

LIFE, MADE LIGHTER WITH WEGOVY^{®1-6a}

^aWegovy[®] is indicated for weight management in adults and adolescents, for reduction in risk of CV events in adults with a BMI of ≥ 27 kg/m² and established CVD without diabetes, and for the treatment of non-cirrhotic MASH in adults with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) (Provisional approval).^{1*}

STEP UP Trial^{1,7}

A Phase 3b, randomised, double-blind, placebo-controlled and active-controlled trial of Wegovy[®] 7.2 mg vs 2.4 mg and placebo in adults with a BMI ≥ 30 kg/m² and without diabetes.⁷



21%

MEAN WEIGHT LOSS

over 72 weeks with
Wegovy[®] 7.2 mg vs 2.4 mg
with placebo^{1,7b}

^bSTEP UP: Co-primary endpoint: Mean weight loss of 20.7% with Wegovy[®] 7.2 mg vs 2.4 mg with placebo (trial product estimand, $p < 0.0001$ vs placebo; 18.7% vs 3.9% with placebo for treatment policy estimand, $p < 0.0001$ vs placebo) when taken over 72 weeks as an adjunct to a reduced-energy diet and increased physical activity.^{1,7i}



~1 in 3

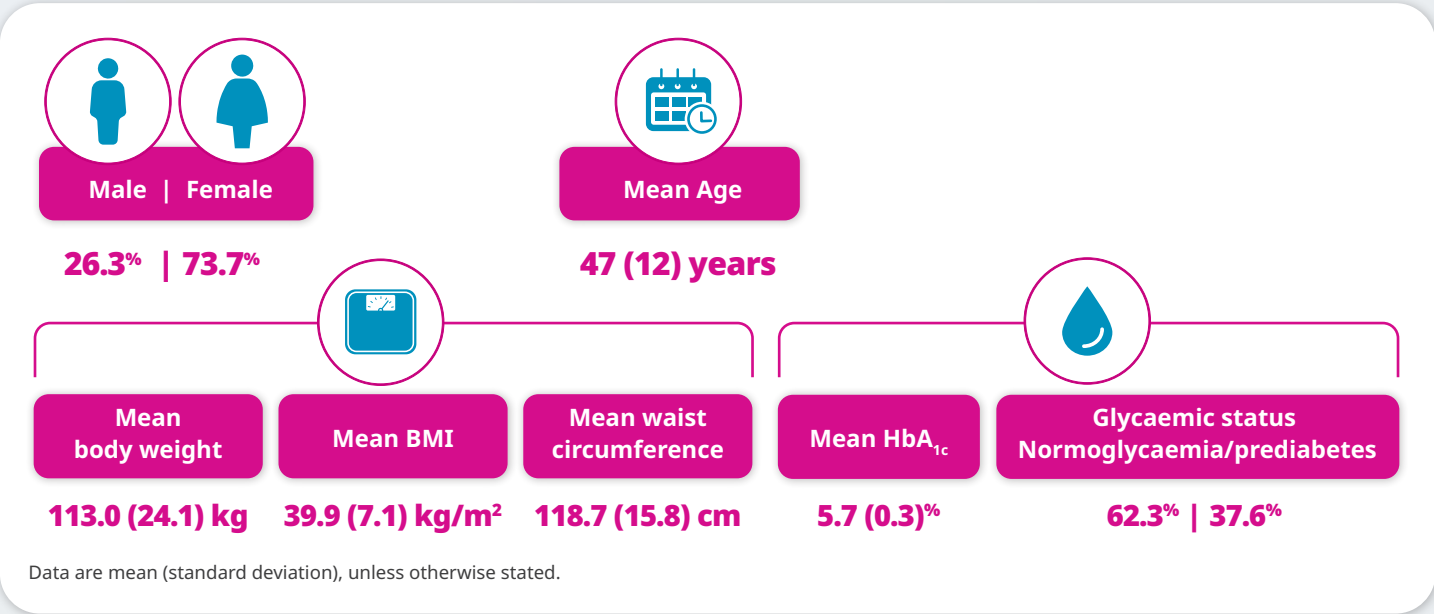
**PATIENTS ACHIEVED
 $\geq 25\%$ WEIGHT LOSS**

over 72 weeks with
Wegovy[®] 7.2 mg vs 0%
with placebo^{1,7c}

^cSTEP UP: Confirmatory secondary endpoint: 33.2% of patients achieved $\geq 25\%$ weight loss with Wegovy[®] 7.2 mg vs 0% with placebo (trial product estimand, $p < 0.0001$ vs placebo; 31.2% vs 0% with placebo for treatment policy estimand, $p < 0.0001$ vs placebo). Mean baseline body weight was 112.4 kg for Wegovy[®] 7.2 mg and 112.4 kg with placebo.^{1,7}

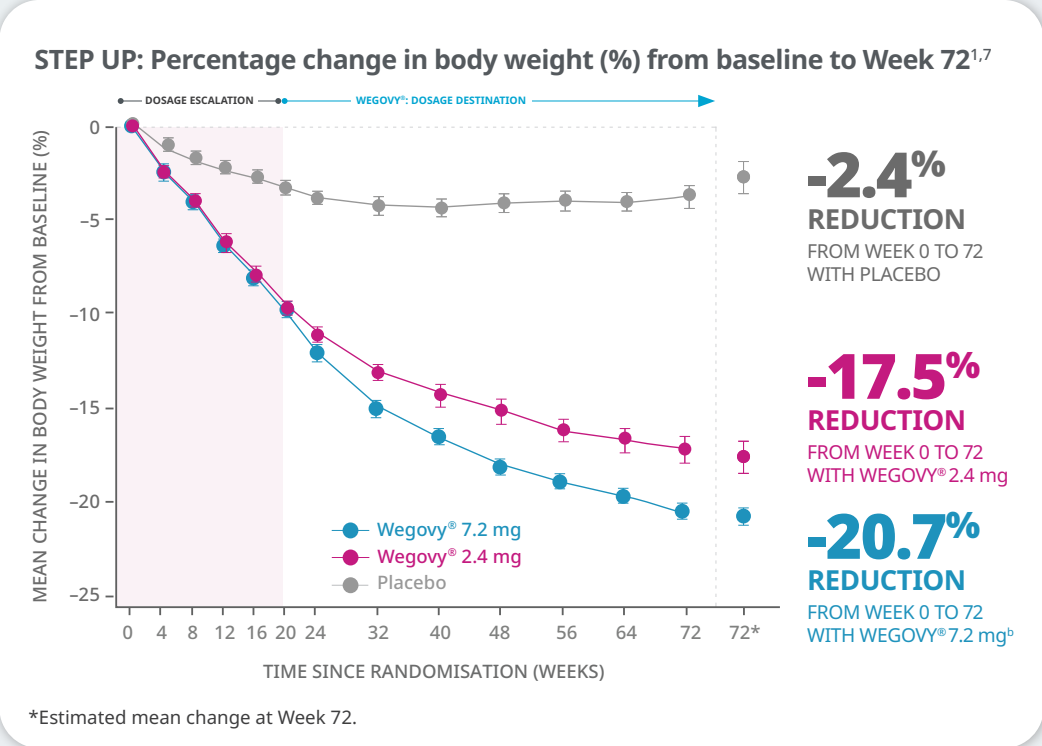
*Weight management: As an adjunct to diet and exercise for adults with initial BMI of ≥ 30 kg/m² (obesity) or ≥ 27 to 30 kg/m² (overweight) + ≥ 1 weight-related comorbidity; As an adjunct to diet and exercise for adolescents with initial obesity (BMI ≥ 95 th percentile as defined on sex and age-specific BMI growth chart(s) and body weight > 60 kg). Treatment should be discontinued if adolescent patients have not reduced their BMI by at least 5% after 12 weeks on the 2.4 mg or maximum tolerated dose. CV risk reduction: As an adjunct to standard of care for adults. MASH: This indication was approved via the **provisional approval** pathway based on resolution of steatohepatitis and improvement in liver fibrosis. Continued approval of this indication depends on verification and description of clinical benefit in confirmatory trials.¹

Baseline characteristics were balanced across **STEP UP** treatment groups⁷



21% mean weight loss over 72 weeks with Wegovy® 7.2 mg^{1,7b}

^bSTEP UP: Co-primary endpoint: Mean weight loss of 20.7% with Wegovy® 7.2 mg vs 2.4% with placebo (trial product estimand, p<0.0001 vs placebo; 18.7% vs 3.9% with placebo for treatment policy estimand, p<0.0001 vs placebo) when taken over 72 weeks as an adjunct to a reduced-energy diet and increased physical activity.^{1,7†}



^cSTEP UP: Confirmatory secondary endpoint: 33.2% of patients achieved ≥25% weight loss with Wegovy® 7.2 mg vs 0% with placebo (trial product estimand, p<0.0001 vs placebo; 31.2% vs 0% with placebo for treatment policy estimand, p<0.0001 vs placebo). Mean baseline body weight was 112.4 kg for Wegovy® 7.2 mg and 112.4 kg with placebo.^{1,7}

^dSTEP UP: Supportive secondary endpoint: Absolute mean (SE) weight loss of 22.9 (0.4) kg for Wegovy® 7.2 mg vs 2.8 (0.9) kg with placebo (trial product estimand, p<0.0001 vs placebo; 20.9 (0.4) kg vs 4.6 (0.7) kg with placebo for treatment policy estimand, p<0.0001 vs placebo). Mean baseline body weight was 112.4 kg for Wegovy® 7.2 mg and 112.4 kg with placebo.^{1,7}

Data are for the full analysis set, and observed data are from the on-treatment observation period. Treatment comparisons were estimated using the trial product estimand. Error bars are SE of the mean.

STEP UP: A trial of the new Wegovy[®] 7.2 mg dose^{1,7}

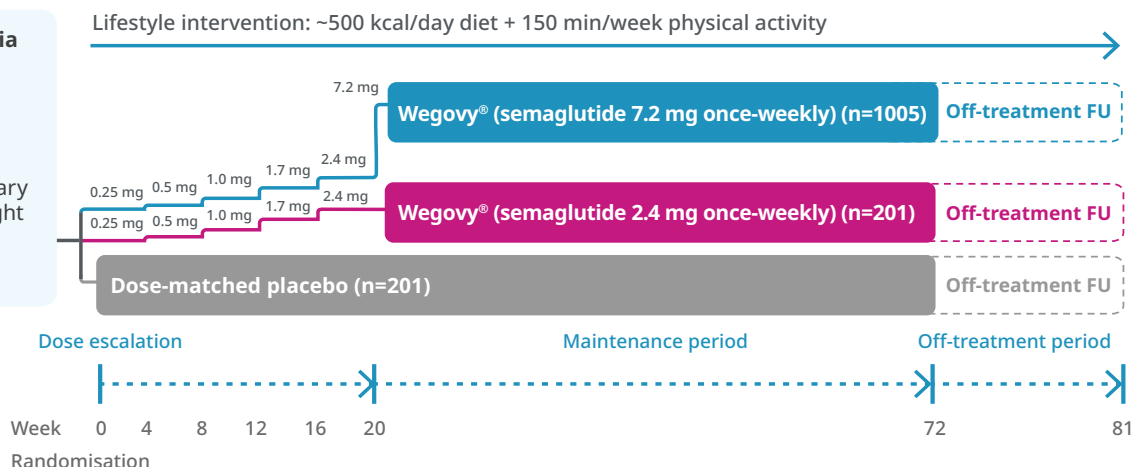
Randomised, double-blind, multinational, placebo- and active-controlled trial

Key inclusion criteria

- Adults (≥18 years)
- BMI ≥30 kg/m²
- ≥1 self-reported unsuccessful dietary effort to lose weight
- Without T2D (HbA_{1c} <6.5%)

N=1407

5:1:1 randomisation



Trial endpoints⁷

Co-primary

At week 72, the change in body weight (%) and proportion of participants **achieving a body weight reduction of ≥5% for Wegovy[®] 7.2 mg** vs placebo

Secondary

For Wegovy[®] 7.2 mg vs placebo at week 72:

- The proportion of participants **achieving categorical weight loss of ≥10%, ≥15%, ≥20%, and ≥25%**
- Change in **waist circumference (cm)**

For Wegovy[®] 7.2 mg vs Wegovy[®] 2.4 mg at week 72:

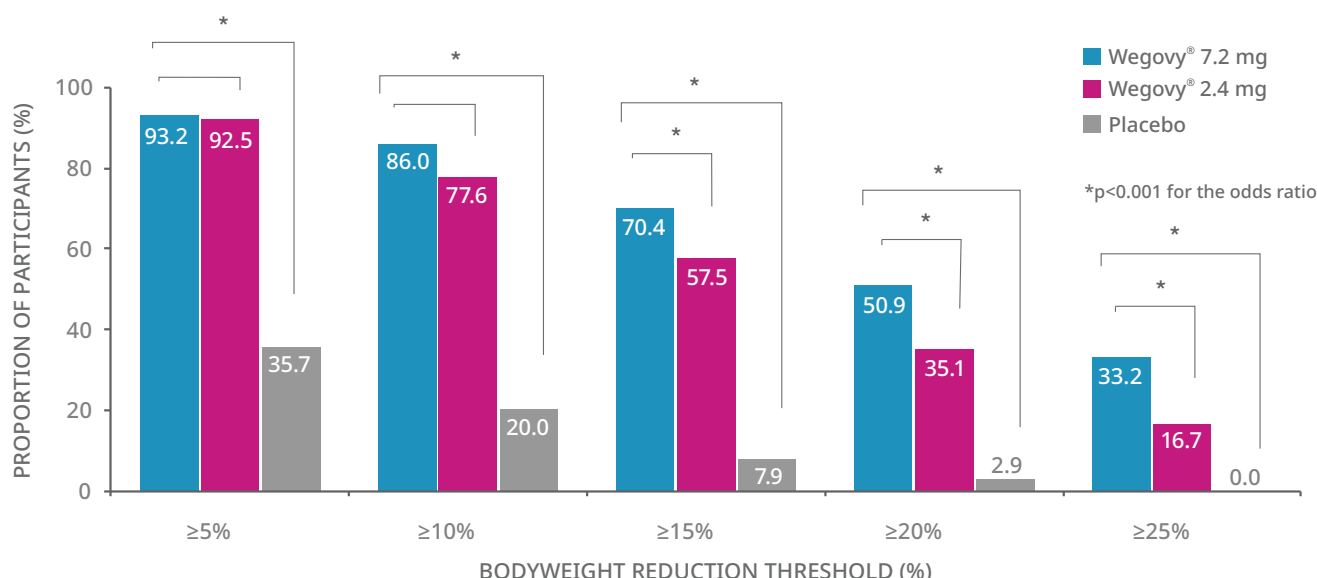
- Change in **body weight (%)**
- The proportion of participants **achieving categorical weight loss of ≥20% and ≥25%**

Safety

Adverse events assessed by monitoring participants receiving the trial product

Greater weight loss with Wegovy® 7.2 mg across all weight loss categories^{7e}

^eThe proportion of participants achieving bodyweight reduction thresholds at Week 72^{7f}



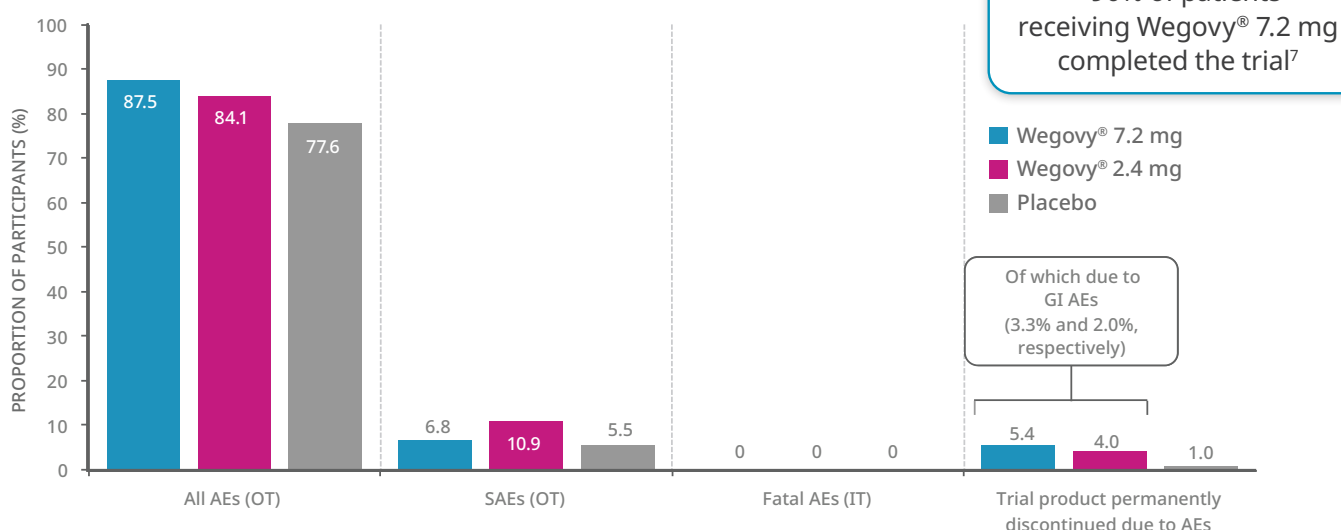
⁵STEP UP: Treatment comparisons were estimated using the trial product estimand. For the treatment policy estimand: Wegovy® 7.2 mg vs placebo: ≥5% weight loss, 90.7% vs 36.8% (p<0.0001); ≥10% weight loss, 82.4% vs 20.5% (p<0.0001); ≥15% weight loss, 66.5% vs 7.6% (p<0.0001); ≥20% weight loss, 47.7% vs 2.9% (p<0.0001); ≥25% weight loss, 31.2% vs 0% (p<0.0001). Wegovy® 7.2 mg vs Wegovy® 2.4 mg: ≥5% weight loss, 90.7% vs 89.9% (p=0.47); ≥10% weight loss, 82.4% vs 75.1% (p=0.02); ≥15% weight loss, 66.5% vs 54.5% (p=0.002); ≥20% weight loss, 47.7% vs 33.3% (p=0.0006); ≥25% weight loss, 31.2% vs 15.3% (p<0.0001).^{1,7}

Data are for the full analysis set, and observed data are from the on-treatment observation period. Comparisons of Wegovy® 7.2 mg versus Wegovy® 2.4 mg reported in this figure for the proportion of participants with body weight reductions of 5% or greater, 10% or greater, and 15% or greater were conducted in a *post-hoc* manner. *Post-hoc* analyses were not controlled for multiplicity, and findings for these endpoints should not be used to infer definitive treatment effects.

Wegovy®: Consistent safety profile across maintenance doses^{7g}

⁹STEP UP: The overall safety profile of Wegovy® 7.2 mg was consistent with the GLP-1 RA class, with most adverse events mild to moderate in severity and resolved without permanent discontinuation of treatment. Gastrointestinal adverse events were more frequent with Wegovy® 7.2 mg (71%) vs 2.4 mg (61%), including nausea (44% vs 38%), diarrhoea (27% vs 28%), vomiting (25% vs 16%), and constipation (23% vs 19%). Dysaesthesia was more frequent with Wegovy® 7.2 mg (23%) vs 2.4 mg (6%). Data are for the safety analysis set and are from the on-treatment observation period.^{7h}

STEP UP: Adverse event rates⁷



The safety profile of Wegovy® 7.2 mg was consistent with the GLP-1 RA class and previous trials of Wegovy®, supporting a favourable benefit-risk profile^{3,4,7}

Data are on-treatment (OT) or in-trial (IT) observation period.

STEP UP: Adverse events of special interest⁷

AEs, n (%)	Wegovy® 7.2 mg (n=1004)	Wegovy® 2.4 mg (n=201)	Placebo (n=201)
Gastrointestinal AEs (OT)	711 (70.8)	123 (61.2)	86 (42.8)
Dysaesthesia (OT)	230 (22.9)	12 (6.0)	1 (0.5)
Cardiovascular disorders (OT)	75 (7.5)	22 (10.9)	17 (8.5)
Psychiatric disorder AEs (OT)	69 (6.9)	16 (8.0)	15 (7.5)
Neoplasms (IT)	56 (5.6)	11 (5.5)	10 (5.0)
Allergic reactions (OT)	49 (4.9)	12 (6.0)	7 (3.5)
Gallbladder-related disorders (OT)	29 (2.9)	6 (3.0)	1 (0.5)
Hepatic disorders (OT)	26 (2.6)	6 (3.0)	2 (1.0)
Injection-site reactions (OT)	25 (2.5)	2 (1.0)	3 (1.5)
Medication error, abuse, or misuse, overdose (OT)	25 (2.5)	8 (4.0)	7 (3.5)
Malignant neoplasms (IT)	10 (1.0)	2 (1.0)	2 (1.0)
Rare events (OT)	10 (1.0)	0	1 (0.5)
Kidney disorders (OT)	5 (0.5)	1 (0.5)	1 (0.5)
Acute pancreatitis (OT)	3 (0.3)	0	0
Hypoglycaemia (OT)	3 (0.3)	2 (1.0)	0
Intestinal obstruction (OT)	1 (<0.1)	0	0

Dysaesthesia events were mild for most participants who experienced them (77% (177/230) in the 7.2 mg group, 75% (9/12) in the 2.4 mg group and 100% (1/1) in the placebo group; most events occurred during dose escalation and were resolved without permanent discontinuation⁷

Data are on-treatment (OT) or in-trial (IT) observation period.

Summary

- ✓ In STEP UP, Wegovy® 7.2 mg provided a mean weight loss of 21% vs 2.4% in patients receiving placebo over 72 weeks^{1,7b}
- ✓ ~1 in 3 patients achieved ≥25% weight loss with Wegovy® 7.2 mg^{1,7c}
- ✓ ~90% of patients randomised to Wegovy® 7.2 mg completed the STEP UP trial⁷

^bSTEP UP: Co-primary endpoint: Mean weight loss of 20.7% with Wegovy® 7.2 mg vs 2.4% with placebo (trial product estimand, p<0.0001 vs placebo; 18.7% vs 3.9% with placebo for treatment policy estimand, p<0.0001 vs placebo) when taken over 72 weeks as an adjunct to a reduced-energy diet and increased physical activity.^{1,7i}

^cSTEP UP: Confirmatory secondary endpoint: 33.2% of patients achieved ≥25% weight loss with Wegovy® 7.2 mg vs 0% with placebo (trial product estimand, p<0.0001 vs placebo; 31.2% vs 0% with placebo for treatment policy estimand, p<0.0001 vs placebo). Mean baseline body weight was 112.4 kg for Wegovy® 7.2 mg and 112.4 kg with placebo.^{1,7}

ONCE-WEEKLY
wegovy[®]
semaglutide injection

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

PBS Information: This product is not listed on the PBS.

Please review full Product Information before prescribing, available at
<https://rss.medsinfo.com.au/no/pi.cfm?product=nopwegov>



Scan the QR code to see
full **Wegovy**[®] (semaglutide)
Product Information

[†]Data from the STEP UP trial are based on the trial product estimand, which describes the treatment effect if all people adhered to treatment, whereas the primary treatment policy estimand describes the treatment effect regardless of treatment adherence.⁷

[#]Dysaesthesia included AEs reported as allodynia, burning sensation, dysaesthesia, hyperaesthesia, hyperpathia, pain of skin, paraesthesia, sensitive skin, skin burning sensation, skin discomfort and skin sensitisation; Dysaesthesia events were reported as mild in 77% (177/230) patients in the 7.2 mg group, 75% (9/12) in the 2.4 mg group and 100% (1/1) in the placebo group. Data are for the safety analysis set (the full randomised population who were exposed to at least one dose of the trial product) and are from the on-treatment observation period. Participants could experience more than one AE.⁷

AE: adverse event; **BMI:** body mass index; **CI:** confidence interval; **CV:** cardiovascular; **CVD:** cardiovascular disease; **ETD:** estimated treatment difference; **HbA_{1c}:** haemoglobin A1c; **IT:** in-trial; **GI:** gastrointestinal; **GLP-1 RA:** glucagon-like peptide-1 receptor agonist; **MASH:** metabolic dysfunction-associated steatohepatitis; **OR:** odds ratio; **OT:** on-treatment; **PBS:** Pharmaceutical Benefits Scheme; **SE:** standard error; **T2D:** type 2 diabetes.

References: **1.** Wegovy[®] (semaglutide 2.4 mg) Approved Product Information. Available at: <https://rss.medsinfo.com.au/no/pi.cfm?product=nopwegov>. **2.** Sanyal AJ, et al. *N Engl J Med.* 2025; 392(21):2089-2099 (Including supplementary materials). **3.** Wilding JPH, et al. *N Engl J Med.* 2021;384:989-1002 (Including supplementary appendix). **4.** Lincoff AM, et al. *N Engl J Med.* 2023;389:2221-32. **5.** Deanfield J, et al. *Obes Facts* 2024;17 Suppl 1:491-492. **6.** Newsome P et al. Weight-dependent and -independent effects of semaglutide in participants with MASH: secondary analysis of the phase 3 ESSENCE trial. AASLD abstract 0010. Presented at: The Liver Meeting; November 7-11, 2025; Washington, DC. **7.** Wharton S, et al. *Lancet Diabetes Endocrinol* 2025;13(11):949-63 (including supplement).