</b>	-	-	0.10 (-0.04, 0.24)
<b>Lipodystrophy</b>	-	-	0.00 (-0.60, 0.60)
<b>Endocrine disorders</b>	-	-	-0.01 (-0.15, 0.13)
<b>Hypertension</b>	-	-	0.03 (-0.13, 0.19)
<b>Substance abuse</b>	-	-	<b>-0.23 (-0.39, -0.08)</b>
<b>Medications associated with weight gain</b>	-	-	-0.06 (-0.21, 0.09)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
Medications associated with weight loss	-	-	-0.02 (-0.20, 0.16)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.42 (0.29, 0.55)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.2.6. Normal weight: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights)

Table 98. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced patients who were normal weight (n=4334) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=1477)	23.37 (23.26, 23.49)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=1611)	23.29 (23.17, 23.41)	-0.05 (-0.18, 0.08)	-0.23 (-0.36, -0.09)
RAL (n=161)	22.97 (22.57, 23.36)	-0.32 (-0.63, 0.00)	-0.26 (-0.57, 0.05)
RPV (n=690)	23.35 (23.17, 23.52)	-0.09 (-0.25, 0.07)	-0.16 (-0.32, 0.01)



	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DRV/c, DRV/r (n=395)	23.24 (22.99, 23.48)	-0.11 (-0.33, 0.10)	-0.23 (-0.44, 0.02)
Female	-	-	0.36 (0.19, 0.54)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.13 (0.00, 0.27)
Race/ethnicity: Other non-Hispanic	-	-	-0.34 (-0.61, -0.06)
Race/ethnicity: Hispanic	-	-	0.08 (-0.06, 0.22)
Lipodystrophy	-	-	-0.03 (-0.54, 0.48)
Endocrine disorders	-	-	0.00 (-0.13, 0.14)
Hypertension	-	-	0.02 (-0.13, 0.17)
Substance abuse	-	-	-0.24 (-0.40, -0.09)
Medications associated with weight gain	-	-	-0.05 (-0.20, 0.09)
Medications associated with weight loss	-	-	-0.04 (-0.21, 0.13)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.42 (0.30, 0.55)

<sup>±</sup> Mean (range) = 1.05 (0.38 to 2.12)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup> Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.2.7. Overweight: Unadjusted and adjusted differences in mean BMI at 12 months

Table 99. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced patients who were overweight (n=4053)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=1398)	27.71 (27.58, 27.84)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=1424)	27.77 (27.64, 27.90)	0.09 (-0.07, 0.24)	-0.05 (-0.15, 0.12)
RAL (n=185)	27.78 (27.43, 28.13)	0.05 (-0.26, 0.37)	-0.10 (-0.21, 0.42)
RPV (n=666)	27.86 (27.67, 28.04)	0.10 (-0.09, 0.29)	0.02 (-0.17, 0.22)
DRV/c, DRV/r (n=380)	27.62 (27.37, 27.86)	-0.04 (-0.27, 0.20)	-0.10 (-0.33, 0.13)
Female	-	-	0.44 (0.24, 0.64)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.23 (0.06, 0.39)
Race/ethnicity: Other non-Hispanic	-	-	0.03 (-0.42, 0.48)
Race/ethnicity: Hispanic	-	-	0.16 (-0.01, 0.32)
Lipodystrophy	-	-	-0.34 (-0.92, 0.24)
Endocrine disorders	-	-	-0.09 (-0.23, 0.06)
Hypertension	-	-	0.10 (-0.06, 0.25)
Substance abuse	-	-	-0.27 (-0.46, 0.08)
Medications associated with weight gain	-	-	0.17 (0.00, 0.34)
Medications associated with weight loss	-	-	0.01 (-0.18, 0.20)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.30 (0.14, 0.45)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.2.8. Overweight: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights)

Table 100. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced patients who were overweight (n=4053) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=1398)	27.75 (27.63, 27.87)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=1424)	27.78 (27.65, 27.91)	0.08 (-0.07, 0.23)	-0.05 (-0.15, 0.12)
RAL (n=185)	27.78 (27.42, 28.14)	0.02 (-0.30, 0.35)	-0.10 (-0.21, 0.42)
RPV (n=666)	27.88 (27.70, 28.06)	0.10 (-0.08, 0.29)	0.02 (-0.17, 0.22)
DRV/c, DRV/r (n=380)	27.68 (27.41, 27.95)	-0.01 (-0.26, 0.24)	-0.10 (-0.33, 0.13)
Female	-	-	0.44 (0.24, 0.65)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.24 (0.07, 0.40)
Race/ethnicity: Other non-Hispanic	-	-	0.04 (-0.40, 0.48)
Race/ethnicity: Hispanic	-	-	0.15 (-0.01, 0.31)
Lipodystrophy	-	-	-0.30 (-0.88, 0.28)
Endocrine disorders	-	-	-0.07 (-0.22, 0.07)
Hypertension	-	-	0.09 (-0.06, 0.24)
Substance abuse	-	-	-0.23 (-0.43, -0.03)
Medications associated with weight gain	-	-	0.16 (0.00, 0.32)
Medications associated with weight loss	-	-	0.01 (-0.18, 0.20)
BMI <sup>†</sup>	-	N/A	N/A

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.31 (0.15, 0.46)

<sup>±</sup> Mean (range) = 1.04 (0.64 to 2.60)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.2.9. Obese: Unadjusted and adjusted differences in mean BMI at 12 months

Table 101. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced patients who were obese (n=2054)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=839)	34.69 (34.34, 35.05)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=864)	35.19 (34.84, 35.53)	0.27 (-0.04, 0.57)	0.03 (-0.30, 0.36)
RAL (n=109)	34.23 (33.26, 35.20)	-0.80 (-1.43, -0.16)	-0.81 (-1.44, -0.18)
RPV (n=446)	35.01 (34.53, 35.49)	0.09 (-0.28, 0.45)	-0.12 (-0.50, 0.25)
DRV/c, DRV/r (n=246)	35.21 (34.57, 35.86)	0.01 (-0.44, 0.46)	-0.12 (-0.57, 0.33)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
Female	-	-	0.70 (0.41, 1.00)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.25 (-0.07, 0.58)
Race/ethnicity: Other non-Hispanic	-	-	-1.36 (-2.31, -0.42)
Race/ethnicity: Hispanic	-	-	-0.12 (-0.48, 0.24)
Lipodystrophy	-	-	-0.45 (-1.70, 0.80)
Endocrine disorders	-	-	-0.21 (-0.49, 0.07)
Hypertension	-	-	0.19 (-0.09, 0.47)
Substance abuse	-	-	-0.36 (-0.76, 0.04)
Medications associated with weight gain	-	-	0.12 (-0.18, 0.42)
Medications associated with weight loss	-	-	-0.01 (-0.36, 0.33)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.41 (0.11, 0.70)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.2.10. Obese: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights)

Table 102. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced patients who were obese (n=2504) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=839)	34.74 (34.42, 35.07)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=864)	35.24 (34.89, 35.59)	0.26 (-0.03, 0.56)	0.01 (-0.32, 0.33)
RAL (n=109)	34.36 (33.31, 35.41)	-0.74 (-1.42, -0.06)	-0.76 (-1.43, -0.08)
RPV (n=446)	35.07 (34.60, 35.55)	0.15 (-0.20, 0.51)	-0.07 (-0.44, 0.30)
DRV/c, DRV/r (n=246)	35.20 (34.51, 35.89)	0.01 (-0.47, 0.48)	-0.11 (-0.58, 0.36)
Female	-	-	0.63 (0.34, 0.92)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.23 (-0.09, 0.55)
Race/ethnicity: Other non-Hispanic	-	-	-1.18 (-2.14, -0.22)
Race/ethnicity: Hispanic	-	-	-0.13 (-0.49, 0.24)
Lipodystrophy	-	-	-0.38 (-1.57, 0.81)
Endocrine disorders	-	-	-0.23 (-0.50, 0.05)
Hypertension	-	-	0.20 (-0.07, 0.47)
Substance abuse	-	-	-0.37 (-0.77, 0.04)
Medications associated with weight gain	-	-	0.16 (-0.13, 0.44)
Medications associated with weight loss	-	-	-0.04 (-0.38, 0.30)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.44 (0.14, 0.73)

<sup>†</sup> Mean (range) = 1.06 (0.58 to 2.82)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.6.3. Differences in mean BMI at 24-months

#### 1.6.3.1. Overall: Unadjusted and adjusted differences in mean BMI at 24-months (with and without TAF use)

Table 103. Unadjusted and adjusted differences in mean BMI at 24-months among treatment-experienced patients (n=6047)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	B: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>b</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=2128)	27.51 (27.27, 27.75)	0.00 (Ref)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=2136)	27.55 (27.31, 27.79)	0.05 (-0.12, 0.21)	0.01 (-0.15, 0.18)	-0.05 (-0.23, 0.13)
RAL (n=253)	27.99 (27.29, 27.69)	-0.33 (-0.69, 0.03)	-0.28 (-0.64, 0.08)	-0.27 (-0.63, 0.09)
RPV (n=993)	27.87 (27.51, 28.22)	0.00 (-0.21, 0.21)	0.02 (-0.19, 0.23)	-0.02 (-0.23, 0.19)
DRV/c, DRV/r (n=537)	28.10 (27.61, 28.58)	-0.07 (-0.33, 0.19)	-0.14 (-0.40, 0.12)	-0.15 (-0.40, 0.12)
Female	-	-	0.47 (0.26, 0.67)	0.47 (0.26, 0.67)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.12 (-0.06, 0.30)	0.12 (-0.06, 0.30)
Race/ethnicity: Other non-Hispanic	-	-	-0.34 (-0.77, 0.09)	-0.34 (-0.77, 0.09)
Race/ethnicity: Hispanic	-	-	0.25 (0.07, 0.44)	0.25 (0.07, 0.44)
Lipodystrophy	-	-	-0.70 (-1.31, -0.09)	-0.69 (-1.30, -0.08)
Endocrine disorders	-	-	-0.04 (-0.20, 0.13)	-0.04 (-0.20, 0.12)
Hypertension	-	-	0.29 (0.11, 0.46)	0.28 (0.11, 0.46)
Substance abuse	-	-	-0.27 (-0.47, -0.06)	-0.27 (-0.47, -0.06)
Medications associated with weight gain	-	-	0.01 (-0.17, 0.19)	0.01 (-0.17, 0.20)
Medications associated with weight loss	-	-	-0.25 (-0.46, -0.05)	-0.25 (-0.46, -0.05)
BMI <sup>†</sup>	-	N/A	N/A	N/A
Age <sup>†</sup>	-	-	N/A	N/A
CD4 count <sup>†</sup>	-	-	N/A	N/A
Viral load <sup>†</sup>	-	-	N/A	N/A

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	B: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>b</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
TAF use	-	-	-	0.17 (-0.02, 0.36)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>b</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), and substance abuse (yes, no)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.6.3.2. Overall: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)

Table 104. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients (n=6047) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=2128)	27.56 (27.32, 27.80)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=2136)	27.60 (27.36, 27.84)	0.04 (-0.12, 0.20)	-0.05 (-0.22, 0.12)
RAL (n=253)	28.01 (27.28, 28.73)	-0.32 (-0.68, 0.05)	-0.26 (-0.62, 0.11)
RPV (n=993)	27.91 (27.56, 28.26)	0.01 (-0.19, 0.21)	-0.01 (-0.22, 0.21)
DRV/c, DRV/r (n=537)	28.13 (27.63, 28.63)	-0.07 (-0.34, 0.19)	-0.14 (-0.40, 0.12)
Female	-	-	0.43 (0.23, 0.63)



	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.11 (-0.07, 0.29)
Race/ethnicity: Other non-Hispanic	-	-	-0.30 (-0.72, 0.12)
Race/ethnicity: Hispanic	-	-	0.21 (0.03, 0.40)
Lipodystrophy	-	-	-0.69 (-1.23, -0.14)
Endocrine disorders	-	-	-0.04 (-0.20, 0.12)
Hypertension	-	-	0.26 (0.09, 0.43)
Substance abuse	-	-	-0.25 (-0.45, -0.05)
Medications associated with weight gain	-	-	0.03 (-0.15, 0.21)
Medications associated with weight loss	-	-	-0.27 (-0.48, -0.07)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.17 (-0.03, 0.37)

<sup>±</sup> Mean (range) = 1.09 (0.68 to 1.84)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.6.3.3. Underweight: Unadjusted and adjusted differences in mean BMI at 24 months

Table 105. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients who were underweight (n=133)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI change at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
<b>DTG (n=49)</b>	19.66 (18.88, 20.43)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=45)</b>	18.65 (17.84, 19.45)	-0.89 (-2.04, 0.26)	-0.56 (-1.84, 0.72)
<b>RAL (n=5)</b>	21.64 (19.22, 24.07)	2.17 (-0.43, 4.77)	2.29 (-0.40, 4.97)
<b>RPV (n=25)</b>	19.76 (18.68, 20.85)	0.22 (-1.14, 1.57)	0.82 (-0.61, 2.26)
<b>DRV/c, DRV/r (n=9)</b>	18.53 (16.72, 20.33)	-1.01 (-3.00, 0.98)	-1.29 (-3.27, 0.70)
<b>Female</b>	-	-	0.54 (-0.63, 1.70)
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	-0.90 (-2.10, 0.30)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	-2.37 (-5.06, 0.32)
<b>Race/ethnicity: Hispanic</b>	-	-	-0.27 (-1.80, 1.26)
<b>Lipodystrophy</b>	-	-	-4.13 (-9.83, 1.57)
<b>Endocrine disorders</b>	-	-	-0.11 (-1.77, 1.54)
<b>Hypertension</b>	-	-	0.06 (-1.67, 1.80)
<b>Substance abuse</b>	-	-	-0.75 (-2.21, -0.70)
<b>Medications associated with weight gain</b>	-	-	-0.08 (-1.30, 1.14)
<b>Medications associated with weight loss</b>	-	-	0.91 (-0.60, 2.42)
<b>BMI<sup>†</sup></b>	-	N/A	N/A
<b>Age<sup>†</sup></b>	-	-	N/A
<b>CD4 count<sup>†</sup></b>	-	-	N/A
<b>Viral load<sup>†</sup></b>	-	-	N/A
<b>TAF use</b>	-	-	-0.35 (-1.64, 0.93)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.3.4. Underweight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)

Table 106. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients who were underweight (n=133) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=49)	19.60 (18.81, 20.40)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=45)	18.59 (17.72, 19.45)	-0.90 (-2.11, 0.30)	-0.67 (-2.02, 0.68)
RAL (n=5)	21.59 (19.12, 24.07)	2.15 (-0.50, 4.81)	2.23 (-0.54, 4.99)
RPV (n=25)	19.98 (19.01, 20.94)	0.48 (-0.80, 1.75)	0.99 (-0.41, 2.39)
DRV/c, DRV/r (n=9)	18.53 (16.46, 20.60)	-0.97 (-3.21, 1.27)	-1.11 (-3.35, 1.14)
Female	-	-	0.30 (-0.89, 1.50)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	-0.71 (-1.96, 0.54)
Race/ethnicity: Other non-Hispanic	-	-	-1.96 (-4.57, 0.65)
Race/ethnicity: Hispanic	-	-	-0.04 (-1.62, 1.54)
Lipodystrophy	-	-	-4.32 (-9.75, 1.11)
Endocrine disorders	-	-	-0.13 (-1.80, 1.54)
Hypertension	-	-	-0.24 (-1.92, 1.45)
Substance abuse	-	-	-0.55 (-2.06, 0.95)
Medications associated with weight gain	-	-	0.08 (-1.15, 1.30)
Medications associated with weight loss	-	-	0.95 (-0.70, 2.60)
BMI <sup>†</sup>	-	-	-
Age <sup>†</sup>	-	-	-
CD4 count <sup>†</sup>	-	-	-
Viral load <sup>†</sup>	-	-	-

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
TAF use	-	-	-0.21 (-1.59, 1.16)

<sup>±</sup> Mean (range) = 1.10 (0.71 to 2.77)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.3.5. Normal weight: Unadjusted and adjusted differences in mean BMI at 24 months

Table 107. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients who were normal weight (n=2335)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=826)	23.72 (23.55, 23.90)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=867)	23.48 (23.30, 23.65)	-0.24 (-0.44, -0.04)	-0.39 (-0.61, -0.17)
RAL (n=88)	22.98 (22.43, 23.53)	-0.60 (-1.07, -0.13)	-0.54 (-1.01, -0.07)
RPV (n=370)	23.41 (23.14, 23.68)	-0.31 (-0.57, -0.04)	-0.34 (-0.60, -0.07)
DRV/c, DRV/r (n=184)	23.52 (23.14, 23.90)	-0.24 (-0.58, 0.10)	-0.31 (-0.66, 0.02)
Female	-	-	0.51 (0.21, 0.81)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.01 (-0.21, 0.23)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
Race/ethnicity: Other non-Hispanic	-	-	-0.28 (-0.74, 0.18)
Race/ethnicity: Hispanic	-	-	0.13 (-0.10, 0.36)
Lipodystrophy	-	-	-0.07 (-0.93, 0.79)
Endocrine disorders	-	-	0.02 (-0.19, 0.24)
Hypertension	-	-	0.02 (-0.23, 0.26)
Substance abuse	-	-	-0.28 (-0.52, -0.04)
Medications associated with weight gain	-	-	0.02 (-0.22, 0.26)
Medications associated with weight loss	-	-	-0.17 (-0.46, 0.12)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.36 (0.12, 0.60)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.3.6. Normal weight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)

Table 108. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients who were normal weight (n=2335) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=826)	23.71 (23.53, 23.88)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=867)	23.47 (23.30, 23.64)	-0.23 (-0.42, -0.03)	-0.34 (-0.55, -0.13)
RAL (n=88)	23.00 (22.43, 23.56)	-0.58 (-1.06, -0.10)	-0.52 (-1.00, -0.04)
RPV (n=370)	23.43 (23.17, 23.69)	-0.28 (-0.54, -0.03)	-0.30 (-0.55, -0.04)
DRV/c, DRV/r (n=184)	23.50 (23.10, 23.90)	-0.23 (-0.59, 0.12)	-0.30 (-0.65, 0.05)
Female	-	-	0.43 (0.13, 0.74)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.00 (-0.22, 0.22)
Race/ethnicity: Other non-Hispanic	-	-	-0.27 (-0.71, 0.17)
Race/ethnicity: Hispanic	-	-	0.08 (-0.14, 0.31)
Lipodystrophy	-	-	-0.05 (-0.84, 0.74)
Endocrine disorders	-	-	0.05 (-0.16, 0.26)
Hypertension	-	-	0.00 (-0.24, 0.24)
Substance abuse	-	-	-0.24 (-0.48, -0.01)
Medications associated with weight gain	-	-	0.04 (-0.20, 0.28)
Medications associated with weight loss	-	-	-0.19 (-0.47, 0.10)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.32 (0.07, 0.58)

<sup>†</sup> Mean (range) = 1.10 (0.68 to 1.87)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.6.3.7. Overweight: Unadjusted and adjusted differences in mean BMI at 24 months

Table 109. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients who were overweight (n=2229)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=798)	27.74 (27.56, 27.92)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=768)	27.92 (27.74, 28.10)	0.22 (-0.01, 0.44)	0.05 (-0.19, 0.29)
RAL (n=97)	27.94 (27.42, 28.45)	0.00 (-0.49, 0.48)	0.10 (-0.38, 0.59)
RPV (n=356)	28.18 (27.91, 28.45)	0.33 (0.05, 0.62)	0.22 (-0.07, 0.51)
DRV/c, DRV/r (n=210)	27.86 (27.51, 28.21)	0.08 (-0.27, 0.43)	0.03 (-0.31, 0.38)
Female	-	-	0.36 (0.07, 0.65)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.40 (0.15, 0.64)
Race/ethnicity: Other non-Hispanic	-	-	-0.27 (-0.89, 0.35)
Race/ethnicity: Hispanic	-	-	0.16 (-0.08, 0.40)
Lipodystrophy	-	-	-0.76 (-1.51, 0.00)
Endocrine disorders	-	-	0.01 (-0.20, 0.22)
Hypertension	-	-	0.26 (0.03, 0.48)
Substance abuse	-	-	-0.29 (-0.57, -0.01)
Medications associated with weight gain	-	-	0.15 (-0.09, 0.39)
Medications associated with weight loss	-	-	-0.22 (-0.50, 0.06)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
TAF use	-	-	0.35 (0.09, 0.60)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup> Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.6.3.8. Overweight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)

Table 110. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients who were overweight (n=2229) with inverse probability-of-censoring (IPC) weights<sup>†</sup>

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=798)	27.73 (27.55, 27.91)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=768)	27.88 (27.70, 28.06)	0.18 (-0.04, 0.40)	0.03 (-0.20, 0.26)
RAL (n=97)	27.92 (27.38, 28.46)	0.00 (-0.50, 0.49)	0.10 (-0.40, 0.59)
RPV (n=356)	28.16 (27.89, 28.43)	0.32 (0.04, 0.60)	0.21 (-0.08, 0.49)
DRV/c, DRV/r (n=210)	27.85 (27.49, 28.21)	0.07 (-0.28, 0.42)	0.02 (-0.33, 0.37)
Female	-	-	0.38 (0.10, 0.67)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.39 (0.15, 0.64)
Race/ethnicity: Other non-Hispanic	-	-	-0.23 (-0.80, 0.34)
Race/ethnicity: Hispanic	-	-	0.17 (-0.08, 0.41)



	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
Lipodystrophy	-	-	-0.79 (-1.46, -0.12)
Endocrine disorders	-	-	-0.01 (-0.21, 0.20)
Hypertension	-	-	0.26 (0.04, 0.48)
Substance abuse	-	-	-0.28 (-0.56, 0.01)
Medications associated with weight gain	-	-	0.14 (-0.10, 0.38)
Medications associated with weight loss	-	-	-0.21 (-0.49, 0.06)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.35 (0.07, 0.62)

<sup>±</sup> Mean (range) = 1.10 (0.68 to 2.03)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.6.3.9. Obese: Unadjusted and adjusted differences in mean BMI at 24 months

Table 111. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients who were obese (n=1350)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=455)	34.83 (34.33, 35.32)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=456)	35.54 (35.04, 36.03)	0.26 (0.22, 0.74)	0.13 (-0.38, 0.65)
RAL (n=63)	35.56 (34.23, 36.90)	-0.39 (-1.35, 0.58)	-0.43 (-1.39, 0.53)
RPV (n=242)	35.05 (34.37, 35.73)	0.14 (-0.43, 0.72)	0.01 (-0.58, 0.60)
DRV/c, DRV/r (n=134)	35.40 (34.49, 36.32)	0.05 (-0.65, 0.76)	-0.19 (-0.89, 0.51)
Female	-	-	0.96 (0.50, 1.42)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.34 (-0.16, 0.84)
Race/ethnicity: Other non-Hispanic	-	-	-0.50 (-2.18, 1.19)
Race/ethnicity: Hispanic	-	-	0.30 (-0.28, 0.87)
Lipodystrophy	-	-	-1.07 (-2.76, 0.62)
Endocrine disorders	-	-	-0.39 (-0.84, 0.05)
Hypertension	-	-	0.44 (0.00, 0.87)
Substance abuse	-	-	-0.11 (-0.73, 0.49)
Medications associated with weight gain	-	-	0.06 (-0.41, 0.54)
Medications associated with weight loss	-	-	-0.41 (-0.94, 0.11)
BMI <sup>†</sup>	-	-	-
Age <sup>†</sup>	-	-	-
CD4 count <sup>†</sup>	-	-	-
Viral load <sup>†</sup>	-	-	-
TAF use	-	-	-0.13 (-0.66, 0.39)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.6.3.10. Obese: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)

Table 112. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients who were obese (n=1350) with inverse probability-of-censoring (IPC) weights<sup>±</sup>

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI change at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=455)	34.87 (34.38, 35.37)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=456)	35.63 (35.13, 36.12)	0.24 (-0.23, 0.71)	0.09 (-0.41, 0.60)
RAL (n=63)	35.49 (34.14, 36.84)	-0.51 (-1.48, 0.46)	-0.48 (-1.45, 0.48)
RPV (n=242)	35.03 (34.35, 35.71)	0.09 (-0.48, 0.65)	-0.03 (-0.62, 0.55)
DRV/c, DRV/r (n=134)	35.45 (34.51, 36.38)	0.12 (-0.59, 0.83)	-0.07 (-0.77, 0.64)
Female	-	-	0.94 (0.49, 1.40)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.29 (-0.21, 0.80)
Race/ethnicity: Other non-Hispanic	-	-	-0.44 (-2.29, 1.42)
Race/ethnicity: Hispanic	-	-	0.28 (-0.31, 0.87)
Lipodystrophy	-	-	-1.08 (-2.54, 0.39)
Endocrine disorders	-	-	-0.38 (-0.82, 0.06)
Hypertension	-	-	0.38 (-0.05, 0.81)
Substance abuse	-	-	-0.14 (-0.74, 0.47)
Medications associated with weight gain	-	-	0.11 (-0.36, 0.58)
Medications associated with weight loss	-	-	-0.46 (-0.97, 0.05)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	-0.03 (0.59, 0.54)

<sup>±</sup> Mean (range) = 1.10 (0.70 to 8.29)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### **1.7. Association between core agent group and changes in BMI (among treatment-experienced, suppressed patients only)**



## 1.7.1. Differences in mean BMI at 6-months

## 1.7.1.1. Overall: Unadjusted and adjusted differences in mean BMI at 6 months (with and without TAF use)

Table 113. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced, suppressed patients (n=9613)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	B: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>b</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=3161)	27.21 (27.02, 27.40)	0.00 (Ref)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=3348)	27.33 (27.15, 27.52)	-0.03 (-0.12, 0.05)	-0.03 (-0.11, 0.06)	-0.15 (-0.25, -0.06)
RAL (n=491)	27.20 (26.72, 27.68)	-0.22 (-0.39, -0.06)	-0.24 (-0.40, -0.07)	-0.22 (-0.39, -0.06)
RPV (n=1766)	27.59 (27.33, 27.84)	0.09 (-0.01, 0.19)	0.09 (-0.01, 0.20)	0.01 (-0.09, 0.12)
DRV/c, DRV/r (n=847)	27.74 (27.37, 28.10)	-0.26 (-0.39, -0.12)	-0.29 (-0.42, -0.16)	-0.30 (-0.44, -0.17)
Female	-	-	0.19 (0.09, 0.29)	0.19 (0.08, 0.29)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.07 (-0.02, 0.16)	0.07 (-0.02, 0.16)
Race/ethnicity: Other non-Hispanic	-	-	-0.15 (-0.37, 0.06)	-0.16 (-0.38, 0.05)
Race/ethnicity: Hispanic	-	-	0.07 (-0.02, 0.16)	0.07 (-0.02, 0.16)
Lipodystrophy	-	-	-0.02 (-0.32, 0.29)	0.02 (-0.29, 0.32)
Endocrine disorders	-	-	-0.03 (-0.11, 0.05)	-0.03 (-0.11, 0.05)
Hypertension	-	-	0.05 (-0.04, 0.13)	0.04 (-0.05, 0.13)
Substance abuse	-	-	-0.10 (-0.21, 0.01)	-0.11 (-0.21, 0.00)
Medications associated with weight gain	-	-	0.07 (-0.02, 0.16)	0.08 (-0.01, 0.17)
Medications associated with weight loss	-	-	-0.01 (-0.12, 0.09)	-0.01 (-0.12, 0.09)
BMI <sup>†</sup>	-	N/A	N/A	N/A
Age <sup>†</sup>	-	-	N/A	N/A
CD4 count <sup>†</sup>	-	-	N/A	N/A
Viral load <sup>†</sup>	-	-	N/A	N/A
TAF use	-	-	-	0.27 (0.19, 0.35)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>b</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), and substance abuse (yes, no)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

**Example of interpretation of Table 113 (Adjustment C, EVG/c vs. DTG):** On average, after 6 months on the core agent, BMI increased by 0.12 kg/m<sup>2</sup> less with EVG/c than with DTG.

### 1.7.1.2. Overall: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)

Table 114. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced, suppressed patients (n=9613) with inverse probability-of-censoring (IPC) weights<sup>†</sup>

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=3161)	27.23 (27.06, 27.41)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=3348)	27.47 (27.29, 27.66)	-0.01 (-0.10, 0.07)	-0.15 (-0.24, -0.06)
RAL (n=491)	27.19 (26.75, 27.64)	-0.19 (-0.34, -0.03)	-0.18 (-0.33, -0.02)
RPV (n=1766)	27.56 (27.30, 27.82)	0.10 (0.00, 0.20)	0.00 (-0.10, 0.11)
DRV/c, DRV/r (n=847)	27.76 (27.37, 28.15)	-0.24 (-0.38, -0.10)	-0.28 (-0.42, -0.14)
Female	-	-	0.16 (0.06, 0.25)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.09 (0.00, 0.18)
Race/ethnicity: Other non-Hispanic	-	-	-0.17 (-0.42, 0.07)
Race/ethnicity: Hispanic	-	-	0.07 (-0.02, 0.15)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
Lipodystrophy	-	-	0.00 (-0.27, 0.26)
Endocrine disorders	-	-	-0.02 (-0.10, 0.06)
Hypertension	-	-	0.03 (-0.05, 0.11)
Substance abuse	-	-	-0.09 (-0.22, 0.03)
Medications associated with weight gain	-	-	0.06 (-0.03, 0.15)
Medications associated with weight loss	-	-	-0.04 (-0.13, 0.06)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.28 (0.20, 0.37)

<sup>±</sup> Mean (range) = 1.14 (0.24 to 3.07)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.1.3. Underweight: Unadjusted and adjusted differences in mean BMI at 6 months

Table 115. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced, suppressed patients who were underweight (n=185)



	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=60)	18.65 (17.95, 19.36)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=70)	18.75 (18.10, 19.40)	0.07 (-0.89, 1.03)	0.15 (-0.95, 1.25)
RAL (n=11)	18.36 (16.72, 20.01)	-0.28 (-2.09, 1.54)	-0.67 (-2.56, 1.21)
RPV (n=33)	19.23 (18.28, 20.18)	0.60 (-0.58, 1.78)	0.77 (-0.50, 2.03)
DRV/c, DRV/r (n=11)	18.06 (16.42, 19.71)	-0.50 (-2.31, 1.30)	-0.17 (-1.98, 1.64)
Female	-	-	-0.37 (-1.41, 0.67)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	-0.45 (-1.51, 0.61)
Race/ethnicity: Other non-Hispanic	-	-	-0.17 (-2.07, 1.74)
Race/ethnicity: Hispanic	-	-	0.62 (-0.64, 1.87)
Lipodystrophy	-	-	-0.86 (-4.86, 3.13)
Endocrine disorders	-	-	0.45 (-0.73, 1.64)
Hypertension	-	-	1.64 (0.27, 3.02)
Substance abuse	-	-	0.72 (-0.56, 1.99)
Medications associated with weight gain	-	-	-1.04 (-2.16, 0.07)
Medications associated with weight loss	-	-	-0.95 (-2.24, 0.34)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	-0.10 (-1.08, 0.88)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.1.4. Underweight: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)

\*\*\*\*\* IPC weighting could not be performed due to large weights (Mean (range) = 39419095.96 (0.12 to 5084555256))

#### 1.7.1.5. Normal weight: Unadjusted and adjusted differences in mean BMI at 6 months

Table 116. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced, suppressed patients who were normal weight (n=3527)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=1172)	23.01 (22.89, 23.13)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=1237)	23.06 (22.94, 23.17)	-0.04 (-0.15, 0.07)	-0.20 (-0.32, -0.08)
RAL (n=169)	22.66 (22.34, 22.97)	-0.22 (-0.44, 0.00)	-0.23 (-0.45, -0.01)
RPV (n=662)	23.09 (22.93, 23.25)	-0.07 (-0.19, 0.06)	-0.16 (-0.29, -0.03)
DRV/c, DRV/r (n=287)	22.96 (22.72, 23.20)	-0.17 (-0.34, 0.01)	-0.20 (-0.38, -0.03)
Female	-	-	-0.04 (-0.19, 0.10)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.12 (0.00, 0.23)
Race/ethnicity: Other non-Hispanic	-	-	0.00 (-0.24, 0.23)
Race/ethnicity: Hispanic	-	-	0.11 (-0.01, 0.23)
Lipodystrophy	-	-	0.05 (-0.37, 0.48)
Endocrine disorders	-	-	0.03 (-0.08, 0.14)
Hypertension	-	-	0.02 (-0.10, 0.14)
Substance abuse	-	-	-0.10 (-0.24, 0.03)
Medications associated with weight gain	-	-	0.03 (-0.09, 0.15)
Medications associated with weight loss	-	-	0.04 (-0.11, 0.18)
BMI <sup>†</sup>	-	N/A	N/A

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.39 (0.29, 0.50)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.1.6. Normal weight: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)

Table 117. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced, suppressed patients who were normal weight (n=3527) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=1172)	23.12 (23.01, 23.22)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=1237)	23.14 (23.01, 23.27)	-0.07 (-0.18, 0.04)	-0.21 (-0.34, -0.09)
RAL (n=169)	22.96 (22.70, 23.22)	-0.24 (-0.43, -0.05)	-0.24 (-0.43, -0.05)
RPV (n=662)	23.17 (23.01, 23.33)	-0.07 (-0.20, 0.06)	-0.16 (-0.29, -0.03)
DRV/c, DRV/r (n=287)	22.87 (22.62, 23.13)	-0.38 (-0.56, -0.19)	-0.40 (-0.59, -0.22)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
Female	-	-	-0.01 (-0.14, 0.12)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.16 (0.05, 0.28)
Race/ethnicity: Other non-Hispanic	-	-	-0.03 (-0.28, 0.22)
Race/ethnicity: Hispanic	-	-	0.12 (0.00, 0.24)
Lipodystrophy	-	-	-0.11 (-0.51, 0.28)
Endocrine disorders	-	-	0.03 (-0.07, 0.13)
Hypertension	-	-	-0.02 (-0.14, 0.09)
Substance abuse	-	-	-0.12 (-0.29, 0.05)
Medications associated with weight gain	-	-	0.06 (-0.06, 0.17)
Medications associated with weight loss	-	-	0.11 (-0.02, 0.24)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.37 (0.26, 0.48)

<sup>±</sup> Mean (range) = 1.30 (0.29 to 15.41)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.1.7. Overweight: Unadjusted and adjusted differences in mean BMI at 6 months

Table 118. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced, suppressed patients who were overweight (n=3670)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI change at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
<b>DTG (n=1224)</b>	27.55 (27.43, 27.67)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=1286)</b>	27.57 (27.45, 27.68)	-0.03 (-0.15, 0.09)	<b>-0.15 (-0.28, -0.01)</b>
<b>RAL (n=198)</b>	27.33 (27.04, 27.62)	-0.20 (-0.44, 0.03)	-0.18 (-0.42, 0.05)
<b>RPV (n=637)</b>	27.61 (27.45, 27.77)	0.02 (-0.13, 0.16)	-0.07 (-0.22, 0.09)
<b>DRV/c, DRV/r (n=325)</b>	27.38 (27.16, 27.61)	<b>-0.23 (-0.42, -0.04)</b>	<b>-0.26 (-0.45, -0.06)</b>
<b>Female</b>	-	-	<b>0.19 (0.03, 0.35)</b>
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	<b>0.13 (0.00, 0.27)</b>
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	-0.26 (-0.63, 0.10)
<b>Race/ethnicity: Hispanic</b>	-	-	0.07 (-0.05, 0.20)
<b>Lipodystrophy</b>	-	-	0.17 (-0.24, 0.59)
<b>Endocrine disorders</b>	-	-	0.02 (-0.09, 0.14)
<b>Hypertension</b>	-	-	0.03 (-0.10, 0.15)
<b>Substance abuse</b>	-	-	-0.09 (-0.25, 0.07)
<b>Medications associated with weight gain</b>	-	-	<b>0.15 (0.02, 0.28)</b>
<b>Medications associated with weight loss</b>	-	-	-0.03 (-0.18, 0.12)
<b>BMI<sup>†</sup></b>	-	N/A	N/A
<b>Age<sup>†</sup></b>	-	-	N/A
<b>CD4 count<sup>†</sup></b>	-	-	N/A
<b>Viral load<sup>†</sup></b>	-	-	N/A
<b>TAF use</b>	-	-	<b>0.25 (0.12, 0.37)</b>

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.1.8. Overweight: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)

Table 119. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced, suppressed patients who were overweight (n=3670) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
DTG (n=1224)	27.59 (27.47, 27.71)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=1286)	27.56 (27.46, 27.66)	-0.02 (-0.14, 0.09)	<b>-0.14 (-0.27, -0.01)</b>
RAL (n=198)	27.39 (27.09, 27.68)	-0.21 (-0.45, 0.02)	-0.19 (-0.42, 0.04)
RPV (n=637)	27.65 (27.46, 27.84)	0.03 (-0.14, 0.18)	-0.06 (-0.22, 0.11)
DRV/c, DRV/r (n=325)	27.50 (27.23, 27.76)	<b>-0.24 (-0.46, -0.03)</b>	-0.20 (-0.42, 0.02)
Female	-	-	<b>0.15 (0.01, 0.29)</b>
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.13 (-0.01, 0.26)
Race/ethnicity: Other non-Hispanic	-	-	-0.27 (-0.79, 0.24)
Race/ethnicity: Hispanic	-	-	0.05 (-0.07, 0.17)
Lipodystrophy	-	-	0.18 (-0.06, 0.41)
Endocrine disorders	-	-	0.03 (-0.08, 0.14)
Hypertension	-	-	0.04 (-0.07, 0.15)
Substance abuse	-	-	-0.16 (-0.34, 0.01)
Medications associated with weight gain	-	-	<b>0.15 (0.02, 0.27)</b>
Medications associated with weight loss	-	-	-0.07 (-0.21, 0.07)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
<b>TAF use</b>	-	-	<b>0.26 (0.14, 0.38)</b>

<sup>±</sup> Mean (range) = 1.30 (0.23 to 11.62)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.1.9. Obese: Unadjusted and adjusted differences in mean BMI at 6 months

Table 120. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced, suppressed patients who were obese (n=2231)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
<b>DTG (n=705)</b>	34.34 (33.99, 34.70)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=755)</b>	34.73 (34.39, 35.07)	-0.02 (-0.26, 0.22)	-0.10 (-0.36, 0.17)
<b>RAL (n=113)</b>	34.61 (33.73, 35.50)	-0.20 (-0.66, 0.27)	-0.23 (-0.70, 0.23)
<b>RPV (n=434)</b>	35.04 (34.59, 35.49)	<b>0.42 (0.14, 0.69)</b>	<b>0.35 (0.06, 0.64)</b>
<b>DRV/c, DRV/r (n=224)</b>	34.86 (34.23, 35.48)	<b>-0.37 (-0.72, -0.02)</b>	<b>-0.49 (-0.85, -0.14)</b>
<b>Female</b>	-	-	<b>0.39 (0.15, 0.63)</b>
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	-0.06 (-0.31, 0.19)

	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
Race/ethnicity: Other non-Hispanic	-	-	-0.56 (-1.33, 0.20)
Race/ethnicity: Hispanic	-	-	-0.10 (-0.38, 0.17)
Lipodystrophy	-	-	-0.30 (-1.17, 0.57)
Endocrine disorders	-	-	-0.15 (-0.36, 0.07)
Hypertension	-	-	0.04 (-0.18, 0.26)
Substance abuse	-	-	-0.12 (-0.44, 0.21)
Medications associated with weight gain	-	-	0.11 (-0.12, 0.34)
Medications associated with weight loss	-	-	-0.02 (-0.28, 0.25)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.13 (-0.10, 0.36)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.1.10. Obese: Unadjusted and adjusted differences in means BMI at 6 months (with IPC weights)

Table 121. Unadjusted and adjusted differences in mean BMI at 6 months among treatment-experienced, suppressed patients who were obese (n=2231) with inverse probability-of-censoring (IPC) weights<sup>†</sup>



	Unadjusted mean BMI at 6 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 6 months <sup>c</sup> (95% CI)
<b>DTG (n=705)</b>	34.54 (34.12, 34.96)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=755)</b>	35.50 (35.10, 35.91)	0.00 (-0.26, 0.26)	-0.16 (-0.44, 0.12)
<b>RAL (n=113)</b>	34.97 (33.97, 35.98)	-0.07 (-0.55, 0.41)	-0.09 (-0.57, 0.40)
<b>RPV (n=434)</b>	35.37 (34.92, 35.82)	<b>0.51 (0.23, 0.78)</b>	<b>0.38 (0.09, 0.66)</b>
<b>DRV/c, DRV/r (n=224)</b>	35.73 (35.06, 36.40)	-0.30 (-0.65, 0.05)	<b>-0.44 (-0.79, -0.08)</b>
<b>Female</b>	-	-	<b>0.42 (0.18, 0.66)</b>
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	-0.12 (-0.37, 0.14)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	<b>-0.59 (-1.50, -0.32)</b>
<b>Race/ethnicity: Hispanic</b>	-	-	-0.19 (-0.46, 0.08)
<b>Lipodystrophy</b>	-	-	-0.40 (-1.50, 0.71)
<b>Endocrine disorders</b>	-	-	-0.16 (-0.38, 0.06)
<b>Hypertension</b>	-	-	0.04 (-0.18, 0.26)
<b>Substance abuse</b>	-	-	-0.03 (-0.41, 0.36)
<b>Medications associated with weight gain</b>	-	-	-0.02 (-0.25, 0.21)
<b>Medications associated with weight loss</b>	-	-	-0.07 (-0.31, 0.18)
<b>BMI<sup>†</sup></b>	-	N/A	N/A
<b>Age<sup>†</sup></b>	-	-	N/A
<b>CD4 count<sup>†</sup></b>	-	-	N/A
<b>Viral load<sup>†</sup></b>	-	-	N/A
<b>TAF use</b>	-	-	<b>0.24 (0.01, 0.47)</b>

<sup>†</sup> Mean (range) = 1.20 (0.27 to 4.40)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.2. Differences in mean BMI at 12-months

#### 1.7.2.1. Overall: Unadjusted and adjusted differences in mean BMI at 12 months (with and without TAF use)

Table 122. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced, suppressed patients (n=7857)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	B: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>b</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=2658)	27.39 (27.18, 27.59)	0.00 (Ref)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=2670)	27.53 (27.32, 27.74)	0.07 (-0.05, 0.19)	0.04 (-0.08, 0.16)	-0.11 (-0.24, 0.02)
RAL (n=383)	27.34 (26.79, 27.89)	-0.19 (-0.43, 0.04)	-0.21 (-0.44, 0.03)	-0.18 (-0.42, 0.05)
RPV (n=1472)	27.71 (27.43, 27.99)	0.16 (0.02, 0.30)	0.12 (-0.02, 0.26)	0.01 (-0.13, 0.16)
DRV/c, DRV/r (n=674)	27.81 (27.40, 28.23)	-0.22 (-0.40, -0.03)	-0.29 (-0.48, -0.11)	-0.31 (-0.49, -0.12)
Female	-	-	0.46 (0.32, 0.60)	0.46 (0.32, 0.60)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.15 (0.02, 0.27)	0.14 (0.02, 0.26)
Race/ethnicity: Other non-Hispanic	-	-	-0.17 (-0.47, 0.12)	-0.19 (-0.48, 0.11)
Race/ethnicity: Hispanic	-	-	0.04 (-0.09, 0.16)	0.03 (-0.10, 0.15)
Lipodystrophy	-	-	-0.36 (-0.79, 0.06)	-0.31 (-0.74, 0.11)
Endocrine disorders	-	-	-0.07 (-0.18, 0.04)	-0.07 (-0.18, 0.04)
Hypertension	-	-	0.11 (-0.01, 0.23)	0.11 (-0.01, 0.23)
Substance abuse	-	-	-0.24 (-0.39, -0.09)	-0.25 (-0.40, -0.10)
Medications associated with weight gain	-	-	0.01 (-0.11, 0.14)	0.01 (-0.11, 0.14)
Medications associated with weight loss	-	-	-0.08 (-0.22, 0.07)	-0.07 (-0.22, 0.07)
BMI <sup>†</sup>	-	N/A	N/A	N/A
Age <sup>†</sup>	-	-	N/A	N/A
CD4 count <sup>†</sup>	-	-	N/A	N/A

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	B: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>b</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
Viral load <sup>†</sup>	-	-	N/A	N/A
TAF use	-	-	-	0.34 (0.22, 0.45)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>b</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), and substance abuse (yes, no)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.2.2. Overall: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights)

Table 123. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced, suppressed patients (n=7857) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=2658)	27.53 (27.33, 27.73)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=2670)	27.73 (27.51, 27.94)	0.09 (-0.03, 0.21)	-0.12 (-0.25, 0.01)
RAL (n=383)	27.42 (26.84, 28.01)	-0.18 (-0.43, 0.06)	-0.17 (-0.42, 0.07)
RPV (n=1472)	27.85 (27.57, 28.13)	0.17 (0.04, 0.31)	0.01 (-0.13, 0.15)
DRV/c, DRV/r (n=674)	27.94 (27.50, 28.39)	-0.21 (-0.40, -0.02)	-0.30 (-0.49, -0.11)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
Female	-	-	0.44 (0.29, 0.58)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.14 (0.02, 0.26)
Race/ethnicity: Other non-Hispanic	-	-	-0.19 (-0.47, 0.09)
Race/ethnicity: Hispanic	-	-	0.01 (-0.12, 0.14)
Lipodystrophy	-	-	-0.29 (-0.70, 0.13)
Endocrine disorders	-	-	-0.08 (-0.19, 0.03)
Hypertension	-	-	0.10 (-0.01, 0.22)
Substance abuse	-	-	-0.23 (-0.38, -0.07)
Medications associated with weight gain	-	-	0.03 (-0.09, 0.15)
Medications associated with weight loss	-	-	-0.09 (-0.23, 0.05)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.37 (0.25, 0.48)

<sup>±</sup> Mean (range) = 1.04 (0.59 to 3.34)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.2.3. Underweight: Unadjusted and adjusted differences in mean BMI at 12 months

Table 124. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced, suppressed patients who were underweight (n=156)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI change at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
<b>DTG (n=47)</b>	19.21 (18.36, 20.06)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=55)</b>	19.02 (18.23, 19.81)	-0.13 (-1.30, 1.05)	-0.08 (-1.36, 1.20)
<b>RAL (n=10)</b>	19.25 (17.40, 21.09)	0.00 (-2.08, 2.07)	0.03 (-2.09, 2.16)
<b>RPV (n=33)</b>	19.11 (18.10, 20.13)	-0.10 (-1.43, 1.24)	-0.28 (-1.67, 1.11)
<b>DRV/c, DRV/r (n=11)</b>	18.19 (16.43, 19.95)	-0.89 (-2.87, 1.10)	-0.36 (-2.38, 1.66)
<b>Female</b>	-	-	0.48 (-0.69, 1.66)
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	-0.14 (-1.35, 1.07)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	0.28 (-1.99, 2.55)
<b>Race/ethnicity: Hispanic</b>	-	-	1.43 (-0.03, 2.89)
<b>Lipodystrophy</b>	-	-	-1.73 (-7.65, 4.19)
<b>Endocrine disorders</b>	-	-	0.38 (-0.98, 1.73)
<b>Hypertension</b>	-	-	2.10 (0.54, 3.66)
<b>Substance abuse</b>	-	-	-1.07 (-2.53, 0.39)
<b>Medications associated with weight gain</b>	-	-	-0.85 (-2.10, 0.41)
<b>Medications associated with weight loss</b>	-	-	1.04 (-0.66, 2.74)
<b>BMI<sup>†</sup></b>	-	N/A	N/A
<b>Age<sup>†</sup></b>	-	-	N/A
<b>CD4 count<sup>†</sup></b>	-	-	N/A
<b>Viral load<sup>†</sup></b>	-	-	N/A
<b>TAF use</b>	-	-	0.51 (-0.64, 1.66)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.2.4. Underweight: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights)

Table 125. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced, suppressed patients who were underweight (n=156) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=47)	18.79 (18.03, 19.55)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=55)	19.28 (18.29, 20.28)	0.56 (-0.81, 1.93)	-0.19 (-1.77, 1.40)
RAL (n=10)	20.04 (18.84, 21.25)	1.19 (-0.24, 2.63)	-0.34 (-2.17, 1.48)
RPV (n=33)	19.44 (18.46, 20.42)	0.76 (-0.51, 2.04)	0.12 (-1.42, 1.65)
DRV/c, DRV/r (n=11)	17.56 (16.30, 18.82)	-1.03 (-2.58, 0.51)	-0.33 (-2.01, 1.34)
Female	-	-	1.16 (-0.03, 2.34)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	-0.52 (-1.84, 0.79)
Race/ethnicity: Other non-Hispanic	-	-	-0.61 (-3.22, 2.01)
Race/ethnicity: Hispanic	-	-	0.99 (-0.69, 2.66)
Lipodystrophy	-	-	-0.96 (-11.56, 9.63)
Endocrine disorders	-	-	1.08 (-0.31, 2.48)
Hypertension	-	-	2.47 (0.96, 3.97)
Substance abuse	-	-	-0.83 (-2.21, 0.55)
Medications associated with weight gain	-	-	-1.55 (-2.55, -0.54)
Medications associated with weight loss	-	-	1.49 (-0.84, 3.82)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
<b>TAF use</b>	-	-	0.88 (-0.40, 2.16)

<sup>±</sup> Mean (range) = 2.47 (0.35 to 82.09)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.2.5. Normal weight: Unadjusted and adjusted differences in mean BMI at 12 months

Table 126. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced, suppressed patients who were normal weight (n=2852)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
<b>DTG (n=958)</b>	23.21 (23.07, 23.36)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=998)</b>	23.22 (23.07, 23.36)	-0.08 (-0.22, 0.07)	<b>-0.27 (-0.43, -0.11)</b>
<b>RAL (n=126)</b>	22.85 (22.46, 23.25)	-0.23 (-0.54, 0.07)	-0.21 (-0.52, 0.09)
<b>RPV (n=538)</b>	23.38 (23.18, 23.57)	0.01 (-0.16, 0.18)	-0.12 (-0.30, 0.06)
<b>DRV/c, DRV/r (n=232)</b>	23.28 (22.98, 23.57)	-0.19 (-0.42, 0.04)	<b>-0.26 (-0.50, -0.03)</b>
<b>Female</b>	-	-	0.12 (-0.08, 0.32)
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	<b>0.18 (0.03, 0.33)</b>

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
Race/ethnicity: Other non-Hispanic	-	-	-0.20 (-0.51, 0.11)
Race/ethnicity: Hispanic	-	-	0.06 (-0.10, 0.21)
Lipodystrophy	-	-	0.05 (-0.51, 0.61)
Endocrine disorders	-	-	0.05 (-0.09, 0.19)
Hypertension	-	-	-0.05 (-0.21, 0.12)
Substance abuse	-	-	-0.24 (-0.42, -0.06)
Medications associated with weight gain	-	-	-0.05 (-0.21, 0.12)
Medications associated with weight loss	-	-	0.00 (-0.18, 0.19)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.40 (0.25, 0.54)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.2.6. Normal weight: Unadjusted and adjusted differences in means BMI at 12-months (with IPC weights)

Table 127. Unadjusted and adjusted differences in mean BMI at 12-months among treatment-experienced, suppressed patients who were normal weight (n=2852) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>



	Unadjusted mean BMI at 12-months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=958)	23.24 (23.11, 23.38)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=998)	23.27 (23.13, 23.41)	-0.05 (-0.20, 0.09)	-0.25 (-0.41, -0.09)
RAL (n=126)	22.91 (22.49, 23.34)	-0.23 (-0.55, 0.10)	-0.19 (-0.52, 0.13)
RPV (n=538)	23.42 (23.23, 23.61)	0.02 (-0.15, 0.19)	-0.13 (-0.30, 0.05)
DRV/c, DRV/r (n=232)	23.27 (22.98, 23.57)	-0.18 (-0.42, 0.06)	-0.24 (-0.47, 0.00)
Female	-	-	0.12 (-0.08, 0.31)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.20 (0.05, 0.36)
Race/ethnicity: Other non-Hispanic	-	-	-0.20 (-0.49, 0.09)
Race/ethnicity: Hispanic	-	-	0.04 (-0.11, 0.20)
Lipodystrophy	-	-	-0.02 (-0.49, 0.45)
Endocrine disorders	-	-	0.06 (-0.08, 0.20)
Hypertension	-	-	-0.05 (-0.21, 0.10)
Substance abuse	-	-	-0.25 (-0.43, -0.07)
Medications associated with weight gain	-	-	-0.04 (-0.20, 0.12)
Medications associated with weight loss	-	-	0.00 (-0.18, 0.18)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.39 (0.25, 0.53)

<sup>†</sup> Mean (range) = 1.06 (0.56 to 2.68)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.2.7. Overweight: Unadjusted and adjusted differences in mean BMI at 12 months

Table 128. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced, suppressed patients who were overweight (n=3000)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=1049)	27.63 (27.49, 27.76)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=995)	27.73 (27.59, 27.88)	0.12 (-0.04, 0.28)	-0.04 (-0.22, 0.14)
RAL (n=159)	27.65 (27.29, 28.01)	0.09 (-0.22, 0.40)	0.11 (-0.20, 0.42)
RPV (n=543)	27.80 (27.60, 27.99)	0.18 (-0.01, 0.38)	0.04 (-0.16, 0.24)
DRV/c, DRV/r (n=254)	27.39 (27.10, 27.67)	-0.25 (-0.51, 0.01)	<b>-0.32 (-0.57, -0.06)</b>
Female	-	-	<b>0.60 (0.38, 0.81)</b>
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	<b>0.18 (0.00, 0.35)</b>
Race/ethnicity: Other non-Hispanic	-	-	0.05 (-0.40, 0.51)
Race/ethnicity: Hispanic	-	-	0.10 (-0.07, 0.26)
Lipodystrophy	-	-	-0.44 (-1.00, 0.11)
Endocrine disorders	-	-	-0.07 (-0.22, 0.08)
Hypertension	-	-	0.07 (-0.09, 0.24)
Substance abuse	-	-	-0.17 (-0.39, 0.04)
Medications associated with weight gain	-	-	0.13 (-0.04, 0.30)
Medications associated with weight loss	-	-	-0.11 (-0.31, 0.09)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
TAF use	-	-	0.30 (0.13, 0.46)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup> Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.2.8. Overweight: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights)

\*\*\*\*\* IPC weighting could not be performed due to large weights (Mean (range) = 1.5109309E23 (0.57 to 4.5327927E26))

#### 1.7.2.9. Obese: Unadjusted and adjusted differences in mean BMI at 12 months

Table 129. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced, suppressed patients who were obese (n=1849)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DTG (n=604)	34.22 (33.82, 34.62)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=622)	34.88 (34.48, 35.27)	0.26 (-0.09, 0.60)	0.03 (-0.36, 0.42)
RAL (n=88)	34.11 (33.06, 35.17)	-0.60 (-1.29, 0.09)	-0.65 (-1.34, 0.05)
RPV (n=358)	34.88 (34.36, 35.40)	0.34 (-0.07, 0.74)	0.12 (-0.31, 0.54)

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
DRV/c, DRV/r (n=177)	34.96 (34.22, 35.71)	0.14 (-0.66, 0.38)	-0.29 (-0.82, 0.23)
Female	-	-	0.64 (0.29, 0.98)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.01 (-0.35, 0.38)
Race/ethnicity: Other non-Hispanic	-	-	-0.56 (-1.65, 0.52)
Race/ethnicity: Hispanic	-	-	-0.27 (-0.67, 0.13)
Lipodystrophy	-	-	-0.47 (-1.72, 0.79)
Endocrine disorders	-	-	-0.22 (-0.54, 0.10)
Hypertension	-	-	0.22 (-0.10, 0.54)
Substance abuse	-	-	-0.36 (-0.82, 0.11)
Medications associated with weight gain	-	-	0.02 (-0.32, 0.35)
Medications associated with weight loss	-	-	-0.08 (-0.47, 0.30)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.32 (-0.02, 0.65)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.2.10. Obese: Unadjusted and adjusted differences in means BMI at 12 months (with IPC weights)

Table 130. Unadjusted and adjusted differences in mean BMI at 12 months among treatment-experienced, suppressed patients who were obese (n=1849) with inverse probability-of-censoring (IPC) weights<sup>±</sup>

	Unadjusted mean BMI at 12 months (95% CI)	A: Unadjusted comparison between groups of mean BMI change at 12 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 12 months <sup>c</sup> (95% CI)
<b>DTG (n=604)</b>	34.34 (33.96, 34.72)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=622)</b>	34.96 (34.55, 35.36)	0.18 (-0.17, 0.53)	-0.02 (-0.41, 0.36)
<b>RAL (n=88)</b>	34.32 (33.15, 35.48)	-0.58 (-1.34, 0.19)	-0.63 (-1.38, 0.12)
<b>RPV (n=358)</b>	34.99 (34.47, 35.50)	0.37 (-0.03, 0.77)	0.13 (-0.29, 0.54)
<b>DRV/c, DRV/r (n=177)</b>	35.00 (34.20, 35.79)	-0.19 (-0.73, 0.36)	-0.34 (-0.89, 0.20)
<b>Female</b>	-	-	0.58 (0.24, 0.91)
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	0.01 (-0.36, 0.38)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	-0.45 (-1.46, -0.56)
<b>Race/ethnicity: Hispanic</b>	-	-	-0.26 (-0.68, 0.15)
<b>Lipodystrophy</b>	-	-	-0.36 (-1.61, 0.88)
<b>Endocrine disorders</b>	-	-	-0.23 (-0.55, 0.09)
<b>Hypertension</b>	-	-	0.22 (-0.09, 0.54)
<b>Substance abuse</b>	-	-	-0.28 (-0.75, 0.19)
<b>Medications associated with weight gain</b>	-	-	0.12 (-0.21, 0.44)
<b>Medications associated with weight loss</b>	-	-	-0.14 (-0.52, 0.25)
<b>BMI<sup>†</sup></b>	-	N/A	N/A
<b>Age<sup>†</sup></b>	-	-	N/A
<b>CD4 count<sup>†</sup></b>	-	-	N/A
<b>Viral load<sup>†</sup></b>	-	-	N/A
<b>TAF use</b>	-	-	0.38 (0.04, 0.72)

<sup>±</sup> Mean (range) = 1.07 (0.39 to 5.33)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.3. Differences in mean BMI at 24-months

#### 1.7.3.1. Overall: Unadjusted and adjusted differences in mean BMI at 24 months (with and without TAF use)

Table 131. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced, suppressed patients (n=4305)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	B: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>b</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
<b>DTG (n=1511)</b>	27.51 (27.23, 27.80)	0.00 (Ref)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=1444)</b>	27.62 (27.33, 27.90)	0.04 (-0.13, 0.22)	-0.04 (-0.21, 0.14)	-0.06 (-0.26, 0.13)
<b>RAL (n=212)</b>	27.85 (27.10, 27.60)	-0.25 (-0.60, 0.10)	-0.25 (-0.60, 0.10)	-0.25 (-0.60, 0.10)
<b>RPV (n=783)</b>	27.84 (27.45, 28.23)	0.20 (-0.01, 0.41)	0.11 (-0.10, 0.32)	0.09 (-0.12, 0.31)
<b>DRV/c, DRV/r (n=355)</b>	28.20 (27.62, 28.78)	-0.21 (-0.49, 0.07)	<b>-0.29 (-0.57, -0.01)</b>	<b>-0.29 (-0.57, -0.01)</b>
<b>Female</b>	-	-	0.56 (0.34, 0.77)	0.56 (0.34, 0.77)
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	0.25 (0.06, 0.43)	0.25 (0.06, 0.43)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	-0.26 (-0.69, 0.18)	-0.26 (-0.69, 0.18)
<b>Race/ethnicity: Hispanic</b>	-	-	0.13 (-0.06, 0.32)	0.23 (-0.06, 0.32)
<b>Lipodystrophy</b>	-	-	-0.69 (-1.26, -0.13)	-0.69 (-1.25, -0.12)
<b>Endocrine disorders</b>	-	-	-0.09 (-0.26, 0.07)	-0.09 (-0.26, 0.07)
<b>Hypertension</b>	-	-	0.23 (0.06, 0.41)	0.23 (0.06, 0.41)
<b>Substance abuse</b>	-	-	-0.17 (-0.39, 0.05)	-0.17 (-0.39, 0.05)
<b>Medications associated with weight gain</b>	-	-	0.00 (-0.19, 0.18)	0.00 (-0.19, 0.18)
<b>Medications associated with weight loss</b>	-	-	-0.18 (-0.39, 0.03)	-0.18 (-0.39, 0.03)
<b>BMI<sup>†</sup></b>	-	N/A	N/A	N/A

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	B: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>b</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
Age <sup>†</sup>	-	-	N/A	N/A
CD4 count <sup>†</sup>	-	-	N/A	N/A
Viral load <sup>†</sup>	-	-	N/A	N/A
TAF use	-	-	-	0.06 (-0.13, 0.26)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>b</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), and substance abuse (yes, no)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.3.2. Overall: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)

Table 132. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients (n=4305) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=1511)	27.49 (27.21, 27.77)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=1444)	27.61 (27.32, 27.89)	0.03 (-0.14, 0.20)	-0.08 (-0.26, 0.11)
RAL (n=212)	27.78 (27.01, 28.55)	-0.25 (-0.60, 0.11)	-0.24 (-0.60, 0.11)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
RPV (n=783)	27.82 (27.43, 28.21)	0.20 (-0.01, 0.40)	0.09 (-0.12, 0.31)
DRV/c, DRV/r (n=355)	28.14 (27.54, 28.74)	-0.21 (-0.50, 0.07)	-0.30 (-0.58, -0.01)
Female	-	-	0.51 (0.30, 0.72)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.23 (0.05, 0.42)
Race/ethnicity: Other non-Hispanic	-	-	-0.23 (-0.65, 0.19)
Race/ethnicity: Hispanic	-	-	0.11 (-0.08, 0.30)
Lipodystrophy	-	-	-0.67 (-1.19, -0.16)
Endocrine disorders	-	-	-0.10 (-0.26, 0.06)
Hypertension	-	-	0.19 (0.02, 0.36)
Substance abuse	-	-	-0.14 (-0.36, 0.07)
Medications associated with weight gain	-	-	0.03 (-0.15, 0.21)
Medications associated with weight loss	-	-	-0.21 (-0.42, 0.00)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.08 (-0.13, 0.29)

<sup>±</sup> Mean (range) = 1.09 (0.65 to 1.80)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines



### 1.7.3.3. Underweight: Unadjusted and adjusted differences in mean BMI at 24 months

Table 133. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients who were underweight (n=81)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=26)	19.53 (18.45 20.61)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=26)	18.60 (17.51, 19.68)	-0.76 (-2.33, 0.82)	-0.89 (-2.71, 0.93)
RAL (n=5)	21.64 (19.18, 24.11)	2.42 (-0.36, 5.21)	1.30 (-1.50, 4.09)
RPV (n=19)	19.72 (18.46, 20.99)	0.24 (-1.46, 1.95)	0.65 (-1.13, 2.42)
DRV/c, DRV/r (n=5)	18.73 (16.26, 20.19)	-0.45 (-3.23, 2.32)	-1.06 (-3.78, 1.66)
Female	-	-	0.36 (-1.25, 1.97)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	-2.15 (-3.77, -0.52)
Race/ethnicity: Other non-Hispanic	-	-	-2.71 (-5.56, 0.15)
Race/ethnicity: Hispanic	-	-	-0.62 (-2.58, 1.35)
Lipodystrophy	-	-	-3.97 (-9.73, 1.79)
Endocrine disorders	-	-	1.12 (-0.97, 3.22)
Hypertension	-	-	-0.66 (-2.80, 1.48)
Substance abuse	-	-	1.17 (-0.88, 3.21)
Medications associated with weight gain	-	-	-0.18 (-1.84, 1.48)
Medications associated with weight loss	-	-	2.08 (-0.37, 4.53)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	-1.30 (-2.95, 0.35)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.3.4. Underweight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)

Table 134. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced patients who were underweight (n=81) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=26)	18.81 (18.32, 19.29)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=26)	18.59 (17.37, 19.82)	-0.52 (-2.06, 1.02)	-0.72 (-2.84, 1.41)
RAL (n=5)	21.21 (18.76, 23.66)	2.27 (-0.26, 4.80)	1.19 (-1.75, 4.13)
RPV (n=19)	20.48 (19.49, 21.47)	1.36 (0.17, 2.56)	0.99 (-0.96, 2.94)
DRV/c, DRV/r (n=5)	18.92 (15.89, 21.96)	0.02 (-3.11, 3.15)	-0.67 (-3.98, 2.64)
Female	-	-	0.14 (-1.69, 1.96)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	-2.01 (-3.81, -0.22)
Race/ethnicity: Other non-Hispanic	-	-	-2.84 (-5.77, 0.09)
Race/ethnicity: Hispanic	-	-	-0.68 (-2.91, 1.55)
Lipodystrophy	-	-	-4.11 (-10.24, 2.02)
Endocrine disorders	-	-	0.64 (-1.69, 2.98)
Hypertension	-	-	-0.37 (-2.49, 1.75)
Substance abuse	-	-	2.44 (0.11, 4.77)
Medications associated with weight gain	-	-	-0.08 (-1.80, 1.65)
Medications associated with weight loss	-	-	2.04 (-0.94, 5.03)
BMI <sup>†</sup>	-	N/A	N/A

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	-0.93 (-2.91, 1.04)

<sup>±</sup> Mean (range) = 3.50 (0.70 to 166.50)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.3.5. Normal weight: Unadjusted and adjusted differences in mean BMI at 24 months

Table 135. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced, suppressed patients who were normal weight (n=1586)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=552)	23.58 (23.38, 23.79)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=565)	23.39 (23.19, 23.60)	-0.21 (-0.43, 0.00)	-0.34 (-0.58, -0.10)
RAL (n=69)	22.77 (22.19, 23.34)	-0.54 (-1.00, -0.07)	-0.56 (-1.03, -0.08)
RPV (n=288)	23.44 (23.16, 23.73)	-0.19 (-0.46, 0.08)	-0.26 (-0.54, 0.02)
DRV/c, DRV/r (n=112)	23.29 (22.84, 23.75)	-0.45 (-0.83, -0.08)	-0.50 (-0.88, -0.12)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
Female	-	-	0.39 (0.08, 0.71)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.11 (-0.13, 0.35)
Race/ethnicity: Other non-Hispanic	-	-	-0.07 (-0.55, 0.42)
Race/ethnicity: Hispanic	-	-	0.04 (-0.20, 0.27)
Lipodystrophy	-	-	0.01 (-0.76, 0.79)
Endocrine disorders	-	-	0.02 (-0.20, 0.23)
Hypertension	-	-	0.01 (-0.23, 0.26)
Substance abuse	-	-	-0.17 (-0.44, 0.09)
Medications associated with weight gain	-	-	0.10 (-0.15, 0.34)
Medications associated with weight loss	-	-	0.00 (-0.30, 0.29)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.22 (-0.03, 0.47)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

#### 1.7.3.6. Normal weight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)

Table 136. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced, suppressed patients who were normal weight (n=1586) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=552)	23.54 (23.34, 23.75)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=565)	23.39 (23.19, 23.59)	-0.20 (-0.41, 0.01)	-0.30 (-0.53, -0.06)
RAL (n=69)	23.81 (22.20, 23.41)	-0.51 (-1.00, -0.02)	-0.52 (-1.01, -0.03)
RPV (n=288)	23.46 (23.18, 23.75)	-0.16 (-0.43, 0.10)	-0.22 (-0.49, 0.06)
DRV/c, DRV/r (n=112)	23.24 (22.75, 23.72)	-0.47 (-0.86, -0.07)	-0.50 (-0.89, -0.10)
Female	-	-	0.38 (0.05, 0.71)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.09 (-0.14, 0.33)
Race/ethnicity: Other non-Hispanic	-	-	-0.02 (-0.50, 0.46)
Race/ethnicity: Hispanic	-	-	0.01 (-0.23, 0.24)
Lipodystrophy	-	-	0.03 (-0.71, 0.76)
Endocrine disorders	-	-	0.01 (-0.20, 0.22)
Hypertension	-	-	-0.02 (-0.26, 0.21)
Substance abuse	-	-	-0.12 (-0.38, 0.14)
Medications associated with weight gain	-	-	0.14 (-0.10, 0.38)
Medications associated with weight loss	-	-	-0.04 (-0.33, 0.25)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.19 (-0.08, 0.46)

<sup>†</sup> Mean (range) = 1.13 (0.68 to 2.51)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.3.7. Overweight: Unadjusted and adjusted differences in mean BMI at 24 months

Table 137. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced, suppressed patients who were overweight (n=1652)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=603)	27.61 (27.41, 27.81)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=530)	27.88 (27.66, 28.09)	0.26 (0.01, 0.51)	0.08 (-0.19, 0.36)
RAL (n=86)	27.91 (27.38, 28.44)	0.12 (-0.36, 0.61)	0.19 (-0.29, 0.68)
RPV (n=287)	28.15 (27.86, 28.44)	0.49 (0.19, 0.79)	0.27 (-0.04, 0.58)
DRV/c, DRV/r (n=146)	27.66 (27.26, 28.07)	-0.07 (-0.46, 0.32)	-0.06 (-0.45, 0.33)
Female	-	-	0.55 (0.22, 0.87)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.37 (0.11, 0.64)
Race/ethnicity: Other non-Hispanic	-	-	-0.17 (-0.83, 0.48)
Race/ethnicity: Hispanic	-	-	0.21 (-0.06, 0.47)
Lipodystrophy	-	-	-0.78 (-1.54, -0.02)
Endocrine disorders	-	-	-0.01 (-0.24, 0.21)
Hypertension	-	-	0.22 (-0.03, 0.46)
Substance abuse	-	-	-0.15 (-0.49, 0.18)
Medications associated with weight gain	-	-	0.00 (-0.25, 0.26)
Medications associated with weight loss	-	-	-0.20 (-0.50, 0.10)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
TAF use	-	-	0.27 (0.00, 0.55)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.3.8. Overweight: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)

Table 138. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced, suppressed patients who were overweight (n=1652) with inverse probability-of-censoring (IPC) weights<sup>‡</sup>

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=603)	27.62 (27.43, 27.82)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=530)	27.82 (27.60, 28.04)	0.19 (-0.06, 0.44)	0.03 (-0.24, 0.29)
RAL (n=86)	28.22 (27.70, 28.73)	0.40 (-0.07, 0.86)	0.15 (-0.35, 0.65)
RPV (n=287)	28.12 (27.83, 28.42)	0.46 (0.16, 0.75)	0.25 (-0.06, 0.55)
DRV/c, DRV/r (n=146)	27.66 (27.25, 28.08)	-0.11 (-0.50, 0.28)	-0.11 (-0.50, 0.28)
Female	-	-	0.57 (0.26, 0.89)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.37 (0.10, 0.63)
Race/ethnicity: Other non-Hispanic	-	-	-0.15 (-0.75, 0.44)
Race/ethnicity: Hispanic	-	-	0.20 (-0.07, 0.46)

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
Lipodystrophy	-	-	-0.78 (-1.49, -0.08)
Endocrine disorders	-	-	-0.03 (-0.25, 0.19)
Hypertension	-	-	0.22 (-0.02, 0.45)
Substance abuse	-	-	-0.10 (-0.44, 0.24)
Medications associated with weight gain	-	-	0.00 (-0.25, 0.26)
Medications associated with weight loss	-	-	-0.22 (-0.52, 0.07)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	0.29 (-0.01, 0.59)

<sup>±</sup> Mean (range) = 1.11 (0.67 to 15.00)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.3.9. Obese: Unadjusted and adjusted differences in mean BMI at 24 months

Table 139. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced, suppressed patients who were obese (n=986)



	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
<b>DTG (n=330)</b>	34.54 (33.97, 35.10)	0.00 (Ref)	0.00 (Ref)
<b>EVG/c (n=323)</b>	35.50 (34.73, 35.87)	0.18 (-0.35, 0.70)	0.08 (-0.50, 0.66)
<b>RAL (n=52)</b>	35.09 (33.67, 36.50)	-0.58 (-1.58, 0.43)	-0.76 (-1.75, 0.24)
<b>RPV (n=189)</b>	34.89 (34.15, 35.64)	0.29 (-0.33, 0.90)	0.19 (-0.46, 0.83)
<b>DRV/c, DRV/r (n=92)</b>	35.54 (34.47, 36.60)	-0.01 (-0.80, 0.79)	-0.17 (-0.44, 0.78)
<b>Female</b>	-	-	<b>0.70 (0.19, 1.21)</b>
<b>Race/ethnicity: White non-Hispanic</b>	-	-	0.00 (Ref)
<b>Race/ethnicity: Black non-Hispanic</b>	-	-	0.37 (-0.18, 0.91)
<b>Race/ethnicity: Other non-Hispanic</b>	-	-	-0.86 (-2.64, 0.92)
<b>Race/ethnicity: Hispanic</b>	-	-	0.25 (-0.37, 0.87)
<b>Lipodystrophy</b>	-	-	-1.02 (-2.65, 0.61)
<b>Endocrine disorders</b>	-	-	-0.38 (-0.87, 0.10)
<b>Hypertension</b>	-	-	<b>0.50 (0.02, 0.97)</b>
<b>Substance abuse</b>	-	-	-0.26 (-0.93, 0.41)
<b>Medications associated with weight gain</b>	-	-	-0.05 (-0.56, 0.47)
<b>Medications associated with weight loss</b>	-	-	-0.35 (-0.91, 0.21)
<b>BMI<sup>†</sup></b>	-	N/A	N/A
<b>Age<sup>†</sup></b>	-	-	N/A
<b>CD4 count<sup>†</sup></b>	-	-	N/A
<b>Viral load<sup>†</sup></b>	-	-	N/A
<b>TAF use</b>	-	-	-0.38 (-0.94, 0.19)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines

### 1.7.3.10. Obese: Unadjusted and adjusted differences in means BMI at 24 months (with IPC weights)

Table 140. Unadjusted and adjusted differences in mean BMI at 24 months among treatment-experienced, suppressed patients who were obese (n=986) with inverse probability-of-censoring (IPC) weights<sup>±</sup>

	Unadjusted mean BMI at 24 months (95% CI)	A: Unadjusted comparison between groups of mean BMI change at 24 months <sup>a</sup> (95% CI)	C: Adjusted comparison between groups of mean BMI <u>change</u> at 24 months <sup>c</sup> (95% CI)
DTG (n=330)	34.52 (33.97, 35.08)	0.00 (Ref)	0.00 (Ref)
EVG/c (n=323)	35.45 (35.89, 36.02)	0.25 (-0.27, 0.77)	0.07 (-0.49, 0.63)
RAL (n=52)	35.06 (33.66, 36.47)	-0.60 (-1.59, 0.39)	-0.80 (-1.79, 0.18)
RPV (n=189)	34.92 (34.19, 35.66)	0.33 (-0.27, 0.93)	0.21 (-0.42, 0.84)
DRV/c, DRV/r (n=92)	35.61 (34.52, 36.71)	0.11 (-0.70, 0.91)	-0.16 (-0.96, 0.64)
Female	-	-	0.63 (0.13, 1.14)
Race/ethnicity: White non-Hispanic	-	-	0.00 (Ref)
Race/ethnicity: Black non-Hispanic	-	-	0.36 (-0.18, 0.89)
Race/ethnicity: Other non-Hispanic	-	-	-0.74 (-2.62, 1.14)
Race/ethnicity: Hispanic	-	-	0.09 (-0.53, 0.72)
Lipodystrophy	-	-	-1.06 (-2.51, 0.39)
Endocrine disorders	-	-	-0.36 (-0.84, 0.12)
Hypertension	-	-	0.37 (-0.09, 0.84)
Substance abuse	-	-	-0.22 (-0.86, 0.42)
Medications associated with weight gain	-	-	0.08 (-0.43, 0.59)
Medications associated with weight loss	-	-	-0.39 (-0.94, 0.16)
BMI <sup>†</sup>	-	N/A	N/A
Age <sup>†</sup>	-	-	N/A
CD4 count <sup>†</sup>	-	-	N/A
Viral load <sup>†</sup>	-	-	N/A
TAF use	-	-	-0.26 (-0.86, 0.33)

<sup>±</sup> Mean (range) = 1.10 (0.71 to 2.02)

<sup>a</sup> Model adjusted for baseline BMI (continuous)

<sup>c</sup> Model adjusted for baseline BMI (continuous), age (continuous), sex, race/ethnicity (White non-Hispanic, Black non-Hispanic, Hispanic or Other/Unknown), viral load (continuous), CD4 count (continuous), lipodystrophy, endocrine disorders, hypertension, medications associated with weight gain (yes, no), medications associated with weight loss (yes, no), substance abuse (yes, no), and TAF use

<sup>†</sup>Estimates not shown as continuous variables were modeled using restricted cubic splines