

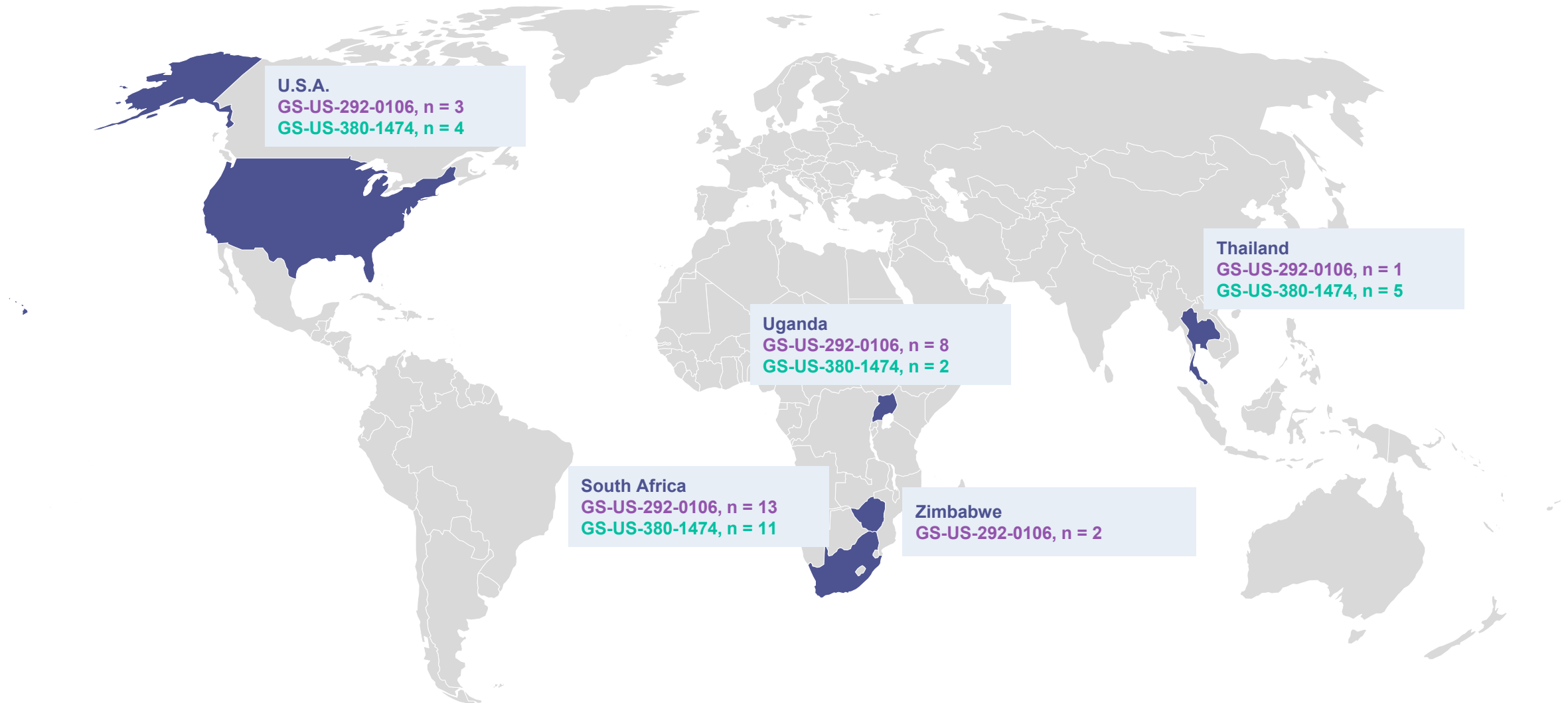
Weight Change and Metabolic Assessment of Virologically Suppressed Children With HIV Aged ≥ 2 Years and Weighing 14 to < 25 Kg Who Received a TAF-Containing Regimen

Supplementary Materials

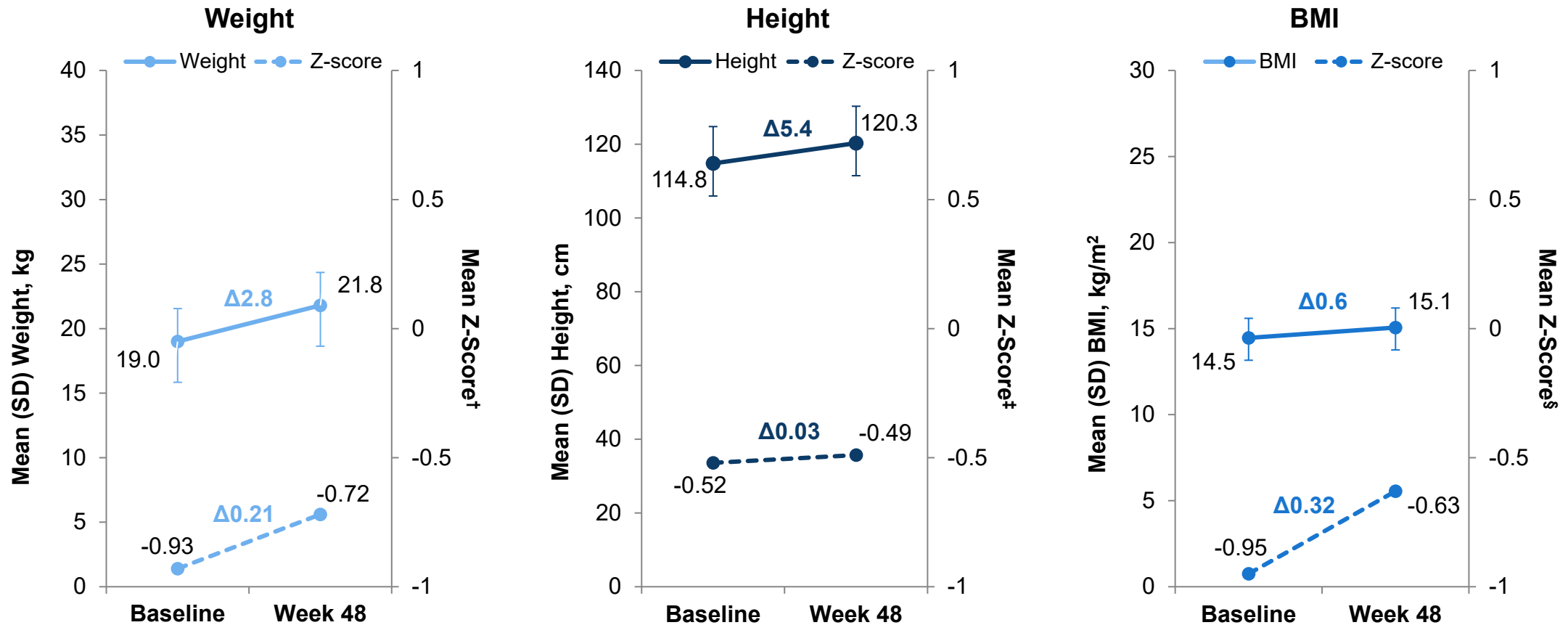
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Enrollment by Country



Weight, Height and BMI at Baseline, and Changes at Week 48*: E/C/F/TAF (N = 27)



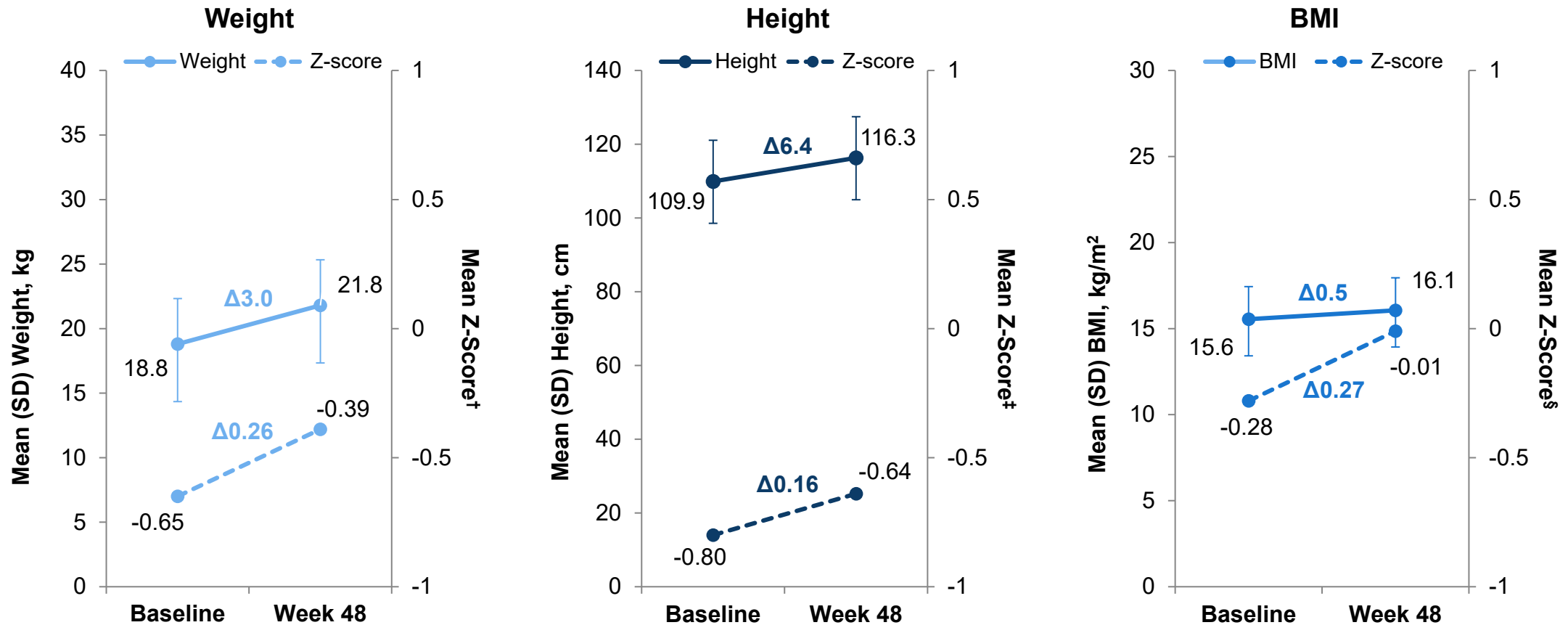
◆ Changes in Z-scores were observed for weight, height and BMI

BMI-for-age percentile increased from baseline to Week 48 by 9.0%

*Z-scores and percentiles were generated based on year 2000 growth charts from the CDC, calculated for child's sex and age¹; †SD for weight z-score was 1.03 kg at baseline and 1.07 kg at Week 48; ‡SD for height was 1.10 cm at baseline and 1.23 cm at Week 48; §SD for BMI z-score was 1.03 kg/m² at baseline and 1.12 kg/m² at Week 48. BMI, body mass index; CDC, Centers for Disease Control and Prevention; E/C/F/TAF, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide; SD, standard deviation

1. CDC. https://www.cdc.gov/nchs/data/series/sr_11/sr11_246.pdf (accessed May 24, 2023)

Weight, Height and BMI at Baseline, and Changes at Week 48*: B/F/TAF (N = 22)



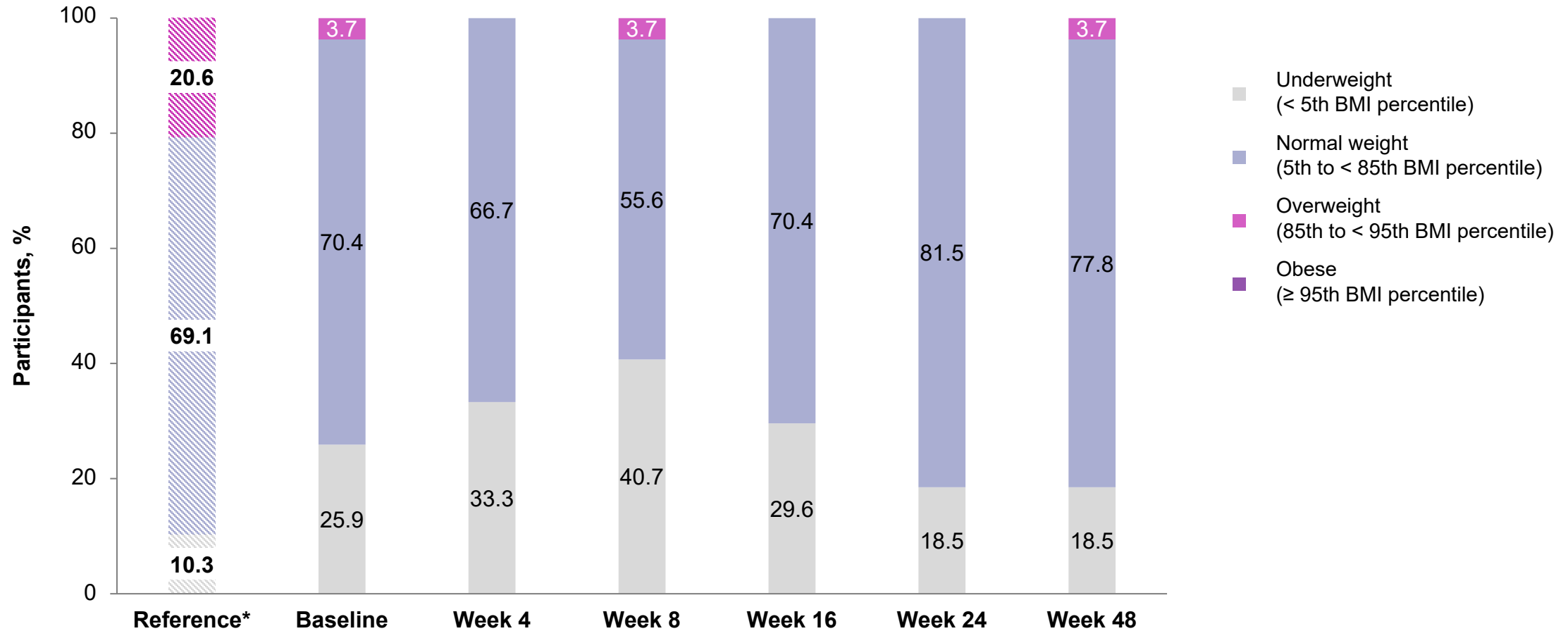
◆ Changes in Z-scores were observed for weight, height and BMI

BMI-for-age percentile increased from baseline to Week 48 by 4.2%

*Z-scores and percentiles were generated based on year 2000 growth charts from the CDC, calculated for child's sex and age¹; †SD for weight z-score was 1.07 kg at baseline and 1.15 kg at Week 48; ‡SD for height was 1.12 cm at baseline and 1.18 cm at Week 48; §SD for BMI z-score was 1.44 kg/m² at baseline and 1.28 kg/m² at Week 48. B/F/TAF, bicitgravir/emtricitabine/tenofovir alafenamide; BMI, body mass index; CDC, Centers for Disease Control and Prevention; SD, standard deviation

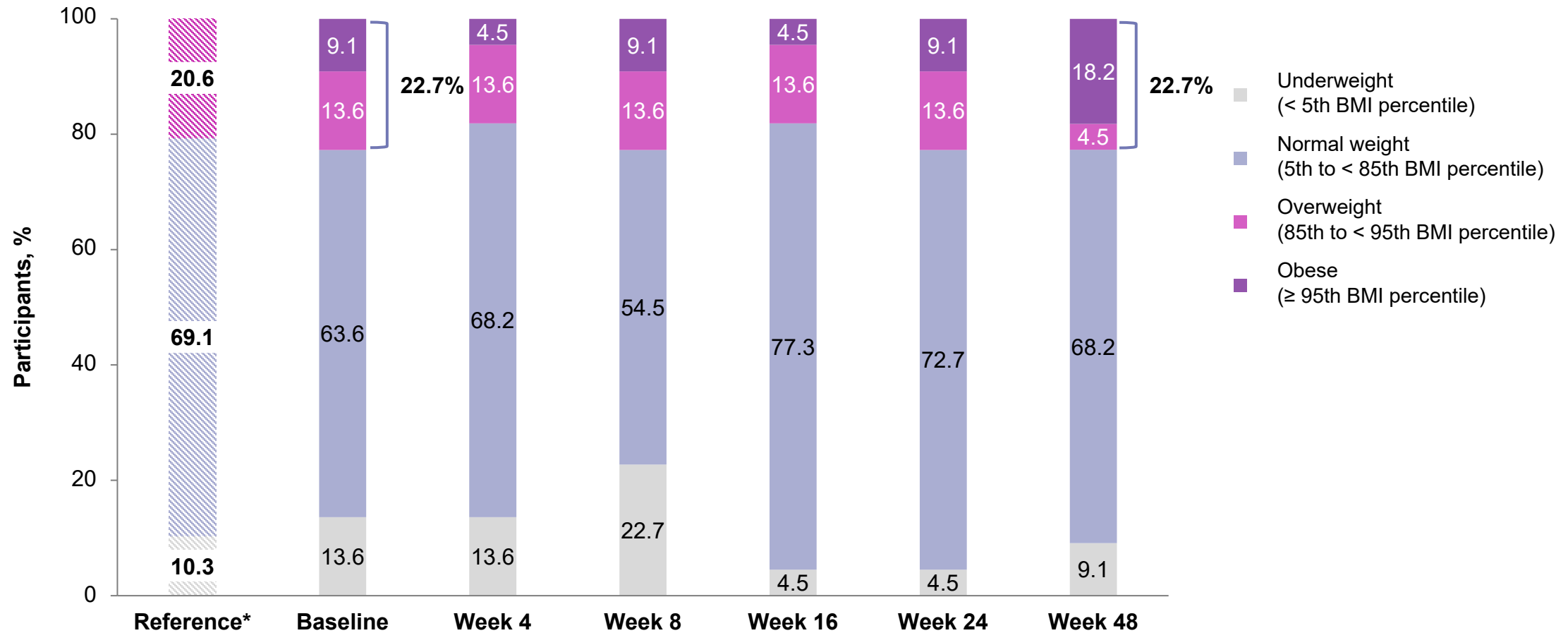
1. CDC. https://www.cdc.gov/nchs/data/series/sr_11/sr11_246.pdf (accessed May 24, 2023)

BMI Categories by Visit: E/C/F/TAF (N = 27)



BMI categories for study data are according to CDC growth charts.^{1,2} *Reference WHO global prevalence data are shown for children aged 5–9 years: underweight, < -2 SD below the median; overweight/obese, > 1 SD above the median.³ BMI, body mass index; CDC, Centers for Disease Control and Prevention; E/C/F/TAF, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide; SD, standard deviation; WHO, World Health Organization
 1. CDC. https://www.cdc.gov/nchs/data/series/sr_11/sr11_246.pdf (accessed May 24, 2023); 2. CDC. <https://www.cdc.gov/obesity/basics/childhood-defining.html> (accessed May 24, 2023);
 3. WHO. <https://www.who.int/data/gho/data/indicators> (accessed May 24, 2023)

BMI Categories by Visit: B/F/TAF (N = 22)



BMI categories for study data are according to CDC growth charts.^{1,2} *Reference WHO global prevalence data are shown for children aged 5–9 years: underweight, < -2 SD below the median; overweight/obese, > 1 SD above the median.³ B/F/TAF, bicitgravir/emtricitabine/tenofovir alafenamide; BMI, body mass index; CDC, Centers for Disease Control and Prevention; SD, standard deviation; WHO, World Health Organization
 1. CDC. https://www.cdc.gov/nchs/data/series/sr_11/sr11_246.pdf (accessed May 24, 2023); 2. CDC. <https://www.cdc.gov/obesity/basics/childhood-defining.html> (accessed May 24, 2023);
 3. WHO. <https://www.who.int/data/gho/data/indicators> (accessed May 24, 2023)

Multivariate Linear Regression of BMI-for-Age Percentile at Week 48: Final Model (N = 49)

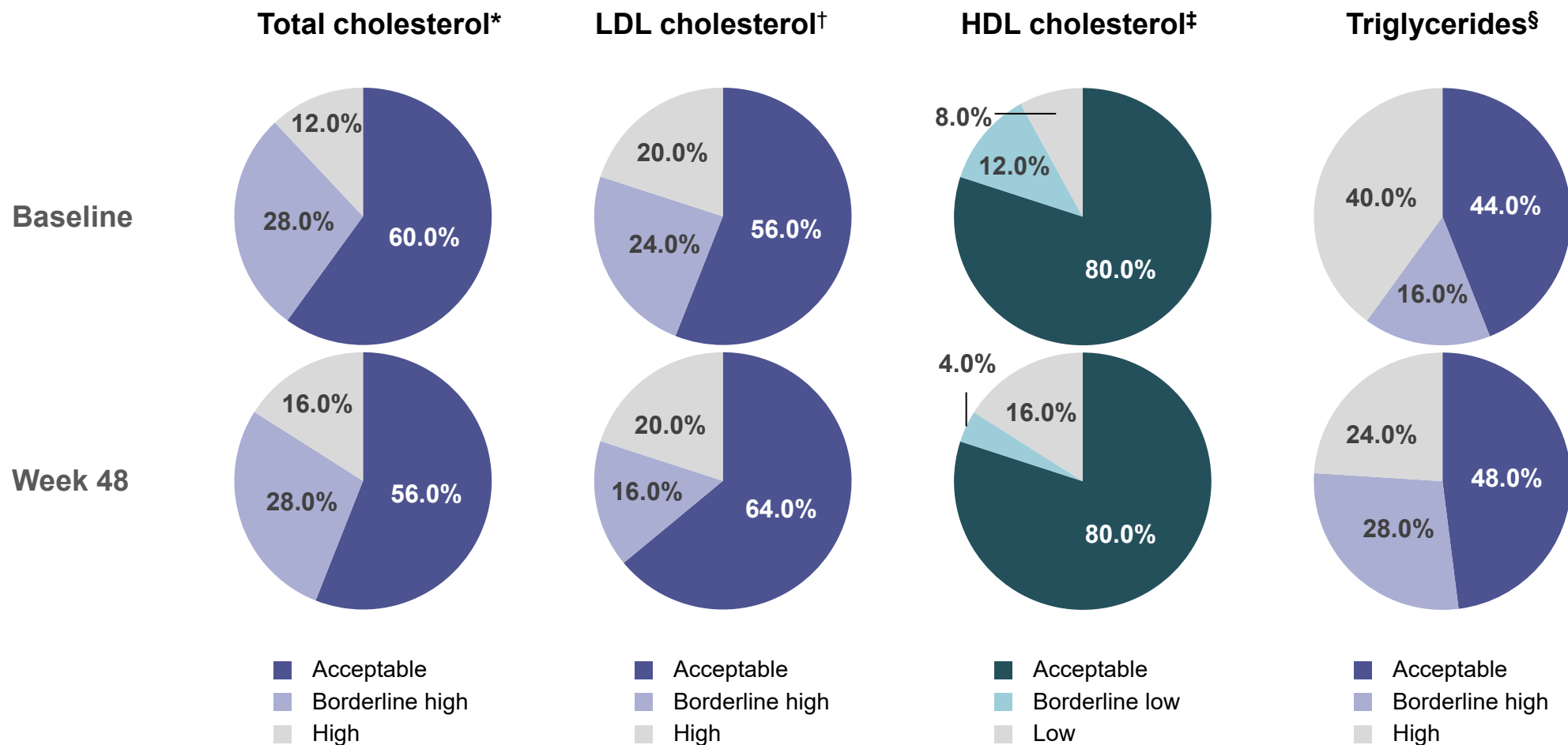
Explanatory variable	Test vs. reference	Estimate (95% CI)	P-value
Sex at birth	Female vs. male (ref.)	11.4 (1.8, 21.0)	0.0213
Baseline ABC	Yes vs. no (ref.)	9.1 (-1.3, 19.5)	0.0858
BMI category at baseline	Underweight vs. overweight/obese (ref.)	18.8 (2.5, 35.1)	0.0248
BMI category at baseline	Normal vs. overweight/obese (ref.)	9.3 (-4.8, 23.4)	0.1916

Bold = $P < 0.15$. BMI categories for study data are according to CDC growth charts.^{1,2} Percentiles were generated based on the year 2000 growth charts from the CDC website. Stepwise model selection was used to identify which explanatory variables were associated with change in BMI-for-Age percentile at Week 48, resulting in the inclusion of the above explanatory variables in the final model.

ABC, abacavir; BMI, body mass index; CDC, Centers for Disease Control and Prevention; CI, confidence interval

1. CDC. https://www.cdc.gov/nchs/data/series/sr_11/sr11_246.pdf (accessed May 24, 2023); 2. CDC. <https://www.cdc.gov/obesity/basics/childhood-defining.html> (accessed May 24, 2023)

Lipid Metabolism Categories at Baseline and Week 48: E/C/F/TAF (N = 25)



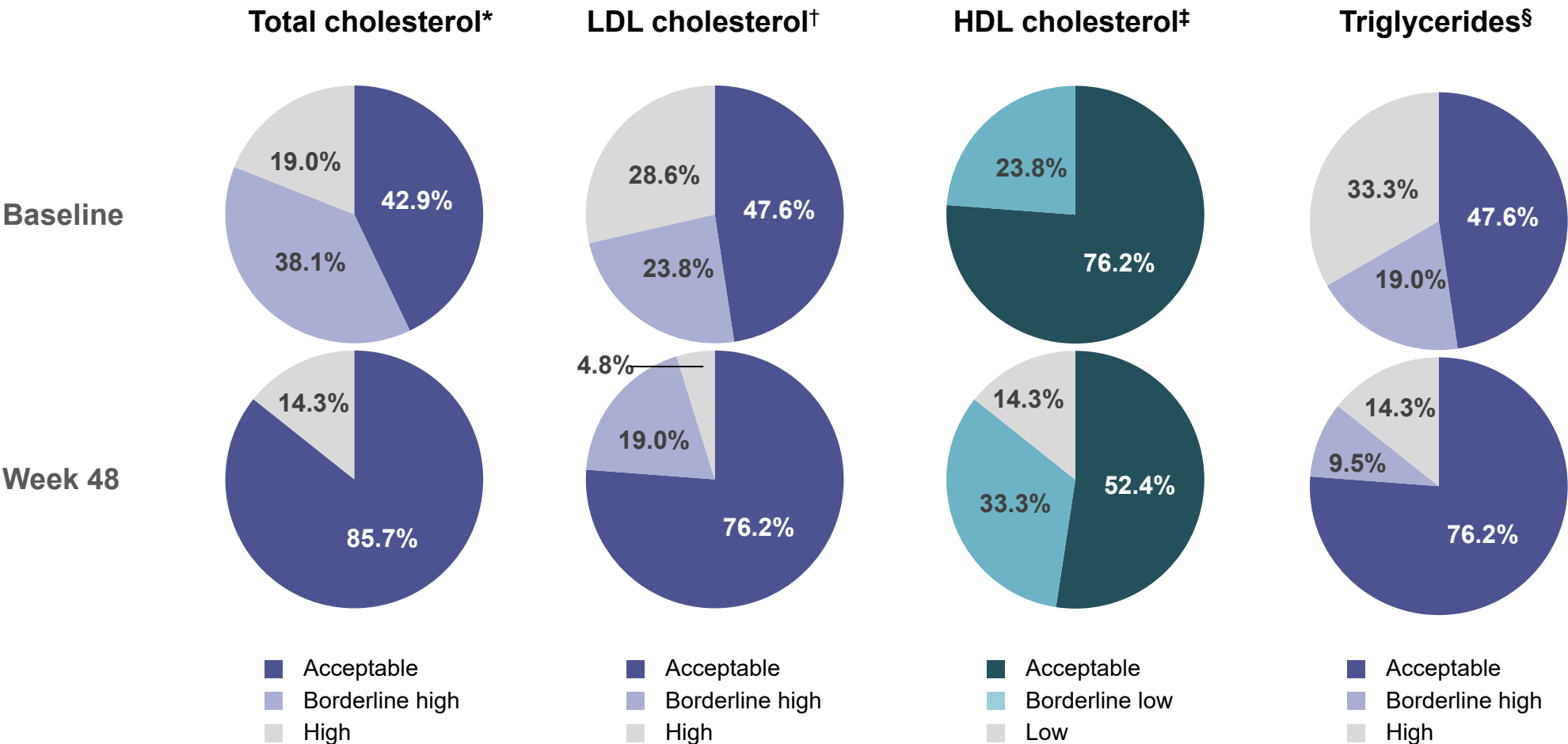
Due to rounding, percentages may not total 100%. Categories were based on integrated guidelines for cardiovascular health and risk reduction in children and adolescents¹

*Fasting total cholesterol (mg/dL): acceptable, < 170; borderline high, ≥ 170 to ≤ 199; high, ≥ 200. †Fasting LDL cholesterol (mg/dL): acceptable, < 110; borderline high, ≥ 110 to ≤ 129; high, ≥ 130. ‡Fasting HDL cholesterol (mg/dL): acceptable, > 45; borderline low, ≥ 40 to ≤ 45; low, < 40. §Fasting triglycerides (mg/dL) for age (0–9 years) at collection: acceptable, < 75; borderline high, ≥ 75 to ≤ 99; high, ≥ 100; for age (10–19 years) at collection: acceptable, < 90; borderline high, ≥ 90 to ≤ 129; high, ≥ 130

E/C/F/TAF, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide; HDL, high-density lipoprotein; LDL, low-density lipoprotein

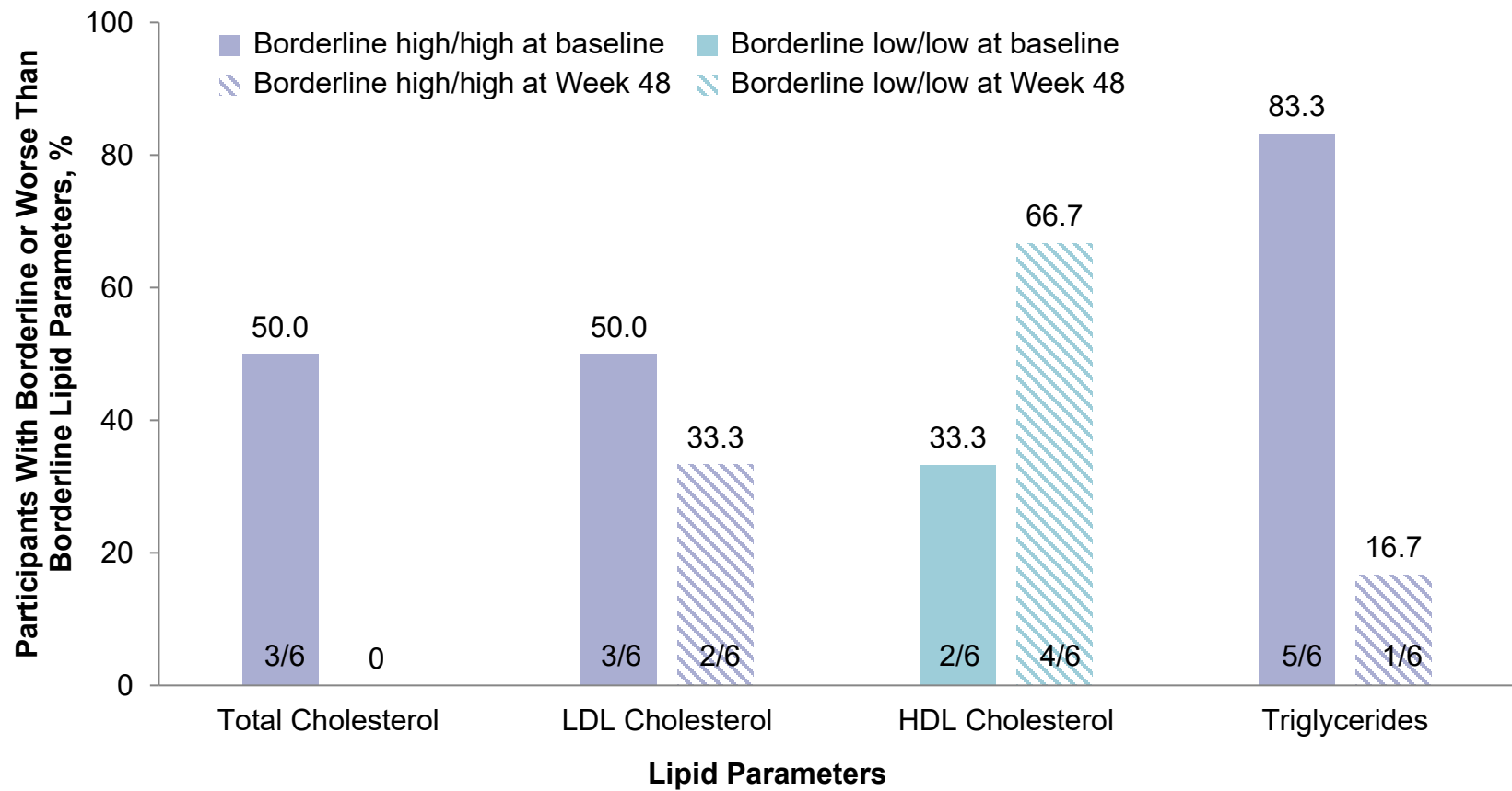
1. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction In Children and Adolescents. Pediatrics 2011;128(Suppl. 5):S213-S256

Lipid Metabolism Categories at Baseline and Week 48: B/F/TAF (N = 21)



Due to rounding, percentages may not total 100%. Categories were based on integrated guidelines for cardiovascular health and risk reduction in children and adolescents¹
*Fasting total cholesterol (mg/dL): acceptable, < 170; borderline high, ≥ 170 to ≤ 199; high, ≥ 200. †Fasting LDL cholesterol (mg/dL): acceptable, < 110; borderline high, ≥ 110 to ≤ 129; high, ≥ 130. ‡Fasting HDL cholesterol (mg/dL): acceptable, > 45; borderline low, ≥ 40 to ≤ 45; low, < 40. §Fasting triglycerides (mg/dL) for age (0–9 years) at collection: acceptable, < 75; borderline high, ≥ 75 to ≤ 99; high, ≥ 100; for age (10–19 years) at collection: acceptable, < 90; borderline high, ≥ 90 to ≤ 129; high, ≥ 130
B/F/TAF, bicitgravir/emtricitabine/tenofovir alafenamide; HDL, high-density lipoprotein; LDL, low-density lipoprotein
1. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction In Children and Adolescents. Pediatrics 2011;128(Suppl. 5):S213-S256

Lipid Parameters at Baseline and Week 48 in Individuals Who Were Categorized as Overweight or Obese at Baseline: Total Population (N = 6)

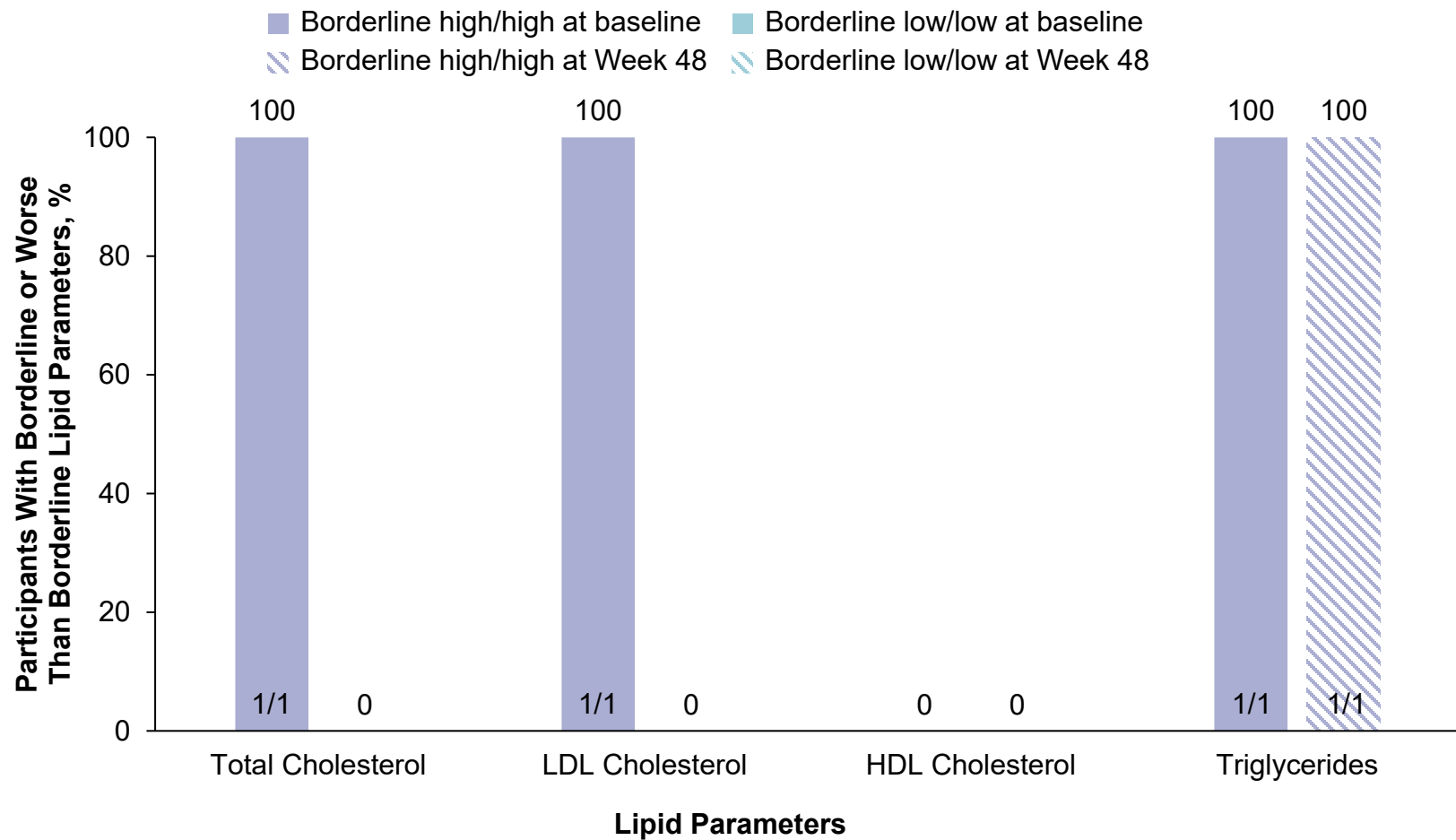


- ◆ Proportion of participants who were overweight or obese at baseline who had borderline high or high levels of total cholesterol, LDL cholesterol and triglycerides decreased from baseline to Week 48
 - Proportion with borderline low or low HDL cholesterol increased from baseline to Week 48

Categories were based on integrated guidelines for cardiovascular health and risk reduction in children and adolescents.¹ Fasting total cholesterol (mg/dL): borderline high, ≥ 170 to ≤ 199; high, ≥ 200. Fasting LDL cholesterol (mg/dL): borderline high, ≥ 110 to ≤ 129; high, ≥ 130. Fasting HDL cholesterol (mg/dL): borderline low, ≥ 40 to ≤ 45; low, < 40. Fasting triglycerides (mg/dL) for age (0–9 years) at collection: borderline high, ≥ 75 to ≤ 99; high, ≥ 100. Fasting triglycerides (mg/dL) for age (10–19 years) at collection: borderline high, ≥ 90 to ≤ 129; high, ≥ 130. HDL, high-density lipoprotein; LDL, low-density lipoprotein

1. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction In Children and Adolescents. Pediatrics 2011;128(Suppl. 5):S213-S256

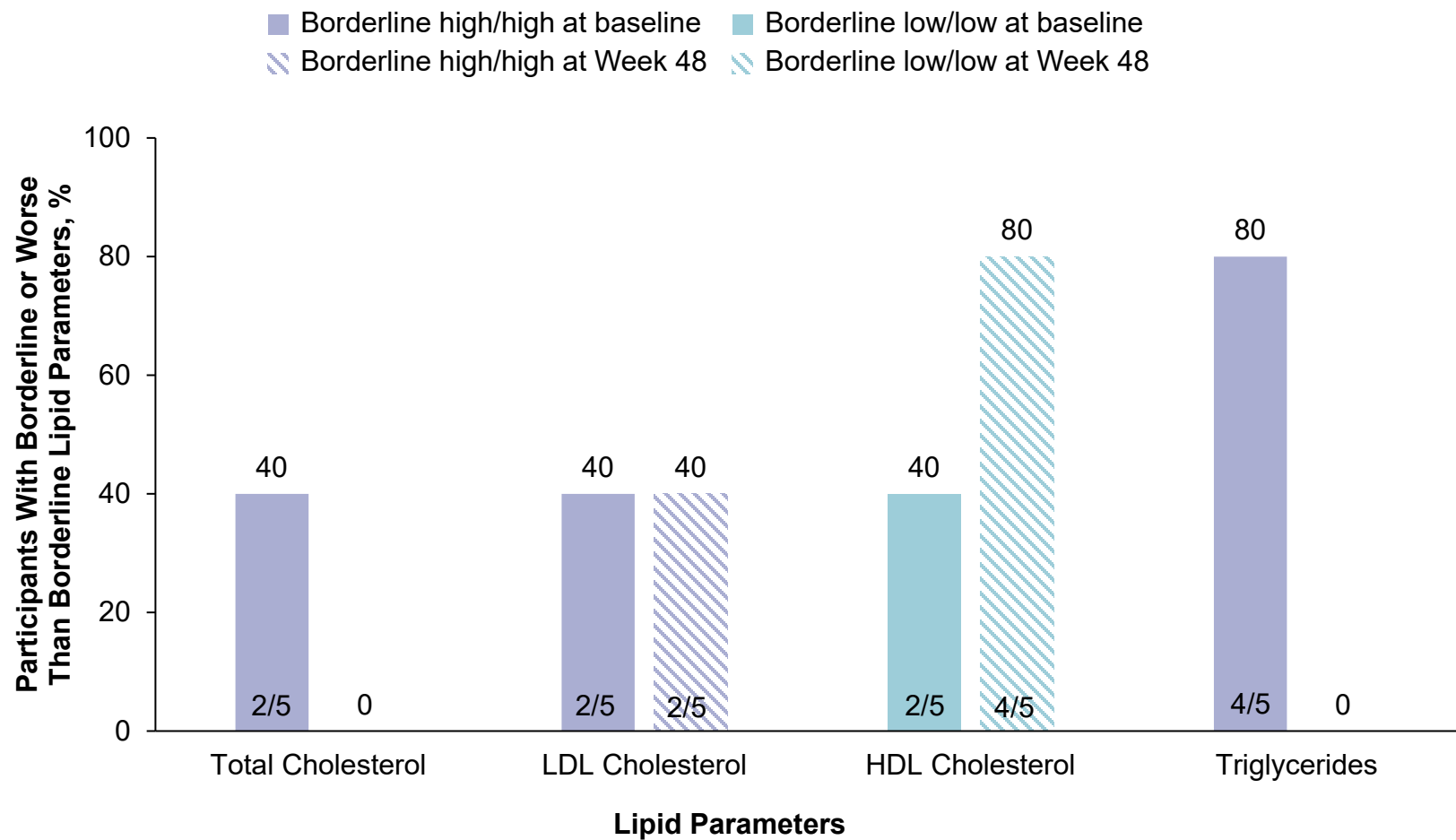
Lipid Parameters at Baseline and Week 48 in Individuals Who Were Categorized as Overweight or Obese at Baseline: E/C/F/TAF (N = 1)



Categories were based on integrated guidelines for cardiovascular health and risk reduction in children and adolescents.¹ Fasting total cholesterol (mg/dL): borderline high, ≥ 170 to ≤ 199 ; high, ≥ 200 . Fasting LDL cholesterol (mg/dL): borderline high, ≥ 110 to ≤ 129 ; high, ≥ 130 . Fasting HDL cholesterol (mg/dL): borderline low, ≥ 40 to ≤ 45 ; low, < 40 . Fasting triglycerides (mg/dL) for age (0–9 years) at collection: borderline high, ≥ 75 to ≤ 99 ; high, ≥ 100 . Fasting triglycerides (mg/dL) for age (10–19 years) at collection: borderline high, ≥ 90 to ≤ 129 ; high, ≥ 130 . E/C/F/TAF, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide; HDL, high-density lipoprotein; LDL, low-density lipoprotein

1. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction In Children and Adolescents. Pediatrics 2011;128(Suppl. 5):S213-S256

Lipid Parameters at Baseline and Week 48 in Individuals Who Were Categorized as Overweight or Obese at Baseline: B/F/TAF (N = 5)



Categories were based on integrated guidelines for cardiovascular health and risk reduction in children and adolescents.¹ Fasting total cholesterol (mg/dL): borderline high, ≥ 170 to ≤ 199 ; high, ≥ 200 . Fasting LDL cholesterol (mg/dL): borderline high, ≥ 110 to ≤ 129 ; high, ≥ 130 . Fasting HDL cholesterol (mg/dL): borderline low, ≥ 40 to ≤ 45 ; low, < 40 . Fasting triglycerides (mg/dL) for age (0–9 years) at collection: borderline high, ≥ 75 to ≤ 99 ; high, ≥ 100 . Fasting triglycerides (mg/dL) for age (10–19 years) at collection: borderline high, ≥ 90 to ≤ 129 ; high, ≥ 130 . B/F/TAF, bicitgravir/emtricitabine/tenofovir alafenamide; HDL, high-density lipoprotein; LDL, low-density lipoprotein

1. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction In Children and Adolescents. Pediatrics 2011;128(Suppl. 5):S213-S256

Lipid Parameter Values at Baseline and Week 48

Parameter	E/C/F/TAF N = 27	B/F/TAF N = 22	Total N = 49
Total cholesterol, mg/dL, median (Q1, Q3)			
Baseline	166 (155, 179)	178 (153, 191)	167 (155, 183)
Week 48	167 (142, 192)	150 (126, 167)	163 (138, 175)
Change from baseline at Week 48	-2 (-15, 21)	-25 (-46, -7)	-11 (-30, 7)
LDL cholesterol, mg/dL, median (Q1, Q3)			
Baseline	102 (92, 125)	113 (94, 131)	107 (93, 128)
Week 48	97 (86, 115)	92 (78, 103)	96 (80, 113)
Change from baseline at Week 48	-9 (-21, 2)	-21 (-43, -3)	-14 (-28, 1)
HDL cholesterol, mg/dL, median (Q1, Q3)			
Baseline	55 (48, 64)	50 (46, 73)	54 (47, 67)
Week 48	57 (46, 69)	46 (43, 61)	51 (43, 65)
Change from baseline at Week 48	1 (-8, 10)	-8 (-11, 1)	-4 (-9, 4)
Triglycerides, mg/dL, median (Q1, Q3)			
Baseline	91 (64, 116)	81 (61, 116)	86 (62, 116)
Week 48	80 (64, 97)	57 (50, 72)	69 (56, 97)
Change from baseline at Week 48	-7 (-41, 34)	-16 (-47, -1)	-11 (-45, 16)

Only laboratory measurements under fasting status were summarized. B/F/TAF, bicitgravir/emtricitabine/tenofovir alafenamide; E/C/F/TAF, elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide; HDL, high-density lipoprotein; LDL, low-density lipoprotein; Q, quartile