Record of the Obesity Treatments Advisory Group Meeting held on 11 December 2025

Obesity Treatments Advisory Group records are published in accordance with the General Terms of Reference Expert Advisory Groups 2024 and the related Terms of Reference for the Specialist Advisory Committees 2021.

Note that this document is not necessarily a complete record of the Obesity Treatments Advisory Group meeting; only the relevant portions of the meeting record relating to Obesity Treatments Advisory Group discussions about an application or Pharmac staff proposal that contain a recommendation are generally published.

The Obesity Treatments Advisory Group may:

(a) recommend that a pharmaceutical be listed by Pharmac on the Pharmaceutical Schedule and the priority it gives to such a listing;

(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or

(c) recommend that Pharmac decline to list a pharmaceutical on the Pharmaceutical Schedule.

Pharmac Advisory Committees and Groups make recommendations, including priority, within their therapeutic groups of interest.

The record of this Advisory Group meeting will be reviewed by PTAC at an upcoming meeting.

Specialist Advisory Committees, Advisory Groups and PTAC may differ in the advice they provide to Pharmac, including recommendations' priority, due to the committees' different, if complementary, roles, expertise, experience, and perspectives.

Pharmac is not bound to follow the recommendations made below. Applications are prioritised by Pharmac against other funding options and progressed accordingly. The relative priority of any one funding choice is dependent on a number of factors, including (but not limited to) the recommendation of PTAC and/or Specialist Advisory Committees and/or Advisory Groups, the mix of other applications being assessed, the amount of funding available, the success of commercial negotiations and/or the availability of clinical data.

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1. Attendance

Present
Liza Lack – Chair
Bruce King
Christine Pihema
James Shand
Joanna McClintock
Rawiri McKree Jansen
Ryan Paul
Sam Whittaker
Wing Cheuk Chan

Apologies
Rinki Murphy

2. Summary of recommendations

	Pharmaceutical and Indication	Recommendation
7.3.	Semaglutide (Wegovy) for chronic weight management for people with a high Body Mass Index (BMI) and comorbidities, subject to Special Authority criteria	High Priority

3. The role of Advisory Groups and Specialist Advisory Committees and records of meetings

3.1. This meeting record of the Obesity Treatments Advisory Group is published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) 2021, Specialist Advisory Committees 2021 and General Terms of Reference Expert Advisory Groups 2024. Terms of Reference describe, *inter alia*, the establishment, activities, considerations, advice, and the publication of such advice of Specialist Advisory Committees, Advisory Groups and PTAC.

3.2. Conflicts of Interest are described and managed in accordance with section 6.4 of the SAC Terms of Reference and the General Terms of Reference Expert Advisory Groups 2024.

3.3. The Obesity Treatments Advisory Group is an Advisory Group of Pharmac. The Obesity Treatments Advisory Group, PTAC and Specialist Advisory Committees have complementary roles, expertise, experience, and perspectives. The Obesity Treatments Advisory Group may therefore, at times, make recommendations for treatments for Obesity that differ from PTAC's or Specialist Advisory Committees including the priority assigned to recommendations, when considering the same evidence. Likewise, PTAC may, at times, make recommendations for treatments for Obesity that differ from the Obesity Treatments Advisory Group 's, or Specialist Advisory Committees may make recommendations that differ from other Specialist Advisory Committees'.

Pharmac considers the recommendations provided by the Obesity Treatments Advisory Group, PTAC, and any other relevant Specialist Advisory Committees when assessing applications for treatments for Obesity.

4. Welcome and introduction

4.1. The Chair welcomed the Group with a karakia followed by whakawhanaungatanga.

4.1.1. The Chair and PTAC member provided a brief overview of the meeting format for members who are new to Pharmac Expert Advisory network, acknowledging the establishment of the Obesity Treatments Advisory Group.

5. Pharmac Update

5.1. The Group noted the Pharmac Update.

5.2. The Group acknowledged the recent changes in Pharmac kaimahi and recent leadership and strategic changes, including the new Chief Executive who started at Pharmac in mid-September and the recent release of the 2025/2026 Letter of Expectations.

5.3. The Group noted an update about the organisation reset programme and that more information can be found on the Pharmac Website.

5.4. The Group noted a general induction overview from Pharmac about expert advice and the role of the members.

6. Matters Arising - Review of Special Authority criteria for SGLT2i / GLP-1 RA for the treatment of type 2 diabetes mellitus with cardio-renal risk

Discussion

6.1. The Group noted that Pharmac is exploring options to review the Special Authority criteria for SGLT2 inhibitors (SGLT2i) and GLP-1 receptor agonists (GLP-1 RA) for the treatment of type 2 diabetes mellitus (T2DM). This follows consideration by the Pharmac Board in June 2025 regarding the use of access criteria and opportunities to widen access. Pharmac had requested consideration of how the clinical measures within the Special Authority criteria could be amended to define widened access, and ensure that the population currently accessing funded treatment through special measures (i.e. ethnicity-based criteria) could continue to be captured.

6.2. The Group noted that a proposal to reduce the 5-year cardiovascular disease (CVD) risk score from ≥15% to ≥10% had been developed by Pharmac staff, following previous clinical advice from the Diabetes Advisory Committee in June 2025. Members noted Pharmac's intent to seek additional advice from this group, acknowledging it is not about obesity treatment, due to the timing of this meeting and relevant expertise of members. The Group further noted that the intent of this proposed amendment was to ensure continued access for people most likely to benefit from treatment who may no longer meet eligibility through other criteria should the ethnicity-based criteria be removed.

6.3. The Group considered that a proposed reduction in the CVD risk threshold criterion from ≥15% to ≥10% over 5 years would capture a substantial number of people who would benefit most from treatment.

6.4. The Group considered a systematic review and network meta-analysis (NMA) of randomised controlled trials conducted by Palmer et al. BMJ. 2021;372:m4573, which assessed the benefits and harms of SGLT2i and GLP-1 RA in adults with T2DM at varying cardiovascular and renal risk levels.

6.4.1. The Group considered the review and NMA to be a robust, high-quality study, with patient-relevant outcomes derived from a large, combined patient population.

6.4.2. The Group noted that the estimated absolute treatment effects across five baseline risk categories using the best available evidence and extrapolated 5-year CVD risk from short-term data. The analysis assumed consistent relative benefits of SGLT2i and GLP-1 RAs across T2DM CV risk groups, in the absence of other risks, although the evidence that informed the estimates for low-CV risk populations is limited.

6.4.3. The Group noted that the results reflect the addition of SGLT-2i and GLP-1 RAs medicines to existing diabetes treatment.

6.4.4. The Group noted that the risk categories do not directly align with those applied in the New Zealand context, but that the "low-risk with more than three risk factors" category in the analysis likely best reflects the baseline risk of a population with a ≥10% 5-year CVD risk. Based on this assumption, the Group considered that individuals with a 10-14% 5-year CVD risk would be expected to derive significant health benefit from access to these medicines.

6.4.5. Group considered that the “very low risk” category reported in the Palmer et al study is likely to reflect a population with a 5-year CVD risk of less than 10%. The Group noted the trials informing Palmer et al.’s “very low risk” analysis generally did not exclusively enrol patients with very low cardiovascular risk, making the certainty of evidence for this category less robust.

6.4.6. The Group noted that more recent studies and meta-analyses demonstrate that SGLT2 inhibitors and GLP-1 receptor agonists provide lower, yet still clinically meaningful, cardio-renal benefits in populations with lower baseline cardiovascular risk than those currently under consideration.

6.4.7. The Group noted the Palmer et al, BMJ,2021;372:m4573 findings on the relative benefits of SGLT2i and GLP-1 RAs:

6.4.7.1. Both lowered all-cause mortality, cardiovascular mortality, non-fatal myocardial infarction, and kidney failure for selected groups who met the specific clinical indications.

6.4.7.2. Greater reduction in heart failure hospitalisations with SGLT2i than with GLP-1 RAs.

6.4.7.3. Greater reduction in non-fatal stroke with GLP-1 RAs. The Group noted no clear clinical explanation for the absence of a statistically significant benefit of this SGLT2i on non-fatal stroke in the study and considered that this may be attributable to factors other than treatment effect, such as baseline characteristics of the trial populations.

6.4.7.4. Other effects included improvements in weight and quality of life. Reported harms also differed, with SGLT2i resulting in increased genital infections, while GLP-1 RAs may increase severe gastrointestinal events.

6.5. The Group noted that SGLT2i and GLP-1 RAs likely exhibit a similar overall impact in the treatment of cardio-renal disease in people with T2DM, while acknowledging that there are slight differences in effect size for some outcomes between the agents in these two classes.

6.6. The Group considered that baseline characteristics from the EMPA REG trial (Zinman, et al. N Engl J Med. 2015;373:2117-28) used in previous modelling are not representative of the proposed population with a ≥10% 5-year CVD risk. The Group considered that baseline characteristics from the DECLARE-TIMI 58 (Wiviott et al. N Engl J Med. 2019;380:347-57) trial or the CANVAS trials (Neal et al. N Engl J Med. 2017;377:644-57) would be more appropriate to use in modelling.

6.7. The Group considered that the assumption most patients not using insulin at baseline would require insulin after three months, regardless of SGLT2i or GLP-1 RA treatment, is not supported in clinical practice. Members considered these medicines have a demonstrable impact on multiple treatment outcomes beyond glycaemic control, making patients less likely to initiate insulin as SGLT2i or GLP-1 RAs generally provides, or is perceived to provide, sufficient T2DM management. Additionally, the Group considered that many patients, particularly younger patients aged under 55 years, would be reluctant to start insulin even if clinically indicated, and the small subset who do initiate insulin while on SGLT2i or GLP-1 RA are unlikely to do so within 12 months of starting therapy.

6.8. The Group noted that most people with T2DM, whether their HbA1c levels exceed or meet the HbA1c threshold, are likely to benefit from funded access to SGLT2i or GLP1-a, given their broad impact on multiple treatment outcomes.

6.9. The Group considered that people with higher HbA1c levels (e.g. ≥75 mmol/mol) would be expected to see a greater absolute reductions in HbA1c than those with lower baseline levels.

6.10. The Group considered that a 5-year CVD threshold of ≥10% to reflect 'high risk' is relatively high compared to other jurisdictions, where some use a 10-year risk ≥10% (equivalent to approximately 4% over 5-years) (For example, the threshold to actively recommend the use of statin for primary prevention of CVD in UK by NICE is at 10-year CVD risk ≥10%). The Group considered that lowering the proposed Special Authority threshold even further (e.g. to a 10-year CVD risk of ≥10%) may be appropriate to align with international standards and include more individuals who would otherwise lose access to SGLT2i or GLP-1 RA with the removal of ethnicity-based criteria. The Group also noted that CVD risk is not routinely used in other countries to determine access to these medicines, making international comparisons regarding funded access based on CVD risk difficult.

6.11. The Group considered the standard CVD risk assessment tool (PREDICT) used in New Zealand would generally not calculate a 5-year risk score greater than 10% for those with T2DM unless additional cardiovascular risk factors had already been identified. In addition, the Group noted that the PREDICT CVD risk calculation does not include renal outcomes which may result in an underestimation of future cardio-renal risk.

6.12. The Group considered that if the Special Authority criteria providing access based on Māori and Pacific ethnicity were removed, many (but not all) individuals from these populations would still qualify under other measures, such as the lower proposed CVD risk threshold (≥10%) and the criterion for high lifetime risk due to being diagnosed with T2DM in childhood or as a young adult. The Group also noted that the interpretation of the term "young adult" can vary among prescribers, with several members referencing the UK Society for Endocrinology definition of up to 40 years of age as a standard threshold.

6.13. The Group noted that as the current Special Authority results in life-long funding eligibility those who are currently receiving funded SGLT-2 inhibitors will remain eligible for treatment, even if they initially qualified under ethnicity-based criteria only. Any changes to the Special Authority criteria would apply only to new patients.

6.14. The Group noted that many Māori and Pacific peoples develop T2DM at a significantly younger age than non-Māori and non-Pacific populations, contributing to earlier onset of diabetes-related complications. Specifically, the Group noted that Māori and Pacific peoples experience a disproportionately high burden of T2DM-related cardio-renal disease, with rates estimated to be six to seven times higher than those observed in other ethnic groups.

6.15. The Group considered that removing ethnicity-based Special Authority criteria may introduce additional barriers to access for Māori and Pacific peoples as it would require additional testing and health care visits.

6.16. The Group also noted that Special Authority criteria that do not require a full CVD risk assessment may not be in the best overall interests of a person with T2DM. The Group considered that any changes should align with a comprehensive diabetes care package, which includes appropriate risk assessments as an essential component of disease management.

6.17. The Group reiterated the significant benefits of SGLT-2 inhibitors and expressed a strong preference for open listing for all patients with T2DM, noting that most patients with T2DM are expected to benefit from this treatment. The Group considered that open listing would be the most effective approach to ensure the entire population impacted by the removal of ethnicity-based criteria is captured.

6.18. The Group noted that current Special Authority criteria for a GLP-1 RA specified that it was to be used after previous treatment with an SGLT2i. The Group considered that this would remain appropriate in the proposed group.

6.19. The Group noted the potential risk in in coupling Special Authority criteria for SGLT-2i and GLP-1 RAs as these treatments have different outcomes and costs, and therefore cost-effectiveness. The Group suggested that independent consideration of these drug classes may be appropriate if joint consideration could negatively impact decisions regarding broader access to SGLT-2i.

Summary for assessment

6.20. The Group considered that the below summarises its interpretation of the most appropriate PICO table (population, intervention, comparator, outcomes) information for the funding of SGLT2i / GLP-1 RA for the treatment of T2DM with cardio-renal risk. This PICO table captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO table is based on the Group's assessment at this time and may differ from that requested by the applicant. The PICO table may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

Population	People with T2DM 2 who have an absolute five-year CVD risk of 10-14% and who have not achieved target HbA1c (of less than 53 mmol/mol) despite regular use of at least one oral antidiabetic agent and/or insulin for at least 3 months	People with T2DM 2 who have an absolute five-year CVD risk of 10-14% and who have not achieved target HbA1c (of less than 53 mmol/mol) despite regular use of metformin, vildagliptin, and empagliflozin for at least 6 months
Intervention	SGLT2i (Empagliflozin selected as the agent to represent the class) Given in combination with standard of care	GLP-1 RA (Dulaglutide may be selected as the agent to represent the class) Given in combination with standard of care
Comparison	Standard of care diabetes treatment	Standard of care diabetes treatment
Outcome	• Decrease in all-cause mortality • Decrease heart failure hospitalisation • Decrease in non-fatal myocardial infarction • Improved renal outcomes (Delay in progression to renal failure) • Delayed progression to requiring insulin treatment	• Decrease in all-cause mortality • Decrease heart failure hospitalisation • Decrease in non-fatal myocardial infarction • Improved renal outcomes (Delay in progression to renal failure) • Delayed progression to requiring insulin treatment • Decrease in non-fatal stroke

7. Semaglutide for chronic weight management, Body Mass Index (BMI) ≥30 kg/m2, with at least one weight-related comorbidity

Application

7.1. The Group reviewed the application for semaglutide for chronic weight management, Body Mass Index (BMI) ≥30 kg/m^2, with at least one weight-related comorbidity.

7.2. The Group took into account, where applicable, Pharmac's relevant decision-making framework when considering this agenda item.

Recommendation

7.3. The Group **recommended** that semaglutide (Wegovy) for chronic weight management for people with a high Body Mass Index (BMI) and comorbidities, be listed with a **high priority**, within the context of obesity treatments, subject to the following Special Authority criteria:

> **Initial application – Obesity**
> Applications from any relevant practitioner. Approval valid for six months.
> 1. All of the following:
> 1.1. Patient is currently receiving multidisciplinary input; and
> 1.2. One of the following:
> 1.2.1. Patient has a BMI of ≥50 kg/m^2; or
> 1.2.2. Patient has a BMI of ≥35 kg/m^2 and any two of the following weight-related comorbidities:
>
> Note: Relevant comorbidities are defined as: dyslipidaemia, hypertension, diabetes, obstructive sleep apnoea, and established cardiovascular disease.
>
> **Renewal application - Obesity (indefinite thereafter)**
> 1. Patient has experienced at least 10% reduction in body weight compared to baseline.

7.4. In making this recommendation, the Group considered:

7.4.1. The high health need of individuals with obesity, particularly those with severe (e.g. Class III) obesity, who experience substantially increased morbidity and mortality risk and reduced quality of life.

7.4.2. The disproportionately higher prevalence and burden of obesity among Māori and Pacific peoples, contributing to significant and long-standing health inequalities.

7.4.3. The therapeutic benefits of semaglutide, including clinically significant and sustained weight reductions, and associated improvements in cardiovascular and metabolic risk factors, compared with standard of care weight-management interventions (including dietary, exercise and psychosocial interventions).

7.4.4. The renewal criteria requires further discussion and refinement at a future meeting.

Discussion

Populations with high health needs

7.5. The Group discussed the health need(s) of people with obesity among Māori, Pacific peoples, disabled peoples including tāngata whaikaha Māori, and other populations identified by the Government Policy Statement on Health 2024-2027 to have high health needs.

7.5.1. The Group noted the substantially higher prevalence of obesity among Māori (46.9%; adjusted RR 1.54 [95% CI 1.43–1.66) and Pacific peoples (69.5%) compared with other population groups (Ministry of Health. 2025, New Zealand Health Survey).

7.5.2. The Group further noted that Māori and Pacific peoples also experience higher rates of prior stroke and ischaemic heart disease alongside disproportionately higher prevalence of cardiovascular risk factors, poorer access to care, and worse cardiovascular-related morbidity and mortality.

7.5.3. The Group further noted that obesity and cardiovascular disease disproportionately affect socioeconomically disadvantaged populations with higher BMI ≥30 kg/m^2 prevalence in NZDep quintile 5 areas (46.8%) compared with quintile 1 (27.6%), reflecting broader determinants of health.

Background

7.6. The Group noted that Pharmac has received three applications for semaglutide from the supplier, including Ozempic for insufficiently controlled type 2 diabetes (reviewed by PTAC in November 2025, and received a high priority rating), Wegovy for people with established cardiovascular disease (clinical advice pending in 2026), and Wegovy for chronic weight management in adults with ≥30 kg/m^2.

7.7. The Group noted that two glucagon-like peptide-1 (GLP-1) agonists, dulaglutide and liraglutide, are currently funded for people with type 2 diabetes who have cardio-renal risk factors.

7.8. The Group noted in August 2025 PTAC reviewed an application for tirzepatide (Mounjaro), a dual glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 agonist for people with insufficiently controlled T2DM, as an adjunct to diet and exercise. The Group noted tirzepatide was recommended with a medium priority, and the key factors for consideration included superior efficacy compared with currently funded treatments, and a more convenient dosing regimen compared with the funded alternatives.

Health need

7.9. The Group noted that, according to the 2024–2025 New Zealand Health Survey (Ministry of Health. 2025, New Zealand Health Survey), an estimated 34.2% of New Zealanders aged ≥15 years had a BMI of ≥30 kg/m^2 (or IOTF equivalent for 15–17 years).

7.9.1. The Group noted one in three adults (34.2%) were classified as obese in 2024/25, an increase from 31.3% in 2019/20. The Group further noted approximately one in two adults (46.8%) living in the most deprived neighbourhoods were classified as obese, compared to about one in four adults (27.6%) living in the least deprived neighbourhoods.

7.10. The Group noted that obesity is independently associated with substantially increased cardiovascular risk. The Group noted evidence that obesity increases the risk of myocardial infarction (MI), stroke, heart failure, and cardiovascular (CVD) mortality (Khan, et al. JAMA Cardiol. 2018;3(4):280-87).

7.11. The Group noted the broad health, social, and economic impacts associated with obesity, including increased risk of cardiovascular disease, type 2 diabetes, obstructive sleep apnoea, impaired physical and joint function, and adverse effects on mental health, employment, and relationships.

7.11.1. The Group noted that obesity (BMI ≥30 kg/m^2) is also associated with substantial reductions in health-related quality of life (HRQoL), including limitations in daily functioning and mobility, and significant psychosocial

impacts such as stigma-related distress and poorer mental wellbeing. The Group noted that these effects intensify with higher BMI classes due to the increasing burden of comorbidities, leading to broad declines across physical, emotional, and social domains of quality of life.

7.12. The Group noted that Te Mana Ki Tua (TMTK) Specialist Weight Management Service, established in July 2023, is a Tier 3 intensive weight-management programme targeting adults ineligible for bariatric surgery and younger adults with type 2 diabetes and a BMI ≥35 kg/m². The Group further noted that approximately 500 patients have been enrolled since 2023, and that TMTK provides wrap-around, interdisciplinary care, including health coaches, dietitians, social workers, health psychologists, endocrinologists, and physiotherapists.

7.12.1. The Group considered that, while multidisciplinary support and structured behavioural interventions provided by TMTK more closely reflect the trial conditions under which semaglutide demonstrated clinical benefit, and may therefore optimise treatment outcomes, restricting access solely to Tier 3 care could disproportionately disadvantage regions and populations with limited service availability, including Māori and Pacific peoples who experience a higher burden of obesity.

Health benefit

7.13. The Group noted that semaglutide is a GLP-1 analogue with 94% sequence homology to human GLP-1, acting as a GLP-1 receptor agonist that binds to and activates the native GLP-1 receptor. The Group further noted that semaglutide regulates glucose and appetite through receptor activity in the pancreas and brain, influencing calorie intake, reward pathways and food choice.

7.14. The Group noted that the evidence presented was generally high quality, with large, well-designed randomised trials demonstrating consistent benefits across populations. However, the Group also noted limitations, including differences in enrolled populations relative to New Zealand (in terms of wrap-around, inter-disciplinary care access) and of long-term durability of weight loss.

7.15. The Group noted STEP-1 (Wilding, et al. N Engl J Med. 2021;384:989-1002), a phase 3, randomised, placebo-controlled, multi-centre trial of 1,961 adults with a BMI of ≥30 kg/m^2, or ≥27 kg/m^2 with ≥1 weight-related comorbidity, excluding diabetes. The Group noted that 1,306 participants were randomised to receive once-weekly subcutaneous semaglutide 2.4 mg plus lifestyle intervention and 655 to placebo plus lifestyle intervention for 68 weeks.

7.15.1. The Group noted that mean percentage change in body weight from baseline to week 68 was -14.9% with semaglutide versus -2.4% with placebo, with an estimated treatment difference (ETD) of -12.4 percentage points (95% CI: -13.4 to -11.5; P<0.001).

7.15.2. The Group noted that 86.4% of participants receiving semaglutide achieved ≥5% weight reduction at week 68, compared with 31.5% receiving placebo.

7.15.3. The Group noted that semaglutide demonstrated statistically significant superiority across confirmatory endpoints, including proportions achieving ≥10% weight loss (69.1% vs. 12.0%) and ≥15% weight loss (50.5% vs. 4.9%), each favouring semaglutide.

7.15.4. The Group noted semaglutide was associated with greater reduction in waist circumference (mean change -13.54 cm, ETD -9.42 cm, 95% CI: -10.30 to -8.53).

7.15.5. The Group noted adverse events (AEs) were common, occurring in 89.7% of participants receiving semaglutide and 86.4% receiving placebo. The Group

further noted that gastrointestinal events were the most frequent (44.2% nausea, 31.5% diarrhoea, 24.8% vomiting with semaglutide). The Group noted that serious adverse events occurred in 9.8% vs. 6.4% (semaglutide vs. placebo), with treatment discontinuation due to AEs in 7.0% vs. 3.1%, respectively.

7.16. The Group noted the STEP-1 Extension study (Wilding, et al. Diabetes Obes Metab. 2022;24:1553-64), in which 327 prior STEP-1 participants were followed for 52 weeks off treatment without lifestyle support. The Group noted substantial weight regain after withdrawal, with a mean increase of 11.6 percentage points in the former semaglutide group and 1.9 percentage points in the former placebo group, resulting in a net loss at week 120 of -6.8% (semaglutide) vs -0.1% (placebo) compared with baseline. The Group further noted that 48.2% of prior semaglutide recipients maintained ≥5% weight loss at week 120, and that improvements in HbA1c, CRP, blood pressure, and lipids largely reverted toward baseline after ceasing treatment.

7.17. The Group noted STEP-2 (Davies, et al. The Lancet. 2021;397:971-84), a phase 3, randomised (1:1:1), placebo-controlled, 68-week study involving 1,210 adults with a BMI of ≥27 kg/m^2 and type 2 diabetes with 53–86 mmol/mol. The Group noted 404 participants received semaglutide 2.4 mg once weekly, 403 received semaglutide 1.0 mg once weekly and 403 received placebo, with all groups receiving concomitant lifestyle intervention.

7.17.1. The Group noted that mean percentage weight change from baseline to week 68 was -9.6% with semaglutide 2.4 mg and -3.4% with placebo, with an ETD of -6.2 percentage points (95% CI: -7.3 to -5.2; p<0.0001).

7.17.2. The Group noted improvements in several exploratory endpoints, including HbA1c, fasting glucose, fasting insulin, diastolic blood pressure, lipids (HDL, LDL, VLDL) and other metabolic parameters, each favouring semaglutide.

7.17.3. The Group noted that AEs were common across all treatment groups, occurring in 87.6% of participants receiving semaglutide 2.4 mg, 81.8% receiving semaglutide 1.0 mg, and 76.9% receiving placebo. The Group further noted that gastrointestinal AEs were the most frequent and consistent with the known class effects of GLP-1 RAs.

7.18. The Group noted STEP-5 (Garvey, et al. Nat Med. 2022;28(10):2083-91), a phase 3, randomised (1:1), placebo-controlled, 104-week study involving 304 adults with overweight (BMI ≥27 kg/m^2 with ≥1 weight-related comorbidity) or obesity (BMI ≥30 kg/m^2), without diabetes. The Group noted 152 participants received semaglutide 2.4 mg once weekly and 152 received placebo, with all groups receiving structured behavioural intervention, including counselling every four weeks to support adherence to a reduced-calorie diet and increased physical activity.

7.18.1. The Group noted that mean percentage change in body weight from baseline to week 104 was -15.2% with semaglutide and -2.6% with placebo, with an ETD of -12.6 percentage points (95% CI: -15.3 to -9.8; p<0.0001).

7.18.2. The Group noted that AEs were common across all treatment groups, occurring in 96.1% of participants receiving semaglutide and 89.5% receiving placebo. The Group further noted that gastrointestinal AEs were the most frequent and consistent, with nausea occurring in 53.3% versus 21.7%, and diarrhoea in 34.9% versus 23.7% (semaglutide vs placebo). The Group noted that serious adverse events occurred in 7.9% versus 11.8%, and treatment discontinuation due to AEs occurred in 5.9% versus 4.8%, respectively.

7.19. The Group noted SELECT (Lincoff, et al. N Engl J Med. 2023;38wh9:2221-32), a phase 3, randomised (1:1), double-blind, placebo-controlled, event-driven study involving 17,604 adults aged ≥45 years with pre-existing cardiovascular disease and a

BMI ≥27 kg/m^2, without diabetes. The Group noted 8,803 participants received once-weekly subcutaneous semaglutide 2.4 mg and 8,801 received placebo, with a mean follow-up of 39.8 months.

7.19.1. The Group noted that the composite cardiovascular endpoint (death from cardiovascular causes, non-fatal myocardial infarction, or non-fatal stroke) occurred in 6.5% of participants receiving semaglutide compared with 8.0% receiving placebo, with a hazard ratio of 0.80 (95% CI: 0.72 to 0.90; p<0.001), favouring semaglutide.

7.19.2. The Group noted that death from cardiovascular causes occurred in 2.5% of participants receiving semaglutide vs 3.0% with placebo, with a hazard ratio of 0.85 (95% CI: 0.85 to 1.01; p=0.07).

7.19.3. The Group noted that serious AEs occurred in 33.4% of participants receiving semaglutide and 36.4% receiving placebo.

7.19.4. The Group noted that treatment discontinuation due to AEs occurred in 16.6% with semaglutide and 8.2% with placebo. The Group further noted that gastrointestinal AEs leading to discontinuation occurred in 10.0% of participants receiving semaglutide vs 2.0% receiving placebo.

7.20. The Group also noted the following:

7.20.1. Chen, et al. Reprod Biol Endocrinol. 2025;23(1):108)

7.20.2. Yao, et al. BMJ. 2024;384:e076410

7.20.3. Taylor, et al. N Z Med J. 2025;138(1620):36-45

7.20.4. Karimi, et al. Front Pharmacol. 2025;16:1438318

7.21. The Group considered that although the STEP trials reported significant reductions in body weight among the groups randomised to semaglutide compared to placebo, it was uncertain how generalisable these study results may be to the New Zealand setting.

7.22. The Group noted that participants in both trial arms received individual counselling sessions every four weeks alongside a reduced calorie diet regimen and increased physical activity. The trial protocol required diet and activity to be recorded daily in a diary or smartphone application. These were reviewed during counselling sessions. The Group considered that while certain specialist clinics in New Zealand can deliver this intensity of multidisciplinary care, it is possible that not all can. The Group noted previous advice Pharmac received from the Diabetes Advisory Committee in April 2023 on the limited availability of weight loss interventions in primary care settings (Diabetes Advisory Committee Record April 2023 [para 7.17]).

7.23. The Group noted there was a lack of trial or observational evidence to inform the likely magnitude of semaglutide-associated weight loss in the absence of these concomitant measures, and that similar gaps in the evidence were identified by PTAC in its assessment of liraglutide (an earlier-generation GLP-1 agonist) for weight management. However, the Group also considered that semaglutide is likely to result in meaningful weight loss and improved outcomes even without intensive concomitant lifestyle interventions, although the magnitude of benefit would likely be smaller than that observed in clinical trials.

Suitability

7.24. The Group noted that semaglutide requires refrigerated storage at 2–8°C and has a three-year shelf life. The Group noted that it may be kept unrefrigerated for up to 42 days at temperatures not exceeding 30°C.

7.25. The Group noted that semaglutide requires a gradual dose-escalation schedule, with up-titration occurring over approximately 16 weeks before reaching the maintenance dose, and that this process requires time to ensure tolerability and minimise gastrointestinal adverse effects.

7.26. The Group noted that device education and troubleshooting are well-established within primary care through nursing and clinical pharmacy support.

Cost and savings

7.27. The Group noted that funding semaglutide for weight management may result in a combination of costs and savings to the wider health sector, with the net impact of the two highly dependent on the price of funding semaglutide and the extent to which weight loss results in reductions in obesity-related complications.

7.28. The Group noted that given the relatively high prevalence of obesity and weight-related comorbidities, the budget impact of funding semaglutide for weight management would be very high. The Group noted that this reflected the health need associated with obesity across the New Zealand population as well as the high cost of semaglutide on a per-person basis.

7.29. The Group noted the significant costs to the health system associated with obesity, such as outpatient visits, emergency department visits and hospitalisations for the management of diabetes, cardiovascular disease and weight-related musculoskeletal conditions. The Group noted that population-wide reductions in the prevalence of obesity, whether due to semaglutide or other non-pharmaceutical interventions, could result in reductions in these health system impacts.

7.30. The Group noted that funding semaglutide may result in an initial increase in demand for clinical appointments to initiate people on semaglutide, manage titration of the medicine and treat adverse effects.

7.31. The Group considered that given the available evidence, the duration of treatment with semaglutide would be long-term (potentially lifetime) given a lack of evidence to inform whether dose reduction or treatment cessation was clinically appropriate. The Group noted that the long-term extension of STEP-1 reported weight regain after stopping semaglutide, which should be considered in Pharmac's assessment. The Group also noted that there was a lack of published trial evidence on using semaglutide at a maintenance dose lower than 2.4 mg or at a frequency other than weekly, and as such, the Pharmac assessment should represent usage at a maintenance dose of 2.4 mg weekly. The Group noted that there are several ongoing trials exploring tapering regimens.

Cost-effectiveness

7.32. The Group noted that the supplier of semaglutide had submitted an economic model to support its application which included simulations of the effect of semaglutide on the likelihood of developing obesity-related complications compared to standard of care weight management services.

7.33. The Group noted that the supplier's model included range of health benefits including progression to type 2 diabetes, reductions in first MACE events, reductions in knee replacements, reductions in cancer incidence and potential reductions in all-cause mortality. The Group considered that, while these benefits were biologically plausible, their magnitude and materiality were highly uncertain. The Group considered that in the STEP trials, no evidence was presented to support a direct impact on any of these comorbidities, except type 2 diabetes onset. The SELECT trial provided evidence to inform a reduction in MACE for the subgroup of people with established cardiovascular disease.

7.34. The Group noted that Pharmac staff sought specific advice on certain aspects of the economic modelling of semaglutide, including the Group's view on whether certain outcomes should be excluded from the modelling and whether other outcomes should be modelled with a lagged effect to account for uncertainty in their timing following a reduction in weight.

7.35. The Group considered that, based on its expert judgement, the following modelled approaches were most appropriate for Pharmac's cost-effectiveness analysis of semaglutide:

7.35.1. On type 2 diabetes, the Group considered that it was appropriate to retain the supplier's approach to modelling reductions and potential avoidance in onset of type 2 diabetes in the base case. The Group noted that the supplier modelled reductions in type 2 diabetes onset based on the QDiabetes-2018 risk prediction algorithm and a prediction model using data from the Framingham Offspring study (Hippisley-Cox et al. BMJ. 2017;359:j5019; Wilson et al. Arch Intern Med. 2007;167:1068-1074). The Group considered however that long-term weight re-gain may result in some people experiencing a delay in onset of type 2 diabetes rather than avoidance altogether. The Group considered that it was appropriate to exclude this benefit in sensitivity analysis to gauge the materiality of this outcome to the cost-effectiveness of semaglutide.

7.35.2. On time to first MACE event among people without a history of cardiovascular events, the Group considered it appropriate to model a lag in reductions of first MACE of at least four years analysis given the magnitude of uncertainty in the timing and materiality of this outcome.

7.35.3. The Group noted that among people without a history of cardiovascular events, the supplier modelled reductions in MACE events based on the QRISK3 algorithm, which estimates cardiovascular risk from certain surrogate outcomes, including current BMI and risk factors (Hippisley-Cox et al. BMJ. 2017;357:j2099). The Group considered, however, that the short-term impacts of weight loss on CVD risk in the primary prevention setting is not well evidenced outside of the setting of type 2 diabetes – with some large observational studies reporting that short term weight loss has no effect on the incidence of atrial fibrillation, heart failure, unstable angina or myocardial infarction rates in the short run (Haase et al. Int J Obes. 2021;45:1249-1258). The Group considered that time to reduction in cardiovascular risk resulting from weight loss, in the primary prevention setting, may be delayed or lagged rather than immediately falling as BMI falls. The Group noted that a lag time of four years corresponds to the follow-up period described in the study by Haase et al (2021).

7.35.4. On time to recurrent MACE event among people with established cardiovascular disease, the Group considered it was appropriate to align modelled reductions in MACE risk according to what was observed in the SELECT trial.

7.35.5. On knee replacements, the Group considered there was insufficient evidence to model a reduction in knee replacement surgery rate among people receiving semaglutide in the base case. The Group noted the supplier's assumption that short term weight loss may result in avoidance of knee replacement surgery for some individuals, based on observational evidence on the relationship between BMI and knee arthroplasty risk (Wendelboe et al. Am J Epidemiol. 2003;157:703-709). The Group was made aware of evidence that semaglutide improves pain and functioning among people with arthritic conditions but the implications for requirements for knee replacement surgery

were unclear. The Group considered however that reductions in BMI, especially from very high levels, may lead to increases in knee replacements and other surgeries especially if someone's weight was a reason for ineligibility for surgery (clinical safety).

7.35.6. The Group considered however that it was potentially plausible that semaglutide may reduce the need for knee replacement surgery for some individuals and this outcome should be modelled in sensitivity analysis given there is some observational evidence to support its inclusion with uncertain applicability to Pharmac's economic assessment.

7.35.7. On cancer, the Group considered it appropriate to include scenarios where a change in BMI reduced the risk of certain cancers, but considered it reasonable to exclude this from the base case in the absence of direct evidence of this relationship. The Group noted that the supplier modelled reductions in incidence of cancer based on observational evidence on the relationship between BMI and risk of breast, colorectal and endometrial cancers. The Group considered however if weight loss is not sustained, there may not be a reduction in cancer risk at all unless GLP-1 agonists reduce cancer risk through mediating factors other than weight loss. The Group further considered that time to reduction in cancer risk may be more lagged, occurring over a time scale closer to three to five years, rather than immediately falling as BMI falls (Levy et al. Cancers. 2025;17:78).

7.35.8. The Group considered that it may be appropriate to include reductions in cancer risk, with a lag time of three or five years, in sensitivity analysis given there is some observational evidence to support its inclusion with uncertain applicability to Pharmac's assessment.

7.35.9. On the approach to modelling all-cause mortality, the Group considered that, although semaglutide may reduce mortality over time due to reductions in obesity-related complications, it was appropriate to exclude immediate reductions in all-cause mortality from all modelled scenarios due to the lack of evidence to support a reduction in all-cause mortality independent of reduced development of other weight-related outcomes and comorbidities.

7.35.10. The Group noted that the supplier modelled immediate reductions all-cause mortality as BMI falls. The Group further noted that this reduction was in addition to mortality reduction from preventing the development of comorbidities. The Group noted this modelling was based on observational evidence on the relationship between BMI and all-cause mortality (Bhaskaran et al. Lancet. 2014;384:755-765). The Group considered however that time to reduction in all-cause mortality risk may be more lagged, occurring over a time scale closer to five to ten years, rather than immediately falling as BMI falls and this is supported by observational studies of people who receive bariatric surgery which report that reduction in mortality risk are not discernible until at least five years after surgery (Sjöström et al. New Engl J Med. 2007;357:741-752).

7.35.11. For the subgroup with established cardiovascular disease, the Group considered it was appropriate to align modelled reductions in all-cause mortality according to what was observed in the SELECT trial.

7.36. The Group noted that most weight-related complications develop and evolve over timescales spanning years. The Group considered that if semaglutide treatment discontinuation rates are high, leading to weight regain in many recipients, or if the weight loss effect induced by semaglutide is not sustained over the long term, the effect of treatment on the risk of developing some of comorbidities may be reduced.

These assumptions were reflected in the Supplier's approach to economic modelling regarding discontinuation and long-term durability of benefit.

Funding criteria

7.37. The Group considered that the trial inclusion criteria for the STEP trials were relatively inclusive, and funding semaglutide for the entire population represented in the STEP-1 and STEP-2 trials was unlikely to be feasible in the current fiscal environment and with the practical constraints in New Zealand's publicly funded health system.

7.38. The Group considered that, if semaglutide were to be publicly funded, this would occur alongside a likely large and growing private market. As a result, many eligible individuals may have already initiated treatment privately and achieved substantial weight loss, meaning they might no longer meet the proposed initiation or renewal Special Authority criteria. However, the Group noted that these situations could be managed through Special Authority waivers, provided the prescriber can demonstrate that the individual met the intent of the relevant initiation and/or renewal criteria prior to starting treatment.

7.39. The Group considered that the funding criteria for initiating semaglutide for weight management should target individuals most likely to benefit from treatment, while also ensuring that eligibility for ongoing treatment is targeted to those who demonstrate a sufficient treatment response.

7.40. The Group noted several options for refining the targeting of funding for semaglutide. These included setting a higher BMI eligibility threshold than that used in the STEP trials, applying alternative cardiometabolic risk factors or other comorbid conditions to define eligibility, specifying a minimum weight loss threshold for a Special Authority renewal to target those who demonstrate the greatest treatment response, and restricting access to semaglutide to individuals receiving care from specific practitioners or services.

7.41. The Group considered it appropriate to set an eligibility threshold at a BMI of 35 kg/m^2, noting that this is comparable to the thresholds used in comparable jurisdictions such as Canada, England and Scotland. However, the Group also considered that this threshold could be raised to a BMI of 40 kg/m^2 if funding treatment down to this level proved to be cost-prohibitive or not cost-effective.

7.42. The Group noted that the STEP-1 and STEP-2 trials required individuals with lower BMIs to have at least one weight-related comorbidity (hypertension, dyslipidaemia, obstructive sleep apnoea, established cardiovascular disease). The Group considered it appropriate to target semaglutide to people with at least two weight-related comorbidities. The Group considered however that this comorbidity-related threshold could be further tightened to more precisely target funding to those with highest health need.

7.43. The Group noted that the prevalence of comorbidities such as hypertension and dyslipidaemia among people with obesity is relatively high, and using these comorbidities in the access criteria may not substantially reduce the size of the group eligible for treatment. The Group noted however that using these comorbidities to target funded access to semaglutide would be aligned with the key trial evidence and as such, was clinically appropriate.

7.44. The Group considered it was appropriate to omit the requirement for any weight-related comorbidity in individuals with a BMI of ≥50 kg/m^2. The Group considered that a very small group of people would have a BMI of ≥50 kg/m^2 and no comorbidities, primarily young individuals at very high risk of developing obesity-related complications. The Group considered that this group had a relatively high health need, and enabling funded access to treatment for all people with this level of excess weight would be desirable.

7.45. The Group considered it appropriate at this stage to set a weight loss threshold for a Special Authority renewal of 10% at six months. The Group noted that across the STEP trials, weight loss at six months follow-up was strongly predictive of longer-term weight loss outcomes. Moreover, the Group considered that a threshold of 10% represents a level of weight loss associated with clinically meaningful improvements to cardiometabolic risk. However, the Group considered it would like to discuss the renewal criteria further at a future meeting.

7.46. The Group considered it appropriate for a Special Authority renewal for semaglutide to be indefinite. The Group considered that limiting the duration of GLP-1 therapy may offer a means of controlling costs, but there is currently limited robust evidence regarding long-term outcomes following discontinuation. Such restrictions may risk the loss of sustained clinical benefits for patients. The Group considered that in the absence of longer-term evidence, it would be assumed that GLP-1 agonist treatment for weight management be lifelong.

7.47. The Group considered that restricting access to semaglutide to those receiving care from certain practitioners or services could substantially reduce the number of individuals eligible for treatment. The Group noted that such targeting would ensure individuals receive concomitant care more closely aligned with the multidisciplinary weight-management settings in which semaglutide has demonstrated efficacy. The Group further noted that there is only one Tier 3 weight-management clinic in South Auckland, although some primary care and private clinics may offer similar types of weight-management interventions.

7.48. The Group considered it potentially appropriate to target funding for semaglutide to people receiving 'comprehensive' weight management care. The Group considered however that there is no single, widely recognised term in New Zealand to describe the types of weight management care provided by weight management clinics or primary care settings. The Group considered that some people may be enrolled in a multidisciplinary weight-management programme or recognised comprehensive treatment programme. The Group considered however that 'comprehensive care' could also be achieved via a range of different modalities and models of care which could include the involvement of GPs, nurse practitioners, pharmacists, health coaches or allied health professionals. Hence, a requirement to be receiving comprehensive care of any kind was included to avoid excluding people with less formal support.

7.49. The Group considered that the impact of restricting semaglutide to people receiving care in specific settings was highly uncertain, and that such an approach could create unintended consequences for equity of access.

Summary for assessment

7.50. The Group considered that the below summarises its interpretation of the most appropriate PICO (population, intervention, comparator, outcomes) information for semaglutide if it were to be funded in New Zealand for weight management. This PICO captures key clinical aspects of the proposal and may be used to frame any future economic assessment by Pharmac staff. This PICO is based on the Group's assessment at this time and may differ from that requested by the applicant. The PICO may change based on new information, additional clinical advice, or further analysis by Pharmac staff.

<table>
<tr><td>Population</td><td>Option 1

Adults with either:
• an initial BMI of ≥35 kg/m^2, in the presence of at least two weight-related comorbidities
• an initial BMI of ≥50 kg/m^2, with no specific requirement to have a weight-related comorbidity</td><td>Option 2

Adults with either:
• an initial BMI of ≥40 kg/m^2, in the presence of at least two weight-related comorbidities
• an initial BMI of ≥50 kg/m^2, with no specific requirement to have a weight-related comorbidity</td></tr>
<tr><td></td><td colspan="2">Note: Target populations in this table are indicative only and subject to revision based on new information, or further analysis by Pharmac staff</td></tr>
<tr><td>Intervention</td><td colspan="2">Semaglutide, injected subcutaneously, at doses as follows:

• 0.25 mg once per week, for weeks 1 to 4
• 0.50 mg once per week, for weeks 5 to 8
• 1.0 mg once per week, for weeks 9 to 12
• 1.7 mg once per week, for weeks 13 to 16
• 2.4 mg once per week as a maintenance dose thereafter

Semaglutide to be used as an adjunct to standard of care weight management interventions.

Semaglutide to be discontinued if individuals do not experience a reduction in weight of at least 10% compared to baseline after six months of treatment.</td></tr>
<tr><td>Comparator(s)</td><td colspan="2">Standard of care weight management interventions (including dietary, exercise and psychosocial interventions)</td></tr>
<tr><td>Outcome(s)</td><td colspan="2">Key outcomes reported in the STEP and SELECT trials
• Change in weight (%) from baseline to end of treatment
• Change in HbA1c (%) from baseline to end of treatment
• Change in systolic blood pressure (SBP) (mmHg) from baseline to end of treatment
• Change in high-density lipoprotein (HDL) (mmol/L) from baseline to end of treatment
• Time to first MACE (SELECT trial only)

Key outcomes to potentially include in economic modelling
• Time to first major adverse cardiovascular events (MACE)
• Time to recurrent MACE
• Time to onset of prediabetes and type 2 diabetes
• Time to diagnosis with cancer (colorectal, breast, endometrial)
• Time to onset of liver disease (including metabolic dysfunction-associated steatohepatitis [MASH] and non-alcoholic fatty liver disease [NAFLD])
• Reduction in symptoms of sleep apnoea (as measured by the apnoea-hypopnea index [AHI])
• Time to development of hyperuricemia
• Time to onset of gout
• Time to knee replacement surgery</td></tr>
<tr><td colspan="3">Table definitions: Population, the target population for the pharmaceutical; Intervention, details of the intervention pharmaceutical; Comparator, details the therapy(s) that the patient population would receive currently (status quo – including best supportive care); Outcomes, details the key therapeutic outcome(s) and source of outcome data.</td></tr>
</table>