Public Summary Document – November 2025 PBAC Meeting

REFERRAL FROM MINISTER FOR ADVICE ON EQUITABLE ACCESS TO OBESITY TREATMENTS

The Minister referred to the PBAC the matter of equitable access to glucagon-like peptide-1 receptor agonist (GLP-1) obesity treatments in Australia for advice.

At its meeting between **5** – **7 November 2025** the PBAC provided the following advice to the Minister (under section 101(3) of the *National Health Act 1953*).

9.02 Minister's request for PBAC advice on equitable access to obesity treatments

1 Purpose of Item

That the PBAC:

1.1 **Discuss and agree** on a response to the request from the Minister for Health and Ageing and Minister for Disability and the National Disability Insurance Scheme (NDIS), for advice on equitable access to obesity treatments through the Pharmaceutical Benefits Scheme (PBS).

2 Background

2.1 On 6 March 2025, the Minister for Health and Ageing and Minister for Disability and the NDIS, wrote to the PBAC Chair to request the committee's advice on access to glucagon-like peptide-1 receptor agonist (GLP-1) obesity treatments through the PBS. The Minister requested advice on the potential future PBS subsidy of obesity treatments, including the most appropriate patient populations, duration of therapy and place in therapy.

2.2 Minister Butler's request included several key questions for PBAC:

- Which Australian cohorts are most likely to benefit from potential availability of obesity medicines through the PBS?
- Are obesity medicines effective as standalone therapies or best used in combination with other interventions, along with supporting models of care?
- Are they most effectively used as the sole intervention, in association with bariatric surgery, or combination of options?
- What is the optimal duration of subsidisation?

2.3 The PBAC considered this request in March 2025 and agreed to form a Working Group of interested PBAC members to guide the development of PBAC's response. The Working Group consisted of: Adjunct Associate Professor Jo Watson, Associate

Professor (Peter) Shane Hamblin, Dr Susannah Morris, Professor Richard Norman, Associate Professor Ines Rio and Associate Professor Melanie Turner.

2.4 The Working Group met on 14 April 2025, to discuss and agree on the approach for responding to the Minister's request, and to provide advice on research projects proposed by the Department to assist PBAC in formulating its advice to the Minister. The Working Group identified several issues and risks associated with PBS subsidy of GLP-1 obesity treatments at this meeting, and agreed that the Department should prioritise the following research projects:

- Epidemiological modelling of population cohorts that might benefit most from PBS subsidy, e.g. adolescents, Aboriginal and Torres Strait Islander persons, and patients with cardiovascular disease (CVD), type 2 diabetes, or other specified comorbidities. Further details provided in Section 3.
- International 'landscape' analysis of subsidisation of obesity treatments including implementation issues. Meeting with health department representatives from the UK and/or Canada to gain an understanding of their deliberations about the roll-out of these medicines in their health systems, including real-world data analysis, wraparound care and access restrictions/protocols. Further details provided in Section 4.
- Horizon scanning analysis for new obesity treatments, including contemporary generics/biosimilars. Further details provided in Section 5.
- Conducting an analysis of pharmacy wholesaler data for obesity medicines to give an indication of private supply. Further details provided in Section 6.

2.5 The PBAC was provided with a verbal progress update from the Department at the July 2025 PBAC meeting. The Chair and Deputy Chair of the PBAC subsequently wrote to the Minister on 27 August 2025, to provide a status update regarding the response.

2.6 The Working Group met again on 26 August 2025, to provide advice to the Department on the epidemiological modelling research project, including data sources and cohorts to be modelled.

2.7 The background information below includes the history of PBAC consideration of GLP-1 obesity treatments, relevant issues associated with wraparound care services and models of service delivery, information on metabolic bariatric surgery, and development of the revised Australian clinical guidelines for obesity management.

PBAC consideration of GLP-1s registered in Australia for the treatment of obesity

2.8 Three GLP-1s are registered in Australia for the treatment of overweight/obesity: liraglutide, semaglutide (Wegovy® only) and tirzepatide. The PBAC has not yet recommended any medicine be listed on the PBS for weight management or treatment of obesity.

2.9 The PBAC has considered submissions to list semaglutide (Wegovy, Novo Nordisk) for people with obesity, and the GLP-1-glucose-dependent insulinotropic polypeptide (GIP) receptor agonist tirzepatide (Mounjaro®, Eli Lilly) for type 2

diabetes with severe obesity, but considered these medicines were not cost-effective at the proposed prices.

2.10 The following background information provides an overview of PBAC consideration of GLP-1s registered in Australia for the treatment of obesity, with a focus on PBAC's views on the appropriate populations for access.

Semaglutide (Wegovy®); Novo Nordisk

2.11 The PBAC considered submissions for semaglutide for people with severe obesity and weight-related comorbidities, but without diabetes, at the March 2022 and November 2023 meetings.

2.12 A PBAC stakeholder meeting for semaglutide was held in August 2021. The outcome statement is available on the PBS website.

2.13 When considering semaglutide (Wegovy) in November 2023, based on the information available at the time, the PBAC provided advice that the most appropriate target population was people with:

- a Body Mass Index (BMI) ≥ 40 kg/m^2 (≥ 37 kg/m^2 for Aboriginal and Torres Strait Islander people/Asian ethnicity) AND
- pre-existing cardiovascular disease (CVD), OR type 2 diabetes, OR ≥ 2 weight-related comorbidities consistent with high cardiometabolic risk (e.g. hypertension, dyslipidaemia, chronic kidney disease, fatty liver disease, pre-diabetes).

2.14 In November 2023, the PBAC offered Novo Nordisk a facilitated resolution workshop with one or more PBAC members. **Redacted text**.

2.15 A submission from Novo Nordisk to list semaglutide on the PBS for the treatment of patients with established CVD living with overweight or obesity was also considered separately at the November 2025 PBAC meeting.

2.16 Novo Nordisk provides wegovy*care*®[1] an online patient support program for people prescribed Wegovy in Australia.

Tirzepatide (Mounjaro®), Eli Lilly

2.17 Eli Lilly has not made a submission to list tirzepatide on the PBS for its TGA-registered indications of weight management or treatment of obstructive sleep apnoea.

2.18 The PBAC first considered and did not recommend a submission for tirzepatide for the indication of type 2 diabetes mellitus (T2DM) in July 2023. The submission did not include a clinical criterion related to obesity.

2.19 In November 2024, when considering a resubmission for tirzepatide, the PBAC advised that the proposed narrower T2DM restriction, for patients with inadequately controlled T2DM and who either have a BMI ≥35 kg/m^2 or identify as Aboriginal or

[1] Novo Nordisk, Welcome to wegovy*care*®, accessed 14 October 2025.

Torres Strait Islander, appropriately targeted subpopulations at high risk of diabetes related complications. However, it was noted this still represented a very large eligible population. The PBAC considered that the ICER was high, inadequately justified, and uncertain, and that a price reduction would be required. The PBAC noted the financial impact for the PBS was extremely high at the prices proposed, although considered it likely overestimated, and that the proposed Risk Share Agreement (RSA) was unlikely to satisfactorily mitigate the risk to government of use outside of the proposed restriction.

2.20 The PBAC considered that an ICER of $25,000-$35,000 per quality-adjusted life year (QALY) would be appropriate for tirzepatide for the T2DM population with comorbid severe obesity.

2.21 The PBAC deferred a third submission to list tirzepatide on the PBS for T2DM in July 2025. The PBAC was concerned about the high likelihood that tirzepatide would be used outside the proposed PBS restrictions for purposes other than the treatment of T2DM. The PBAC did not consider that the proposed financial arrangements would adequately manage this risk. **Redacted text.** The PBAC deferred its decision so that it could have further discussions with the sponsor about listing tirzepatide on the PBS at a price consistent with expected benefits and with arrangements that would appropriately share financial risk. **Redacted text.**

2.22 **Redacted text.**

2.23 **Redacted text.**

Liraglutide (Saxenda®, Novo Nordisk) and biosimilars

2.24 Novo Nordisk, the sponsor of both semaglutide and liraglutide, has not made a submission to list liraglutide (Saxenda®) on the PBS for treatment of obesity. However, in March 2013, the PBAC recommended liraglutide (Victoza®) once daily injection for PBS listing for the treatment of T2DM on a cost-minimisation basis to exenatide (Byetta®) twice daily injections. The March 2013 recommendation to list liraglutide on the PBS was subsequently rescinded as the sponsor did not proceed with listing. Liraglutide has not been listed on the PBS to date. Liraglutide (Saxenda) is being discontinued in Australia and will not be available for purchase after December 2025.[2]

2.25 In March 2025, six biosimilar brands of liraglutide were registered on the Australian Register of Therapeutic Goods (ARTG), with an indication of weight management. Sponsors of these medications are Cipla Australia (3 brands) and Sun Pharma ANZ (3 brands). As of October 2025, these brands are not available for sale at Australian pharmacies.

[2] Novo Nordisk, Important Information: Discontinuation of Saxenda® (liraglutide) in Australia, accessed 5 December 2025.

Models of service delivery and wraparound allied health care

2.26 Minister Butler's request asked the PBAC to consider whether GLP-1s for the treatment of obesity are effective as standalone therapies or best used in combination with other interventions, including supporting wraparound care.

2.27 While there is global heterogeneity in how pharmacotherapies are used and subsidised for the management of obesity, it is generally recognised based on clinical guidelines and stakeholder inputs received by the Department, that models of care that provide holistic care and wraparound allied health services are needed to achieve optimal outcomes from GLP-1 obesity treatments. Patients with obesity are already receiving care for this condition through primary care and specialist services in Australia, although there may be access issues for allied health services (refer to Section 8). However, additional research into the most effective and cost-effective models of service delivery and wraparound care for patients using GLP-1s would be beneficial.

2.28 It is unclear whether there are sufficient allied health professionals, particularly in regional and remote areas, to meet likely demand if a requirement for the patient to have seen a dietitian or exercise physiologist was included in a potential PBS restriction. In addition, the provisions for Medicare Benefits Scheme (MBS) rebated services for chronic condition management are currently being reviewed. Some stakeholders have advised they can use existing MBS items to provide wraparound care to support effective use of GLP-1 obesity treatments. Others consider that these services could be better tailored for obesity management.

Models of service delivery

2.29 A recent publication (Kanellis et al. 2025) proposes three service delivery models in the Australian context, all supported by wraparound allied health care: digital delivery; shared care initiated by specialist services with GP follow-up; and sole prescriber (GP, nurse practitioner (NP)). These models of service delivery are currently operating in Australia for some people accessing GLP-1s for weight management. The article notes that telehealth service delivery models may provide avenues to meet demand for medical weight loss services that cannot be met by conventional models and may improve access to clinical care in rural and remote areas. However, these models have attracted criticism for having a sole focus on prescribing of weight loss medications which may result in reduced clinical governance and a lack of holistic care, potentially resulting in suboptimal health outcomes for weight management and poorer health outcomes overall. This is exacerbated by the potential for health practitioners to have a financial conflict of interest.[3]

[3] Kanellis et al (2025), 'The role of GLP-1 receptor agonists in the management of obesity: risks and opportunities for the Australian health care system', *MJA*, 222(3):118-121.

2.30 Service delivery in Australia currently enables a non-Medicare Benefits Scheme (MBS) service to generate a PBS eligible prescription. MBS service provision requires elements that support appropriate clinical care, e.g. face-to-face consultation provision in the previous 12 months, and referral requirements. The disconnect between the requirement to have an MBS eligible service for PBS provision of medicine is considered by some to be an important factor that underpins inappropriate and fragmented single care models.

2.31 The Eating Disorder Alliance, a collective of Australian national and state consumer and health professional representative groups, has raised concerns about the risk of inappropriate prescribing of GLP-1s for people with, or at risk of, an eating disorder. This group have requested introduction of measures to ensure telehealth providers prescribing GLP-1s are accountable to a safe standard of practice and to ensure that patients have a comprehensive medical assessment prior to prescribing GLP-1s to identify eating disorders and/or disordered eating behaviours.[4]

2.32 The Australian Commission on Safety and Quality in Health Care (ACSQHC) is currently undertaking research into the safety and quality of virtual (telehealth) care with the aim of developing a framework for safe and high-quality virtual care delivery.[5] From 1 November 2025, the established clinical relationship criteria will be introduced to MBS NP telehealth items to align with current GP telehealth requirements. This change will mean patients wanting to claim an MBS telehealth consultation will need to have had one face-to-face consultation with their NP, or another practitioner at the same practice, within 12 months preceding the telehealth service, with exemptions for selected services and patient groups.

Wraparound allied health care

2.33 GLP-1 treatment can result in loss of muscle and bone mass, nutritional deficiencies and dehydration, and appropriate diet and exercise counselling and interventions may be needed to minimise these side effects.[6] It remains unclear whether lifestyle interventions are required to achieve safe and cost-effectiveness use of GLP-1 treatments for obesity in the Australian health care setting. Any potential PBS requirements for wraparound care may impact on the estimated cost-effectiveness of pharmacological treatments.

2.34 In Australia, GP chronic condition management plans (GPCCMP) are available to patients with at least one medical condition that has been (or is likely to be) present for at least 6 months or is terminal. The GPCCMP is intended to support patients that

[4] Eating Disorders Families Australia, Eating Disorder Alliance (EDA) advocates for action on compounded weight loss drugs, 18 June 2025, accessed 22 September 2025.
[5] ACSQHC, Safety and quality in virtual health care, accessed 25 September 2025.
[6] Mozaffarian D et al (2025), 'Nutritional priorities to support GLP-1 therapy for obesity: A joint Advisory from the American College of Lifestyle Medicine, the American Society for Nutrition, the Obesity Medicine Association, and The Obesity Society', *Obesity*, 33(8):1475-1503.

would benefit from a structured approach to the management of their chronic condition, whether or not multidisciplinary care is required. There is no list of eligible conditions. GPs can refer patients with a GPCCMP for up to five individual MBS rebated allied health services per calendar year (10 services for patients of Aboriginal or Torres Strait Islander descent).

2.35 Patients with T2DM may also be eligible for group allied health services. Eligible patients with T2DM can access group diabetes education, exercise physiology or dietetics services. Suitability can be assessed once per calendar year and, if found suitable, a patient can utilise up to 8 group services per calendar year.

2.36 Some patients may also be eligible for an Eating Disorder Treatment and Management Plan (EDP), which provides access to MBS rebated dietetic and psychology services; or a GP Mental Health Treatment Plan (GPMHTP) which provides access to MBS rebated psychology services.

2.37 The MBS Review Advisory Committee (MRAC) commenced a review of allied health chronic disease management services on 20 August 2024. The MRAC will assess whether these services are adequately supporting patients with chronic conditions and whether individual and group MBS allied health services could be improved to better support eligible patients. This review will include consideration of the calendar year limits for individual allied health services, and whether group allied health services should be expanded beyond T2DM, including the health conditions and allied health services for which group therapy may be appropriate. The review is expected to take 18 months to complete.[7]

2.38 Dietitians Australia has requested that the Australian Government require a referral to an Accredited Practising Dietitian on prescription of a GLP-1 and expand MBS items to improve access to nutritional support.[8] Dietitians Australia cite a recent retrospective observational study showing that 12.7% of patients starting GLP-1 therapy had nutritional deficiencies within 6 months of GLP-1 commencement and 22.4% of patients had nutritional deficiencies at one year, most commonly vitamin D deficiency.[9]

[7] Department of Health, Disability and Ageing, Review of MBS allied health chronic disease management services, updated 23 September 2025, accessed 25 September 2025.
[8] Dietitians Australia, Parliamentary Friends of Nutrition 2025: Nutrition First in GLP-1 Care, accessed 25 September 2025.
[9] Butsch WS et al (2025), 'Nutritional deficiencies and muscle loss in adults with type 2 diabetes using GLP-1 receptor agonists: A retrospective observational study', *Obesity Pillars,* 15 (2025): 100186.

2.39 The Department met with representatives from Dietitians Australia on 9 September 2025. Dietitians Australia noted:

- there are around 7,500 Accredited Practising Dietitians (APDs) in Australia and this number is growing by almost 1000 per year with new graduates entering the APD program
- there was a need to explore and compare the effectiveness of different models of wraparound care and funding, such as group allied health sessions
- that dietitians could play a role in identifying patients with eating disorders and/or disordered eating behaviours, improving safety of prescribing
- that in other countries, such as Switzerland and the UK, there was a requirement for patients to undergo 6 months of lifestyle interventions prior to accessing GLP-1 therapy.

2.40 Some Australian states and territories provide free health coaching to make lifestyle changes, e.g. the New South Wales 'Get Healthy Service',[10] or the Queensland 'My Health for Life' program.[11] For some services, participants can choose the delivery method, such as online, telephone, or in-person delivery, and group or individual sessions. State and territory health services may also provide health coaching for patients with specific conditions, such as cardiac rehabilitation programs, and Queensland's 'Self-Management of Chronic Conditions Service' which uses The COACH Program® and is available to people with coronary artery disease, T2DM, pre-diabetes and chronic obstructive pulmonary disease (COPD).[12]

2.41 The Repatriation PBS (RPBS) restrictions for orlistat require that the "patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available)". The PBS restrictions for T2DM medicines including semaglutide (Ozempic®) do not require patients to engage in any specific lifestyle measures; however, the TGA indication for these medicines generally lists them as an "adjunct to diet and exercise". The PBS restrictions to initiate therapy with evolocumab, inclisiran, or icosapent ethyl, state that "The treatment must be in conjunction with dietary therapy and exercise".

2.42 PBS restriction officers have noted it would be difficult to monitor and ensure compliance with any potential PBS criterion related to medicines being used in conjunction with dietary therapy and exercise. Monitoring could be undertaken by the Department if there was a specific requirement for patients to have a GPCCMP in place and to have accessed MBS dietetic and exercise physiology services. However, accessing these services does not in itself ensure patient compliance and it would

[10] NSW Government, Get Healthy Service, accessed 13 October 2025.
[11] Queensland Government, My Health for Life, accessed 13 October 2025.
[12] Queensland Government, Self-Management of Chronic Conditions (SMoCC) Service, accessed 13 October 2025.

increase the cost of treatment which may impact on equity of access. In addition, relevant specialists, such as endocrinologists, who may prescribe GLP-1s are not able to request a GPCCMP as these plans are only available to GPs.

2.43 The Department met with representatives of the RACGP Obesity Specific Interest Group on 24 March 2025 and 7 August 2025, who advised that the group has reached consensus on models of service delivery for patients with obesity prescribed GLP-1s. The RACGP representatives considered that:

- existing MBS care plans and allied health referral pathways were currently being used by GPs to support patients being prescribed GLP-1s, but that increased education, and prescribing frameworks would be beneficial
- there are shortages in the allied health workforce (exercise physiologists, dietitians, psychologists), particularly in public settings
- the Government could adopt a phased roll-out of subsidised access to obesity treatments, similar to that in the UK, that prioritises patients with high BMI and increased number or severity of weight-related comorbidities
- specific needs for wraparound care should be individualised to the patient
- there was a need to provide patients with obesity and those using GLP-1s with coordinated access to information that would assist them in managing their condition, such as high-quality online health advice; and state and territory and local wraparound care services (e.g. Get Healthy Service, National Heart Foundation Walking Groups, etc.).

2.44 In June 2025, the RACGP Obesity Specific Interest Group wrote to Minister Butler and to the Department providing a proposal, '*Health Equity for All: Addressing the Need for Treatment for People with Obesity in Australia',* which is also endorsed by the Australian and New Zealand Obesity Society (ANZOS) and the National Association of Clinical Obesity Services (NACOS). The proposal recommends (as a first step) that access to funded pharmacotherapies for obesity be prioritised for adults with clinical obesity that meet the following criteria:

- BMI ≥40 kg/m^2, or >35 kg/m^2 for Aboriginal and Torres Strait Islander (First Nations) peoples with adjustments for other specific populations*, and
- Either:
    - At least three serious obesity-related health impairments** regardless of severity, or
    - One severe obesity related health impairment**

*BMI adjustments for specific populations reflect World Health Organisation recommendations (usually reduced by 2.5 kg/m^2 for people of South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds) and consensus agreement for Aboriginal and Torres Strait Islander (First Nations) peoples.

**Obesity-related health impairments include cardiovascular diseases, non-diabetic hyperglycaemia, T2DM, chronic kidney disease, metabolic dysfunction-associated fatty liver disease, obstructive sleep apnoea, obesity hypoventilation syndrome, hypertension, dyslipidaemia, male hypogonadism, polycystic ovary syndrome, and hip or knee osteoarthritis.

Lifestyle interventions and effect on weight regain following GLP-1 discontinuation

2.45 Clinical trials have generally shown substantial weight regain following discontinuation of GLP-1s, but a recent retrospective cohort study using US electronic health record data found relatively stable weight trajectories following discontinuation. The reason for this was unclear but the author's suggested that this may be due to additional weight management efforts used by people in real-world settings, or use of other non-GLP-1 medications.[13] Additional real-world studies may provide further insight into weight regain following discontinuation of GLP-1s.

2.46 Weight regain also often occurs following behavioural weight management interventions. A review of weight regain after behavioural weight management interventions found that weight regain occurred at a rate of around 0.12-0.32 kg/year for intervention versus comparator groups, equating to at least 5 years after the program to reach no difference in weight between the intervention and comparator groups.[14]

2.47 One study considered weight regain for patients randomised to one year of supervised exercise, or supervised exercise plus liraglutide, with assessment at one year-post intervention termination. All patients also participated in a pre-intervention eight-week low-calorie diet. The study concluded that supervised exercise plus GLP-1 therapy reduced weight regain after treatment cessation versus treatment with a GLP-1 alone.[15]

2.48 High discontinuation rates seen in real-world settings may have a significant impact on cost-effectiveness of subsidising GLP-1 treatments. An analysis of US patients using GLP-1s for T2DM in a closed health care plan, found that around 70% of

[13] Gasoyan et al. (2025), 'Changes in weight and glycaemic control following obesity treatment with semaglutide or tirzepatide by discontinuation status', *Obesity*, 33(9):1657-1667.

[14] Hartmann-Boyce J et al (2022), 'Weight regain after behavioural weight management programmes and its impact on quality of life and cost effectiveness: Evidence synthesis and health economic analyses', *Diabetes Obes Metab*, 25(2):526-0535.

[15] Jensen SBK et al (2024), 'Healthy weight loss maintenance with exercise, GLP-1 receptor agonist, or both combined followed by one year without treatment: a post-treatment analysis of a randomised placebo-controlled trial', *eClinicalMedicine,* 69:102475.

patients had discontinued therapy by two years.[16] A UK study found that around 65% of patients using GLP-1s for T2DM had discontinued therapy by two years.[17]

Obesity in Australia

2.49 A large proportion of the Australian population could potentially benefit from use of GLP-1 obesity treatments given the high prevalence of overweight and obesity. While the mainstay of obesity management consists of diet and exercise support, very few Australians are following guideline recommendations for adequate exercise and a healthy diet. As noted in Australia's 'National Obesity Strategy 2022-2032', "The root causes of overweight and obesity are complex and deeply embedded in the way we live. It is not simply a lack of self-control."[18] The reasons for this are complex and include: convenience, ubiquitousness and promotion of unhealthy foods; high cost of healthy foods and their limited availability in some rural and remote areas; limited time for exercise due to work, study and other responsibilities; and the convenience and cost of participating in physical activity.

2.50 Patients who do not follow diet and exercise advice when using a GLP-1 for weight management may experience worse side effects, increased loss of muscle mass, reduced weight loss, and nutritional deficiencies, reducing the benefits of treatment. Conversely, a healthy diet and increased physical activity can improve health outcomes for people even if their weight/BMI does not change.

2.51 In 2022, 34% of Australian adults were living with overweight and 32% were living with obesity (13% were living with severe obesity defined as a BMI ≥ 35 kg/m^2). In 2022, 18% of Australian children and adolescents aged 2-17 years were living with overweight and 8.1% were living with obesity. Rates of overweight and obesity are higher in Aboriginal and Torres Strait Islander people; in lower socioeconomic areas compared to higher socioeconomic areas; and in inner regional, outer regional and remote areas compared to major cities.[19]

2.52 In 2022, based on data from the National Health Survey (NHS), around 78% of adults aged 18-64 years were insufficiently physically active (did not complete at least 150 minutes of moderate to vigorous activity across 5 or more days a week) and also did not meet the muscle strengthening component of the Australian Government 'Physical activity and exercise guidelines for all Australians'. In 2022, around 80-90% of children and adolescents did not meet the physical activity and screen-based

[16] Weiss T et al (2020), 'Real-world adherence and discontinuation of glucagon-like peptide-1 receptor agonists therapy in type 2 diabetes mellitus patients in the United States', *Patient Prefer Adherence*, 14:2337.
[17] Weiss T et al (2022), 'Real-world weight change, adherence, and discontinuation among patients with type 2 diabetes initiating glucagon-like peptide-1 receptor agonists in the UK', *BMJ Open Diabetes Res Care*, 10(1):e002517
[18] Australian Government Department of Health, Disability and Ageing, National Obesity Strategy 2022-2032, 4 March 2022.
[19] Australian Institute of Health and Welfare (AIHW), Overweight and obesity, Updated 17 June 2024, accessed 6 October 2025.

activity components (or physical activity components only for people aged 15-17 years) of these guidelines.[20]

2.53 In 2022, 96% of children and adolescents aged 2-17 years and 94% of adults did not meet the recommended daily serves of vegetables; and 36% of children and adolescents aged 2-17 years and 56% of adults did not meet the recommended daily serves of fruit in the 'Australian Dietary Guidelines'. In 2023-24, 31.3% of the average daily energy intake came from discretionary foods (including sugar-sweetened beverages and alcoholic beverages).[21]

2.54 It is not known what proportion of Australian patients are likely to follow diet and exercise advice provided to assist with weight management. Based on the above information it seems likely that less than 5% of Australians would be following this advice and this may impact on the cost-effectiveness of GLP-1 treatment.

2.55 The PBAC noted inputs from consumers (refer to Section 8) which indicated that many had previously found dietary changes and physical activity to be ineffective, or not sufficiently effective, to manage their weight. Some consumers noted that increased weight made it more difficult to exercise, which in turn led to increased weight gain, creating a 'downward spiral'.

Obesity strategy and Australian clinical guidelines update

2.56 The treatment of obesity in Australia is evolving, with revised clinical definitions and updated clinical guidelines currently being developed. The use of BMI as a measure of overweight and obesity, while practical in a clinical setting, has been criticised as inaccurate for identifying excess adiposity complicating its potential use in a PBS restriction. For example, BMI might overestimate adiposity in people with high muscle mass (such as athletes) and underestimate adiposity in people with low muscle mass (such as those with spinal cord injury).

2.57 There is significant variation between countries with regard to prevalence of overweight and obesity. Addressing the wider determinants of health and creating environments that enable people to consume healthier diets, be physical active and get adequate sleep could reduce the requirement for GLP-1 obesity treatments in Australia and the overall costs of overweight and obesity to the health care system. Microsimulation modelling by the Sax Institute found that significant savings of around $7.44 billion could be achieved by reducing childhood overweight and obesity by 5% by 2030 (from 25% to 20%).[22] However, a system dynamics model exploring the impacts of different interventions on rates of childhood and adolescent overweight and obesity found that most interventions would have very little impact,

[20] AIHW, Physical activity, Updated 17 June 2024, accessed 6 October 2025.
[21] ABS, Food and Nutrients, Released 5 September 2025, accessed 17 October 2025
[22] Carrello J, Lung T and Hayes A (2024), 'Economic benefits of reducing childhood and adolescent overweight and obesity in Australia', *Health Res Pract*, 34(3):e3432421.

with individual interventions only reducing rates by around 0.5% or less, highlighting a need for a suite of interventions across all life stages. A sugar-sweetened beverage tax was the most effective and cost-effective intervention modelled.[23] Other countries have successfully implemented population-level dietary changes, such as in Denmark, where intake of whole grains has increased through the Danish Whole Grain Partnership.[24] Further research is needed to identify the most effective and cost-effective interventions to reduce overweight and obesity in Australia.

2.58 The National Obesity Strategy 2022-2032 provides a framework for preventing, reducing and treating overweight and obesity in Australia. Ambition 3.3 in the Strategy is '*Addressing and treating unhealthy weight while preventing weight stigma'*, with example actions including building the evidence base for pharmacotherapies and improving equitable access to TGA-approved obesity medications.

2.59 In January 2025, a global Commission on Clinical Obesity published in the Lancet Diabetes & Endocrinology proposed two new diagnostic categories of obesity based on objective measures of illness at the individual level (rather than solely using BMI). The Commission proposed 'clinical obesity' "…as a chronic, systemic illness characterised by alterations in the function of tissues, organs, the entire individual, or a combination thereof, due to excess adiposity"; and 'pre-clinical obesity' as being associated with a variable level of health risk, but no ongoing illness.[25]

2.60 The Department is working with Deakin University to update the '*Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults, Adolescents and Children in Australia*'. The draft Guidelines were available for comment in late 2024 and the final updated Guidelines were endorsed by the National Health and Medical Research Council on 3 September 2025. The updated Guidelines, including material to support implementation, are expected to be published in early 2026.

2.61 The draft Guidelines provide advice for four age groups (children, adolescents, young and middle-aged adults, and older adults). Considerations for specific subgroups are also included where evidence is available. The draft Guidelines recommend that pharmacological interventions be considered, where clinically appropriate, as part of a comprehensive treatment program for adolescents and adults with overweight and obesity. No recommendation is provided for children or older adults (>65 years) due to a lack of available data for the population/subgroup.

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[23] Chui SK, et al (2025), 'Insights from a codesigned dynamic modelling study of childhood and adolescent obesity in Australia', *BMJ Public Health,* 3(1):e001164.

[24] Lourenco S, et al (2022), 'The Whole Grain Partnership – How a public-private partnership helped increase whole grain intake in Denmark', *Cereal Foods World*, 64(3).

[25] Rubino, F, et al., 'Definition and diagnostic criteria of clinical obesity', *The Lancet Diabetes & Endocrinology* 13.3 (2025): 221-262.

Bariatric surgery in Australia

2.62 Bariatric surgery is generally more effective for weight management than currently available GLP-1 treatments but may be less safe.[26] Access in Australia is limited due to high up-front costs for patients, with around 95% of patients accessing surgery privately.

2.63 The draft Australian Clinical Practice Guidelines contain a strong recommendation to consider bariatric surgery for adolescents with severe obesity, and a conditional recommendation to consider bariatric surgery for adults aged to <65 years. The Practice Points note that bariatric surgery may be considered for adults with class 1 obesity (BMI ≥ 30 to 34.9 kg/m^2) and related comorbidities, and people with class 2 or more obesity (BMI ≥ 35 kg/m^2) regardless of comorbidities. For further information on classification of obesity based on BMI, including population-specific cut-offs, please refer to Appendix A in the draft Guidelines.

Access to bariatric surgery

2.64 In Australia, access to bariatric surgery is predominantly through the private sector, with many patients accessing partial financial support for bariatric procedures through private health insurance. Some patients may also be able to claim relevant MBS items (bariatric procedures 31569 to 31581; and anaesthesia item 20791) if they have "clinically severe obesity", defined as BMI of ≥40 kg/m^2, or BMI of ≥35kg/m^2 with other major medical co-morbidities (such as diabetes, CVD, cancer). The MBS Notes for these items state "The decision to undertake obesity surgery remains a matter for the clinical judgment of the surgeon" after noting that different ethnic groups may experience major health risks at BMI threshold below those in the definition.[27]

2.65 A population-based study of bariatric procedures in NSW found inequities in access, including that regional patients undergo surgery at higher rates than rural patients despite obesity being more prevalent in rural areas. Between 2013-14 and 2021-22, private hospital rates for bariatric procedures were 15.6 times higher than public hospital rates and private hospital rates rose 92.3%, while public hospital rates declined 17.9%.[28]

2.66 The 2024 Annual Report of the Bariatric Surgery Registry has found declining rates of primary bariatric procedures in Australia, with rates having peaked in 2021. In 2024, there were 15,983 completed bariatric surgery procedures, of which 13,141 were primary procedures (77% sleeve gastrectomy and 22% gastric bypass) and 2,842

[26] Klair, N et al. (2023), 'What is best for weight loss? A comparative review of the safety and efficacy of bariatric surgery versus glucagon=-like peptide-1 analogue', *Cureus*, 15(9):e46197.

[27] Department of Health, Disability and Ageing, Medicare Benefits Schedule – Item 31575, accessed 28 September 2025.

[28] Goubar T et al (2025), 'A population-based study of bariatric surgery trends in Australia: Variations reflect continuing inequities in access to surgery', *Obes Surg*, 35(3):1026-1035.

were revision procedures. In 2024, there were 17,294 bariatric procedures recorded in MBS data. In 2024, of people who underwent a primary bariatric procedure around 79% were female, their average age was 42 years, and around 90% had class 2 or 3 obesity (i.e. BMI ≥ 35 kg/m^2). Funding for primary surgery in 2024 was 94.5% private.[29]

Safety and effectiveness of bariatric surgery

2.67 The PBAC did not request that the Department undertake a systematic literature review of the comparative safety and effectiveness of bariatric surgery versus GLP-1 therapy. This section, and the following sections, are intended to provide background information only.

2.68 Bariatric Surgery Registry data indicate that average total percentage weight loss after bariatric procedures in Australia is around 24-31% after one year and 29-35% after four years, depending on the procedure. Of patients on insulin therapy prior to bariatric surgery, 69% no longer needed insulin and 49% required no diabetes medication after one year. For patients on other diabetes medications, 71-78% of patients were off all diabetes medications by one year. After five years, around 61% of patients on prior diabetes treatment, required no diabetes medications.[30] For patients with T2DM, bariatric surgery typically results in reductions in HbA1c of around 2%.[31]

2.69 Bariatric Surgery Registry data show that sleeve gastrectomy is the most common primary metabolic bariatric surgery procedure in Australia, however weight loss is significantly better with bypass procedures. Of patients undergoing sleeve gastrectomy in 2023-24, 1.5% reported a complication within 90 days of surgery, such as unplanned admission to ICU or readmission to hospital, but complication rates were higher for bypass procedures. 3.7% of participants in the Registry for which data were available, underwent a subsequent bariatric procedure, of which around 45% were conversion procedures. The most common reasons for subsequent procedures were: reflux, stricture or stenosis; leak from staple line or anastomosis; weight regain; and AGB port replacement. Since the Registry commenced in 2012, 62 deaths have been recorded within 90-days of a primary or revision procedure out of 179,690 Australian procedures.[32] Bariatric surgery is also associated with micronutrient deficiencies and dumping syndrome.

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[29] Monash University, The Bariatric Surgery Registry Annual Report - 2024, July 2025, Report No. 12, Version 1.0, accessed 26 September 2025.

[30] Brown WA et al (2025), 'Metabolic bariatric surgery generates substantial, sustained weight loss and health improvement in a real-world setting', *ANZ J Surg*, 95(5):895-903.

[31] Schauer PR et al (2017), 'Bariatric surgery versus intensive medical therapy for diabetes – 5-year outcomes', *N Engl J Med*, 376(7):64-651.

[32] Monash University and ANZMOSS, Tracking the results of bariatric surgery in Australia from the 2024 Annual Report of the Bariatric Surgery Registry, accessed 26 September 2025.

2.70 A systematic review and meta-analysis of the effects of bariatric surgery on CVD outcomes and mortality, identified 49 studies in adult patients with BMI >30 kg/m^2, and concluded that bariatric surgery showed significant benefits for coronary artery disease (HR 0.68; 95% CI: 0.52-0.91), myocardial infarction (MI) (HR 0.53; 95% CI: 0.44-0.64), heart failure (HF) (HR 0.45; 95% CI: 0.37-0.55), cerebrovascular accident (HR 0.68; 95% CI: 0.59-0.78) and CV mortality (HR 0.48; 95% CI: 0.40-0.57).[33] One US study considering matched surgical and non-surgical patients between 1998 and 2017, found that bariatric surgery in patients with T2DM and obesity was associated with a lower risk of major adverse cardiovascular outcomes (MACE) with all prespecified secondary outcomes showing statistically significant differences in favour of surgery, including all-cause mortality (adjusted HR 0.59; 95% CI: 0.48-0.72) at eight years.[34] A retrospective, matched, controlled cohort study of UK patients similarly found that bariatric surgery was associated with a significant reduction in all-cause mortality (adjusted HR 0·70; 95% CI: 0·55-0·89), as well as significantly reduced risk of hypertension and HF. A significantly reduced risk of CVD was noted only for the gastric bypass group but did not reach statistical significance for all bariatric surgery procedures (adjusted HR 0·80; 95 % CI: 0·62-1·02; P = 0·074).[35]

Comparative effectiveness of bariatric surgery versus GLP-1s

2.71 Most studies comparing GLP-1s to bariatric surgery have concluded that metabolic bariatric surgery results in greater weight loss, noting that these studies generally pooled results across GLP-1s and included patients on early generation GLP-1s that are associated with lower mean weight loss.[36,37]

2.72 One study that considered the effects of GLP-1s (primarily liraglutide) versus bariatric surgery on rates on obesity-related cancers for adults with obesity and diabetes found similar rates between the two groups despite the greater weight loss benefits of bariatric surgery, and concluded that GLP-1s may work through a different pathway than weight loss alone to decrease the risk of obesity-related cancers.[38]

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[33] Chandrakumar H et al (2023), 'The effects of bariatric surgery on cardiovascular outcomes and cardiovascular mortality: A systematic review and meta-analysis', *Cureus*, 15(2):e34723.
[34] Aminian A et al (2019), 'Association of metabolic surgery with major adverse cardiovascular outcomes in patients with type 2 diabetes and obesity', *JAMA*, 322(13):1271-1282.
[35] Singh P et al (2020), 'Impact of bariatric surgery on cardiovascular outcomes and mortality and population-based cohort study', *Br J Surg*, 107(4):432-442.
[36] Barrett TS et al (2025), 'Obesity treatment with bariatric surgery vs GLP-1 receptor agonists', *JAMA Surg*, Sep 17 2025:e253590.
[37] Sarma S and Palcu P (2022), 'Weight loss between glucagon-like peptide-1 receptor agonists and bariatric surgery in adults with obesity: A systematic review and meta-analysis', *Obesity*, 30:2111-2121.
[38] Sagy YW et al (2025), 'Glucagon-like peptide-1 receptor agonists compared with metabolic bariatric surgery and the risk of obesity-related cancer: and observational, retrospective cohort study', *eClinicalMedicine*, 83: 103213.

2.73 One study using real-world administrative health data (TriNetX data) that considered comparative cardiovascular (CV) outcomes concluded that there was a lower risk of adverse CV outcomes, coronary artery disease, cerebrovascular disease and incident HF after metabolic bariatric surgery versus GLP-1 therapy for ≥2 years in adults with BMI ≥35 kg/m^2.[39] Another observational study considering comparative effects of metabolic bariatric surgery versus GLP-1s in patients with type 2 diabetes and obesity on microvascular and macrovascular outcomes also found a reduced incidence of all-cause mortality (adjust HR 0.68; 95% CI: 0.48-0.96) and significantly lower risks for MACE, nephropathy and retinopathy with bariatric surgery. The study concluded that bariatric surgery was superior to early generation GLP-1s and that comparative studies with newer GLP-1s with more effective weight reduction were warranted.[40]

2.74 An observational, retrospective cohort study found a lower risk of incident congestive heart failure for adults with diabetes and obesity with metabolic bariatric surgery than GLP-1 use (adjusted HR 0.43; 95% CI: 0.27-0.68). Patients were identified who initiated therapy between 2018 and 2021, and were followed for a median of 6.6 years. The effect was maintained after adjusting for weight reduction, indicating that the effect was not mediated through the greater weight reduction associated with bariatric surgery. The study concluded that comparative longer-term studies for newer generation GLP-1s were warranted.[41]

Use of metabolic bariatric surgery with GLP-1 therapy

2.75 In the USA, one study found that 14% of patients who had undergone bariatric surgery commenced a GLP-1 within 5 years of surgery, with GLP-1 initiation greater among those who had sleeve gastrectomy, those with T2DM, and those who experienced less post-surgical weight loss.[42]

2.76 The Australian Bariatric Surgery Registry indicates that there are declining rates of bariatric revision procedures, which have been suggested to be due to increasing use of pharmaceutical weight loss options for these patients rather than opting for bypass surgeries.[43]

2.77 A systematic review and meta-analysis of the safety and effectiveness of GLP-1 use (liraglutide daily 3 mg or semaglutide 1 mg once-weekly) in patients with weight

[39] Maan S et al (2025), 'Metabolic and bariatric surgery versus glucagon-like peptide-1 receptor agonist therapy: A comparison of cardiovascular outcomes in patients with obesity', *Am J Surg*, 242:116242.
[40] Gasoyan H et al (2025), 'Macrovascular and microvascular outcomes of metabolic bariatric surgery versus GLP-1 receptor agonists in patients with diabetes and obesity', *Nature Medicine*, published 16 September 2025.
[41] Sagy YW et al (2024), 'Effectiveness of metabolic bariatric surgery versus glucagon-like peptide-1 receptor agonists for prevention of congestive heart failure', *Nature Medicine*, 30:2337-2342.
[42] Kim M, Schweitzer MA and Kim JS (2025), 'Use of glucagon-like peptide-1 agonists among individuals undergoing bariatric surgery in the US', *JAMA Surg*, 2025:3089.
[43] Monash University, Fewer Australians having bariatric surgery: Monash University-led report, 21 August 2024, accessed 26 September 2025.

regain or insufficient weight loss after bariatric surgery concluded that GLP-1s were safe and effective.[44] One included trial, the BARI-OPTIMISE trial, a small placebo -controlled RCT of once-daily liraglutide 3 mg for patients with poor weight loss following bariatric surgery (≤20% after one year from surgery) demonstrated that liraglutide treatment resulted in a mean difference in percentage body weight of around -8%.[45]

2.78 The PBAC noted inputs received from several consumers who indicated that they were using GLP-1s post-bariatric surgery, as the bariatric surgery was ineffective for them in achieving weight loss, or the benefits were not sustained over time (refer to Section 8).

2.79 GLP-1s have been suggested as an alternative to bariatric surgery, or for use in addition to bariatric surgery, for patients who require weight loss to be eligible for solid organ transplant.[46]

Use of PBS-listed GLP-1s outside of PBS restrictions

2.80 The PBAC has previously advised that there is likely to be a high risk of use of GLP-1 obesity treatment outside of any potential PBS restrictions. This is supported by the current high use of GLP-1s for T2DM outside of the PBS restrictions. It may be important to ensure potential PBS restrictions for GLP-1 obesity treatments are framed in way that allows for compliance activities, is supported by strong risk sharing arrangements, and that usage is monitored closely.

2.81 A Drug Utilisation Sub-Committee (DUSC) review of utilisation of medicines for the treatment of T2DM through the PBS (September 2022) found:

- From 2017 to mid-2022, 18% of people initiating GLP-1 therapy were not supplied metformin, a sulfonylurea or insulin prior to or at initiation, indicating clear use outside of the PBS restrictions.
- According to analysis of the prevalent population in 2021, almost 60% of people supplied a GLP-1 received this medicine in a regimen that is inconsistent with the PBS restrictions:
    - 42% were supplied a GLP-1 in combination with another GLP-1, a di-peptidyl peptidase-4 (DPP4) inhibitor, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, or a combination of these medicines.

[44] Esparham A et al (2024), 'Safety and efficacy of glucagon-like peptide-1 (GLP-1) receptor agonists in patients with weight regain or insufficient weight loss after metabolic bariatric surgery: A systematic review and meta-analysis', *Obesity Reviews*, 25:e13811.
[45] Mok J et al (2023), 'Safety and efficacy of liraglutide, 3.0 mg, once daily vs placebo in patients with poor weight loss following metabolic surgery: the BARI-OPTIMISE randomised clinical trial', *JAMA Surg*, 158(10):1003-1011.
[46] Roddy KL et al (2025), 'Obesity treatment as a bridge to solid organ transplantation: A comparison of bariatric surgery to medical therapy', *Obesity Pillars*, 16: 100199.

- 27% were supplied a GLP-1 without concomitant use of metformin, a sulfonylurea or insulin.
- 9.5% crossed both above categories (i.e. were supplied a GLP-1 in combination with another GLP-1, a DPP4 inhibitor, or an SGLT2 inhibitor; and without concomitant metformin, sulfonylurea or insulin).[47]

2.82 On 1 June 2024, changes were made to the PBS restrictions for GLP-1s to ensure use in accordance with the PBS restrictions and align the restrictions with current clinical guidelines while considering the cost-effectiveness of comparative treatments. The authority type for therapy initiation for GLP-1s was changed to an Authority Required (telephone/electronic) listing, with continuing access to GLP-1s via an Authority Required (STREAMLINED) listing. GLP-1s are only PBS-subsidised for use in combination with at least one of: metformin, a sulfonylurea, or insulin.

2.83 A later DUSC review of semaglutide utilisation (June 2024), identified increasing use of PBS semaglutide in patients aged 20-39 years, which the DUSC considered suggested use for weight loss and other reasons such as fertility. The review also found that 12% of patients who initiated semaglutide in 2023 had no prior supplies of any other diabetes medicine, and that this had increased from 10% in 2022. Of patients supplied a GLP-1 in 2023, 42% were not supplied concomitant metformin, a sulfonylurea or insulin in line with the PBS restrictions.[48]

2.84 In November 2024, the Department dispatched approximately 400 letters to approved pharmacists where they had consistently claimed high volumes of semaglutide since April 2022 despite the global shortage. The purpose of this letter was to remind pharmacists that compounded replica versions were not claimable and to ensure they do not make a claim where there has not been a supply to a patient.

2.85 In March 2025, the Department dispatched over 1,000 letters to medical practitioners who have prescribed semaglutide (Ozempic®) through the PBS to patients with no history of T2DM, to remind them that prescribing off-label must be private (not PBS).

2.86 **Redacted text.**

Adverse events and side effects of GLP-1s

2.87 Potential adverse events or side effects associated with GLP-1 use include:

- gastrointestinal effect, such as nausea, vomiting, diarrhoea and constipation

[47] Department of Health, Disability and Ageing, DUSC Review: Medicines for the treatment of type 2 diabetes, September 2022, accessed 26 September 2025.
[48] Department of Health, Disability and Ageing, DUSC Review: Analysis of semaglutide for type 2 diabetes mellitus, June 2024, accessed 26 September 2025.

- dehydration and malnutrition
- gastroparesis
- acute pancreatitis
- pulmonary aspiration for patients under general anaesthesia or deep sedation
- suicidal behaviour and ideation
- delayed effects of oral medical products, which may be particularly important for medicines where rapid onset of effect is required
- reduced efficacy of oral contraceptives
- reproductive toxicity and excretion in breast milk based on animal studies
- thyroid cancer
- non-arteritic anterior ischaemic optic neuropathy (NAION).[49,50,51]

3 Epidemiological modelling

3.1 The PBAC noted a report developed by the Department containing preliminary population estimates for potential groups for priority access to GLP-1 obesity treatments, based on the advice of the PBAC Working Group. Further information on data sources, codes used, issues/caveats, and further work, are provided below.

Background: Advice from the PBAC Working Group

3.2 The PBAC Working Group provided advice on the population cohorts to be modelled. In providing this advice, the Working Group considered:

- the previous PBAC advice provided to sponsors about the appropriate populations for access to obesity treatments
- current TGA indications for obesity treatments
- a proposal on proposed populations for access to obesity treatments provided by the RACGP Obesity Specific Interest Group
- populations with subsidised access to obesity treatments in the UK
- other potential priority populations identified by the Department through journal and media articles, letters to the Minister, consumer comments on previous PBAC items, and previous PBAC advice.

[49] Australian Product Information, Mounjaro® (tirzepatide) solution for injection, vA10.0, September 2025, accessed 9 December 2025.
[50] Manne-Goehler J. (2025), 'Side effects of GLP-1 receptor agonists', *BMJ*, 390:r1606.
[51] Muller DRP et al. (2023), 'Effects of GLP-1 agonists and SGLT2 inhibitors during pregnancy and lactation on offspring outcomes: a systematic review of the evidence', *Frontiers in Endocrinology*, 10(14):1215356.

3.3 Other potential priority populations for access to obesity treatments may include:

- people with monogenic obesity e.g. mutations in the leptin-melanocortin pathway
- people with syndromic obesity e.g. Prader-Willi syndrome
- people with disability e.g. spinal cord injury
- people with medical conditions that cause weight gain, e.g. hypothyroidism, polycystic ovary syndrome (PCOS)
- people using medications that cause weight gain, e.g. anti-psychotics, steroids
- people with severe mental health illness experiencing weight-related comorbidities
- adolescents and young adults with obesity
- Aboriginal and Torres Strait Islander adolescents on a growth trajectory towards obesity
- people on low incomes, unable to afford to access GLP-1 therapy privately.

3.4 The Working Group agreed that the modelling work could be undertaken using the Person Level Integrated Data Asset (PLIDA) linked to the 2022 National Health Survey (NHS) and the National Aboriginal and Torres Strait Islander Health Survey (NATSIHS) 2022-23, and the 2021 Census of Population and Housing (for cultural/ethnicity data).

3.5 The Working Group agreed to model the following cohorts:

- People with BMI ≥35 kg/m^2, or with BMI ≥32.5 kg/m^2 for all ethnicities considered to be at higher cardiometabolic risk (including Aboriginal and Torres Strait Islander, Asian, Arab, African, Black Caribbean, Pacific Islander, or other First Nations ethnicity), AND any of the following 'restrictive' list of co-morbidities:
  - established cardiovascular disease (CVD), OR
  - chronic kidney disease (CKD), OR
  - type 2 diabetes mellitus (T2DM), OR
  - obstructive sleep apnoea (OSA).
- Aboriginal and Torres Strait Islanders with BMI ≥32.5 kg/m^2.
- People with BMI ≥35 kg/m^2, or with BMI ≥32.5 kg/m^2 for all ethnicities considered to be at higher cardiometabolic risk (see above), AND
  - ≥ 5 weight-related comorbidities
  - ≥ 4 weight-related comorbidities
  - ≥ 3 weight-related comorbidities
  - ≥ 2 weight-related comorbidities
  - ≥ 1 weight-related comorbidity.

3.6 For the analysis above considering the number of weight-related comorbidities, the PBAC Working Group recommended the following 'broader' list be included:

- CVD (included in 'restrictive' list)
- CKD (included in 'restrictive' list)
- T2DM (included in 'restrictive' list)
- OSA (included in 'restrictive' list)
- Dyslipidaemia
- Prediabetes
- Fatty liver disease
- Polycystic ovary syndrome (PCOS)
- Hip and knee osteoarthritis
- Hypertension
- Male hypogonadism.

3.7 The PBAC noted the NHS/NATSIHS codes related to these comorbidities and used for the population modelling. For many conditions, specific codes were not available and broad codes that may have included additional conditions were used.

3.8 The Working Group members agreed to model two definitions of CVD in the preliminary analysis. The CVD1 group broadly aligned with people with established CVD (e.g. prior stroke or myocardial infarction) and CVD2 group contained people with risk factors for CVD. These groups are not mutually exclusive, i.e. some patients may be counted in both groups.

3.9 The PBAC noted that the Census cultural and ethnic groups selected to be included in the lower BMI threshold category for modelling were based on the:

- 'Australian guideline and calculator for assessing and managing cardiovascular disease risk'[52]
- any First Nations groups (Māori and Pacific Islander peoples were included based on a New Zealand study[53])
- any groups identified in Caleyachetty R et al, 2021[54] as having a BMI threshold for obesity less than White/European populations (e.g. Asian, Arab, Black Caribbean, African)

[52] Department of Health and Aged Care. Australian Guideline for assessing and managing cardiovascular disease risk. '3a. Reclassification factors and other considerations'. 2023.
[53] Pylypchuk, R et al. (2018), 'Cardiovascular disease risk prediction equations in 400 000 primary care patients in New Zealand: A derivation and validation study', *The Lancet*, 391(10133):1897-1907.
[54] Chaleyachetty R et al (2021), 'Ethnicity-specific BMI cut-offs for obesity based on type 2 diabetes risk in England: a population-based cohort study', *The Lancet*, 9(7):419-426.

- people of Hispanic ethnicity.[55,56]

3.10 The PBAC Working Group noted:

- Given the large number of ethnicities potentially at higher cardiometabolic risk than White/European populations, there may need to be a pragmatic solution regarding wording for any potential PBS restriction.
- It may be challenging for prescribers and Services Australia to determine ethnicity and interpret PBS restrictions related to this patient characteristic.
- It would be difficult to undertake PBS compliance activities related to BMI.
- The modelling work could be used to highlight the potential limitations of the available datasets and data collection to inform compliance with PBS restrictions.
- Other measures such as waist circumference or waist-to-hip ratio may be more accurate than BMI in determining obesity. However, it was acknowledged that BMI was the most used measure by Australian health practitioners. It was considered that as obesity treatment develops, the appropriateness of using BMI may need to be reviewed.
- There is potential disagreement between studies regarding populations at higher cardiometabolic risk.
- The Census data used self-identified cultural/ethnic group. People may identify differently for health risk purposes than their cultural identity for the Census survey, creating a level of uncertainty in these estimates. However, the Census is the only data source that can be linked to PLIDA that provides information on ethnicity, apart from Aboriginal and Torres Strait Islander status.

3.11 The recent publication by the global Commission on Clinical Obesity published in the Lancet Diabetes & Endocrinology notes that BMI is a useful screening tool but that there should be verification of excessive/abnormal adiposity by direct body fat measurement or an additional anthropometric criterion, such as waist circumference. The article defines clinical obesity as "…a chronic, systemic illness characterised by alterations in the function of tissues, organs, the entire individual, or a combination thereof, due to excess adiposity…. The diagnosis of Clinical Obesity requires:

- Clinical confirmation of obesity status by anthropometric criteria or by direct body fat measurement,

[55] Esparza-Hurtado N et al (2024), 'Novel BMI cutoff points for obesity diagnosis in older Hispanic adults', *Nature Scientific Reports*, 14:27498.
[56] Aggarwal R et al (2022), 'Diabetes screening by rare and ethnicity in the United States: Equivalent body mass index and age thresholds', *Ann Intern Med*, 175(6):765-73.

- Plus one or both of the following criteria:
  - Evidence of reduced organ/tissue function due to obesity (i.e., signs, symptoms and/or diagnostic tests showing abnormalities in the function of one or more tissue/organ system),
  - Significant, age-adjusted limitations of day-to-day activities reflecting the specific impact of obesity on mobility and/or other basic Activities of Daily Living (ADL=bathing, dressing, toileting, continence, eating)".[57]

3.12 Similarly, the Edmonton Obesity Staging System (EOSS) focuses on functional limitations, psychological symptoms, and the extent of comorbidities associated with excess adiposity, and proposes guidance on the management of obesity based on staging.[58]

3.13 The PBAC Working Group also agreed that population estimates for people with monogenic and syndromic obesity, such as Prader-Willi Syndrome (PWS), should be sought as this was a narrow patient population with clear benefit from use of obesity treatment.

Key findings

3.14 The PBAC considered the draft, preliminary population estimates provided by the Department.

3.15 There are a very large number of Australians with obesity-related conditions (**redacted text**…people in 2022) that could potentially benefit from access to GLP-1 treatments. Including a BMI threshold of 35 kg/m^2 has a substantial impact on patient numbers, reducing these…**redacted text**…for many obesity-related conditions. This is important, given BMI has been criticised as a measure of excess adiposity and it would be difficult to undertake PBS compliance activities based on BMI. However, exclusion of a restriction criterion related to BMI (or other measure of excess adiposity) may lead to very large numbers of eligible patients. In addition, it indicates that many people with obesity-related comorbidities do not have a BMI ≥ 35 kg/m^2 (class 2 or 3 obesity), including a substantial proportion of people with multiple comorbidities, including those with CVD and either T2DM or CKD.

3.16 Using a lower BMI threshold of 32.5 kg/m^2 for ethnicities considered to be at higher cardiometabolic risk had a very minor impact on population estimates, with changes generally within the confidence intervals for the population estimates without this threshold adjustment.

[57] Rubino F et al (2025), 'Definition and diagnostic criteria of clinical obesity', *The Lancet Diabetes & Endocrinology*, 13(3):221-262.
[58] Sharma AM and Kushner RF (2009), 'A proposed clinical staging system for obesity', *International Journal of Obesity*, 33:289-295.

3.17 Population estimates for OSA are likely to have been underestimated. No specific code for this condition was available in the survey data and the code used (199999 – Other diseases of the respiratory system) may have led to under-reporting of this condition. A 2016 survey conducted by the National Sleep Foundation reported 8% of Australian adults were diagnosed with OSA.[59]

Population estimates for monogenic and syndromic obesity

3.18 Around 40-70% of the variance in adiposity is likely due to genetic factors. The genetic basis of adiposity is complex and involves many genes with over 500 loci associated with BMI. Polygenic or multifactorial obesity is more commonly associated with later-onset obesity and involves the interplay of genetic, epigenetic, and environmental factors. Monogenic and syndromic obesity are typically associated with early-onset severe obesity, hyperphagia and suboptimal response to nontargeted therapies.[60] Syndromic obesity is also typically associated with dysmorphic features and neurodevelopmental delay.

3.19 Non-syndromic monogenic obesity most commonly involves genetic mutations in the leptin-melanocortin pathway. Monogenic obesity is estimated to account for around 5-6% of individuals with obesity,[61] but a further 7% of individuals with obesity carry potentially obesogenic variants.[62] The most frequent cause is mutations in the melanocortin 4 receptor (*MCR4*) gene, accounting for around 1-6% of cases of early onset or severe adult obesity. Other common causes are mutations in the leptin, leptin receptor (*LEPR*) and pro-opiomelanocortin (*POMC*) genes. A recent study identified that a BMI ≥ 24 kg/m^2 at age 2 years had good diagnostic performance for identifying people with biallelic monogenic obesity, which could be used to prioritise people for genetic testing.[63]

3.20 Setmelanotide (Imcivree®), an MC4R agonist, is approved by the US Food and Drug Administration (FDA) for the treatment of specific genetic forms of obesity (POMC, LEPR, or PCSK1 deficits). Recombinant leptin may be used to treat people with leptin deficiency. Neither setmelanotide nor leptin are registered on the ARTG but could potentially be imported by patients via the TGA's Personal Importation Scheme. GLP-1s may assist in treating obesity in people with monogenic forms. Case studies

[59] Adams RJ et al. (2017), 'Sleep health of Australian adults in 2016: results of the 2016 Sleep Health Foundation national survey'. Sleep Health. 2017 Feb;3(1):35-42.
[60] Futch AK, Malhotra S and Conroy R (2024), 'Differentiating monogenic and syndromic obesities from polygenic obesity: Assessment, diagnosis and management', *Obesity Pillars,* 11:100110
[61] Tamaroff, J et al (2023), 'Prevalence of genetic causes of obesity in clinical practice', *Obes Sci Pract*, 9(5):508-515.
[62] Kunzel R et al (2025), 'Detecting monogenic obesity: a systematic exome-wide workup of over 500 individuals', *Int J Obes*, 49:1400-1411.
[63] Zorn S et al (2025), 'Early childhood height, weight and BMI development in children with monogenic obesity: a European multicentre, retrospective, observational study', *The Lancet*, 9(5):297-305.

in people with *MCR4* variants indicate that GLP-1 treatment results in similar levels of weight loss to patients who do not have *MCR4* variants.[64]

3.21 Assuming monogenic obesity accounts for 5% of obesity in Australian adults and around 10% of obesity in Australian children and adolescents, then approximately 395,000 people in Australia in 2025 may have monogenic obesity (based on Australian Bureau of Statistics population estimates for Australia in 2025 of 5.9 million children and adolescents and 21.7 million adults, and prevalence of obesity in adults of 32% and in children/adolescents of 8.1%). Further research would be needed to accurately estimate the prevalence of monogenic obesity in the Australian population if PBAC considered this a priority population for GLP-1 access. However, a potential PBS restriction requiring patients to have a pathologic variant causing obesity may overwhelm Australia's genetic testing centres.

3.22 There are over 25 syndromic forms of obesity identified, including: Prader-Willi syndrome (PWS), Bardet-Biedl syndrome, Alström syndrome, Smith-Magentis syndrome, WAGR syndrome, Cohen syndrome, Carpenter syndrome, Kallman syndrome, 16p11.2 deletion syndrome and Down Syndrome, among others.[65,66]

3.23 PWS has a birth incidence of 1 in every 10,000-30,000 births. Mortality rates in people with PWS are almost three times higher than rates in people without PWS, with around a third of deaths related to gastrointestinal problems that are likely related to hyperphagia and food-seeking behaviours. Hyperphagia has significant impacts on patient and caregiver quality of life, requiring food security measures and constant supervision.[67] Given high mortality, prevalence is likely to be less than the birth incidence. The Prader-Willi Research Foundation Australia (PWRFA) has provided a response to the consumer comments process for this item supporting a PBS listing for GLP-1 obesity treatments for people with PWS when prescribed by a specialist to manage safety issues specific to this population. PWRFA estimates that there are around 750 individuals with PWS living in Australia. Based on a 2025 Australian population of around 27.6 million, and assuming a prevalence of 1 in 30,000 people, around 920 people with PWS may be living in Australia.

3.24 Smith-Magentis syndrome occurs in around 1 in 25,000 births, and therefore population estimates in Australia are likely to be similar to PWS.

3.25 16p11.2 deletion syndrome has an estimated prevalence of 1 in 3,000 to 10,000, but with variable symptomatic penetrance. Assuming a prevalence of 1 in 7,000, around

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[64] Kalinderi K et al (2024), 'Syndromic and monogenic obesity: New opportunities due to genetic-based pharmacological treatment', *Children*, 11(2):153.

[65] Chen W (2011), 'An overview of monogenic and syndromic obesities in humans', *Pediatr Blood Cancer*, 58(1):122-128.

[66]

[67] Dempsey D et al (2025), 'The burden of illness in Prader-Willi syndrome: a systematic literature review', *Orphanet Journal of Rare Diseases,* 20:374.

4,000 people with 16p11.2 deletion syndrome are expected to be living in Australia in 2025.

3.26 Down syndrome has an estimated prevalence of 5.14 per 10,000 people in Australia,[68] resulting in an estimated population of 14,200 in 2025. The Department could not identify any studies on the use of GLP-1s to treat overweight/obesity in people with Down syndrome. Given the relatively high prevalence of Down syndrome, a clinical trial or publication of case studies examining GLP-1 treatment in this population may be informative.

3.27 The prevalence of Bardet-Biedl syndrome (BBS) varies between countries with estimates ranging from around 1 in 50,000 to 1 in 160,000. People with BBS are typically born with normal weight but 90% develop obesity by 3 years of age. Setmelanotide is approved by the FDA for the treatment of obesity and binge-eating disorders in people with BBS.

3.28 Alström syndrome has an estimated prevalence of 1 in 500,000 to 1 million. WAGR syndrome also has an estimated prevalence of 1 in 500,000.

3.29 Taken together, the Department estimates that around 21,000 people would be likely to be living with a syndromic form of obesity in Australia in 2025. Further work could be done to better estimate this population if requested by the PBAC.

Next steps

3.30 The PBAC Working Group was requested to provide advice on adjustments to the preliminary population estimates, including:

- The codes to be used to define CVD, and whether the CVD1 and CVD2 groups should be merged into a single group or presented separately.
- Preparing an additional table to show the estimated numbers of Aboriginal and Torres Strait Islanders with obesity-related comorbidities (broad list) without a BMI threshold.
- Providing estimates for the number of people with ≥ 1 comorbidity, ≥ 2 comorbidities, etc., for the 'restrictive' list of comorbidities.

3.31 The PBAC noted that the population estimates could be revised based on advice from the PBAC or the PBAC Working Group, and be prepared for publication at a future date, dependent on the advice of the PBAC and agreement by the Minister and the Australian Bureau of Statistics (ABS).

For more detail on PBAC's view, see section 10 PBAC outcome.

[68] Down Syndrome Australia, Statistics, accessed 20 October 2025.

4 International subsidy arrangements for obesity treatments

4.1 The PBAC noted that the Department had not undertaken a systematic review of GLP-1 subsidy arrangements in other countries but had obtained information on subsidy arrangements from relevant articles, reports, and discussions with health agencies in the UK and Canada.

4.2 One review published in 2024,[69] found that 9 out of 13 high-income countries investigated did not provide public coverage for GLP-1s for weight management, including Australia, Belgium, Denmark, Finland, Germany, Italy, Israel, Netherlands, Canada and the USA. However, in the USA, nine US state Medicaid plans provided some coverage for GLP-1s for weight management. The review indicates that total cost and cost-effectiveness have been issues cited by several countries when not subsidising GLP-1s for obesity treatment. The review found that qualified national coverage for semaglutide (Wegovy) for weight management was provided by:

- France: People under the age of 65 years with BMI >35 kg/m^2 after insufficient weight loss with diet and exercise. Reimbursement rate: 65%.
- Iceland: People with BMI >45 kg/m^2, or BMI >35 kg/m^2 and severe comorbidity. Continuation required 5% reduction in body weight at 6 months, 10% at 1 year and 15% at 18 months.
- Japan: BMI >35 kg/m^2, or BMI >27 kg/m^2 and ≥2 weight-related health conditions.
- UK: BMI >35 kg/m^2, or BMI >27 kg/m^2 and ≥1 weight-related health conditions. Patients to receive diet and exercise advice and have tried alternative treatment. Can only be prescribed by obesity specialists at weight management clinics.

4.3 **Redacted text.**

4.4 **Redacted text.**

4.5 **Redacted text.**

4.6 **Redacted text.**

Canada

4.7 In July 2025, Canada's Drug Agency L'Agence des medicaments du Canada (CDA-AMC) recommended the reimbursement of semaglutide (Wegovy) as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with a BMI of ≥ 27 kg/m^2 and pre-existing CVD including conditions characterised by narrowed arteries leading to reduced blood

[69] Dellgren JL, Persad G, and Emanuel EJ (2024), 'International coverage of GLP-1 receptor agonists: a review and ethical analysis of discordant approaches', 404:10455.

flow to the heart, brain, or arms or legs (prior myocardial infarction [MI], prior stroke, or symptomatic peripheral arterial disease [PAD]). Continuation of therapy requires a 5% reduction in BMI or body weight at one year, with reassessment each year to ensure maintenance of weight loss. The conditions for reimbursement include that the cost of Wegovy should be reduced by 67% from the sponsor-submitted price to achieve an incremental cost-effectiveness ratio of CAN $50,000 per quality-adjusted life year (QALY) compared to the current standard of care. [70]

4.8 The Pan-Canadian Pharmaceutical Alliance negotiates medicine costs on behalf of the Canadian provinces, which manage their own health budgets. Semaglutide (Wegovy) is currently listed as 'under consideration for negotiation'.[71] Provincial governments are not obliged to fund therapies recommended by the CDA-AMC and can make their own decisions about funding and access arrangements.

4.9 Patent protection for semaglutide in Canada is set to expire in January 2026, and biosimilar competition is expected to commence in the same year. Generic manufacturer, Sandoz, filed for approval of biosimilar semaglutide with Health Canada in June 2025. Sandoz has not yet confirmed a price for its biosimilar semaglutide but is reported to have indicated that a price reduction of 60-70% of the list price may be expected and there is speculation that semaglutide biosimilars could cost CAN $40-50 per month within a few years as more companies enter the market.[72,73]

United Kingdom (UK)

4.10 The UK National Institute for Health and Care Excellence (NICE) has recently published a position statement on developing reference case extensions in selected disease areas and conditions to support standardised and consistent health economic modelling approaches and inform guidance development. The first disease-specific reference case extension is for management of overweight and obesity and a scope for this work has been published.[74]

[70] CDA-AMC (2025), 'Reimbursement Recommendation: Semaglutide (Wegovy)', *Canadian Journal of Health Technologies*, 5(7): July 2025.
[71] Pan-Canadian Pharmaceutical Alliance, Wegovy (semaglutide), accessed 30 September 2025.
[72] Gonzales F, Semaglutide generics in Canada could reshape pricing as Sandoz prepares for 2026 launch, BPM, 6 August 2025, accessed 30 September 2025.
[73] Foster E, The Unstoppable rise of generics: Sandoz's 70% discount on GLP-1 drugs and the Canadian market's new era, AInvest, 5 August 2025, accessed 30 September 2025.
[74] NICE, Scope for disease-specific reference case extension: Management of overweight and obesity, September 2025, accessed 16 October 2025.

Liraglutide (Saxenda)

4.11 In December 2020, NICE published its technology appraisal guidance for liraglutide (Saxenda). Liraglutide is recommended as an option for managing overweight/obesity alongside a reduced-calorie diet and increased physical activity in adults with:

- BMI ≥35 kg/m^2 (or at least 32.5 kg/m^2 for members of minority ethnic groups known to be at equivalent risk of the consequences of obesity at a lower BMI than the white population), and
- non-diabetic hyperglycaemia (defined as a haemoglobin A1c level of 42 mmol/mol to 47 mmol/mol [6.0% to 6.4%] or a fasting plasma glucose level of 5.5 mmol/litre to 6.9 mmol/litre), and
- high risk of CVD based on risk factors such as hypertension and dyslipidaemia, and
- it is prescribed in secondary care by a specialist multidisciplinary tier 3 weight management service for a maximum duration of two years.[75]

Semaglutide (Wegovy)

4.12 In March 2023, NICE published its technology appraisal guidance for semaglutide (Wegovy) for managing overweight and obesity in adults. Semaglutide is recommended as an option for weight management, alongside a reduced-calorie diet and increased physical activity, for adults with at least one weight-related comorbidity and either: BMI ≥ 35 kg/m^2, or BMI of 30-34.9 kg/m^2 and meeting the criteria for referral to specialist weight management services. BMI thresholds are 2.5 kg/m^2 lower for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds. The guidance recommends considering stopping semaglutide if weight loss is less than 5% after six months. Under the guidance, semaglutide is limited to a two-year duration of use, and must be prescribed within specialist weight management services that provide multidisciplinary care.[76]

4.13 The following issues have been raised with the NICE guidance for semaglutide and its implementation:

- that access to semaglutide is limited due to the restriction to use in specialist weight management services
- that the guidance does not specify the eligible weight-related comorbidities

[75] NICE, Liraglutide guide for managing overweight and obesity – Technology appraisal guidance TA664, published 9 December 2020, accessed 30 September 2025.
[76] NICE, Semaglutide for managing overweight and obesity – Technology appraisal guidance TA875, published 8 March 2023, updated 4 September 2023, accessed 30 September 2025.

- that access is limited to two years given evidence of weight regain after cessation, with Integrated Care Boards (ICBs, i.e. local health area) left to determine if people could be eligible for a subsequent course of treatment
- the total cost of treating the eligible population in an environment of restricted health care resources.[77]

Tirzepatide (Mounjaro)

4.14 In December 2024, the NICE published its technology appraisal guidance for tirzepatide for managing overweight and obesity. Tirzepatide has been recommended for patients with BMI >35 kg/m^2 (2.5 kg/m^2 lower for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African -Caribbean ethnic backgrounds) and at least one weight-related comorbidity. Under NICE guidance, tirzepatide can be used in primary care or specialist weight management services. Due to high budget impact, availability of services and clinical capacity, there will be a phased entry over 12 years. Over this period, NICE will gather real-world evidence on service implementation, cost- and uptake, with a formal review at 3 years.

4.15 In late March 2025, NHS England released its interim guidance for implementing tirzepatide[78] into its weight management pathway, noting full guidance will be issued after the 3-year NICE review. NHS England acknowledges that implementation must be carefully aligned with system capacity, workforce readiness and resource availability to ensure equitable and sustainable access for eligible patients. NHS England has adopted a prioritised cohort approach over 2025-2028, where patient eligibility will increase in stages to approximately 220,000 patients after the first three years. Table 1 shows the cohorts eligible in the first three years.

[77] Kahal H and Walton C (2024), 'A critique of semaglutide (Wegovy®) for obesity management in NICE technology appraisal TA875', *Br J Diabetes*, 24(1):13-15.

[78] NHS England, Interim commissioning guidance: Implementation of the NICE Technology Appraisal TA1026 and the NICE funding variation for tirzepatide (Mounjaro®) for the management of obesity, PRN01879, accessed 30 September 2025.

Table 1: NHS England interim guidance for implementing tirzepatide into weight management - Cohort access groups for implementation in primary care settings

Funding Variation Year[a]	Estimated Cohort Duration	Cohort	Comorbidities	BMI[b] (kg/m^2)
2025/26	12 months	I	≥ 4 qualifying comorbidities[c]	≥ 40
2026/27	9 months	II	≥ 4 qualifying comorbidities[c]	35-39.9
2026 & 2027/2028	15 months	III	3 qualifying comorbidities[c]	≥ 40

Source: NHS England, Interim commissioning guidance: Implementation of the NICE Technology Appraisal TA1026 and the NICE funding variation for tirzepatide (Mounjaro®) for the management of obesity, Table 1 and Table 2, page 7-8.

Notes:

a. Funding variation year refers to financial year.
b. Lower BMI thresholds (usually reduced by 2.5 kg/m^2) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic background.
c. Qualifying comorbidities are:
    - Established atherosclerotic CVD (ischaemic heart disease, cerebrovascular disease, peripheral vascular disease, heart failure)
    - Hypertension – Established diagnosis requiring blood pressure lowering therapy
    - Dyslipidaemia: Treated with lipid-lowering therapy, or with low-density lipoprotein (LDL) ≥ 4.1 mmol/L, or high-density lipoprotein (HDL) <1.0 mmol/L for men or HDL<1.3 mmol/L for women, or fasting (where possible) triglycerides ≥1.7 mmol/L
    - Obstructive sleep apnoea (OSA): Established diagnosis (sleep clinic confirmation via sleep study) and treatment indicated i.e. meets criteria for CPAP or equivalent
    - Type 2 diabetes.

4.16 NHS England has allocated funds to each ICB to allow for phased implementation of pharmacotherapy and supportive weight management services. The allocation was calculated based on obesity prevalence rates at ICB level. ICBs have the flexibility to select which model(s) best meet their populations needs (community-based delivery model; GP delivery model; specialist weight management services with community outreach; and/or specialist weight management services with GP shared-care). NHS England intended to make centrally funded wraparound care services available as an option to all ICBs from June 2025 accessible from primary care setting only for the identified priority cohorts. The NHS also funds a Digital Weight Management Programme available to people with obesity and either diabetes or hypertension, which provides a 12-week online behavioural and lifestyle management support program.[79]

4.17 Following commencement of the roll-out, some ICBs have reported inadequate funding to cover eligible patient populations. Some ICBs are considering further tightening prescribing criteria for tirzepatide to meet budget pressures.[80]

For more detail on PBAC's view, see Section 10. PBAC outcome.

[79] NHS England, The NHS Digital Weight Management Programme, accessed 13 October 2025.
[80] Mahase E (2025), 'Mounjaro: Less than half of England has NHS access to jab months after roll-out, distressing patients and GPs', *BMJ*, 390:r1855.

5 Horizon scanning for obesity treatments

5.1 There are several GLP-1s, including dual and triple agonists, in development; Table 2 provides a sample of these.

5.2 In addition to GLP-1s, there are other treatments or devices that have, or are being, developed for weight management, including:

- Weighted vests, which have been shown to reduce fat mass and waist circumference and increase lean mass, with no effect on body weight.[81]
- Continuous glucose monitoring devices, which may assist people with and without diabetes to understand how food and physical activity affect glucose excursions, encouraging healthier lifestyle choices.
- Hydrogels such as Plenity®, which is approved in the USA for weight management.[82]
- Treatments for hyperphagia, e.g. diazoxide choline has been approved in the USA for the treatment of hyperphagia in patients with PWS.
- Treatments that target other receptors than GLP-1, e.g. bigrumab, a human monoclonal antibody inhibitor of activin type II receptors, which has been shown in phase II clinical trials to reduce fat mass and increase lean mass in people with overweight/obesity and T2DM.[83] Bigrumab is currently being developed by Eli Lilly to preserve muscle mass in patients using GLP-1 obesity treatments.[84]

[81] Bellman J et al (2025), 'Increased weight-load improves body composition by reducing fat mass and waist circumference, and by increasing lean mass in participants with obesity: a single-centre randomised controlled trial', *BMC Medicine*, 23:317.
[82] Aronne LJ (2021), 'Recent advances in therapies utilizing superabsorbent hydrogel technology for weight management: A review', *Obes Sci Pract*, 8(3):363-370.
[83] Kaur M and Misra S (2024), 'Bigrumab: and investigational human monoclonal antibody against activin type II receptors for treating obesity', *J Basic Clin Physiol Pharmacol*, j35(6):325-334.
[84] National Library of Medicine, ClinicalTrials.gov, A study to investigate weight management with bigrumab (LY3985863) and tirzepatide (LY3298176), alone or in combination, in adults with obesity or overweight, accessed 1 October 2025.

Table 2. Sample of GLP-1s in development for the treatment of overweight and obesity (among other conditions)

Drug Name	Sponsor	Action	Development Stage
Orforglipron	Eli Lilly	Oral GLP-1	Phase 3. Aiming for 2025 submission for regulatory approval in the USA[85,86] and late 2026 market launch in Australia.[87]
Retatrutide	Eli Lilly	Tri-agonist of GLP-1, GIPR & GCGR	Phase 3[88]
Cagrilintide + semaglutide	Novo Nordisk	GLP-1 (semaglutide) + amylin and calcitonin receptor agonist (cagrilintide)	Phase 3[89]
Survodutide	Boehringer Ingelheim	Dual GLP-1/GLP-2 receptor agonist	Phase 3[90]
Ecnoglutide	Sciwind Biosciences	GLP-1 with cAMP bias	Phase 3 (injectable)[91] (Oral ecnoglutide in Phase I)
Maridebart cafraglutide	Amgen	Dual agonist of GLP-1 and GIPR	Phase 2[92]/3[93]
Mazdutide	Eli Lilly	Dual agonist of GLP-1 and GCGR	Phase 3[94]
HRS-7535	Jiangsu Hengrui Pharmaceuticals	Oral GLP-1	Phase 3[95]

[85] Eli Lilly, What to know about orforglipron: An investigational oral GLP-1, 8 August 2025, accessed 30 September 2025.
[86] Wharton, S et al (2025), 'Orforglipron, an oral small-molecule GLP-1 receptor agonist for obesity treatment', *New Eng J Med*, 16 September 2025.
[87] Brodie M, 'Lilly's GLP-1 pill lines up TGA pitch', *MedNews*, 17 October 2025.
[88] Naeem M et al (2024), 'Unleashing the power of retatrutide: A possible triumph over obesity and overweight: A correspondence', *Health Sci Rep*, 7(2):e1864.
[89] Garvey, WT et al (2025), 'Coadministered cagrilintide and semaglutide in adults with overweight and obesity', *New Eng J Med*, 393:635-647.
[90] Wharton S et al (2025), 'Survodutide for treatment of obesity: rationale and design of two randomized phase 3 clinical trials (SYNCHRONIZE™-1 and -2)', *Obesity*, 33(1):67-77
[91] Ji L et al (2025), 'Efficacy and safety of a biased GLP-1 receptor agonist ecnoglutide in adults with overweight and obesity: a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial', *Lancet Diabetes Endocrinol*, 13(9):777-789.
[92] Jastreboff AM et al (2025), 'Once-monthly maridebart cafraglutide for the treatment of obesity – A phase 2 trial', *N Engl J Med*, 393(9):843-857.
[93] National Library of Medicine, Clinical Trials.gov, Efficacy and safety of maridebart cafriglutide in adult participants in Japan who have obesity disease (MNARITIME-3-J), accessed 1 October 2025.
[94] Ji L et al (2025), 'Once-weekly mazdutide in Chinese adults with overweight and obesity', *N Engl J Med*, 392:2215-2225.
[95] National Library of Medicine, ClincialTrials.gov, A trial of HRS-7535 tablets in subjects with overweight or obesity, accessed 1 October 2025.

Drug Name	Sponsor	Action	Development Stage
CX11/VCT220	Corxel Pharmaceuticals	Oral GLP-1	Phase 2[96]
Efocipegtrutide	Hanmi Pharmaceuticals	Triple agonist of GLP-1, GIPR and glucagon	Phase 2b[97]
Amycretin	Novo Nordisk	Dual agonist of GLP-1 and amylin	Phase 1b/2a[98]

Abbreviations: cAMP - cyclic adenosine monophosphate; GCGR – human glucagon receptor; GIPR - glucose-dependent insulinotropic polypeptide receptor

5.3 Novo Nordisk holds patent protections in Australia for 'albumin-binding derivatives of therapeutic peptides' including semaglutide and related compounds through to 17 September 2029 (AU2004273573).[99] Eli Lilly holds patent protections for 'GIP and GLP-1 co-agonist compounds' including tirzepatide through to 23 December 2037 (AU2016205435).[100] Novo Nordisk and Eli Lilly hold and have sought several additional patents for these respective molecules, e.g. therapeutic uses and preparation methods, which extend beyond these initial periods. Biosimilars (generics) of semaglutide and tirzepatide may not be available in Australia for several years after expiry of the original compound patents.

5.4 Several liraglutide biosimilars are registered on the ARTG but not yet available for purchase in Australia.

5.5 In Australia, private market prices for semaglutide (Wegovy) have already reduced from launch prices. In August 2024, the launch price for the Wegovy 2.4 mg dose pen was around $460;[101] current prices are around $370 from discount pharmacies.[102] Increased market competition and the entry of semaglutide biosimilars in Canada, expected in 2026 (see Section 4. Canada), are anticipated to reduce market prices for obesity treatments further.

5.6 In addition to their use for the treatment of overweight/obesity, and other TGA -registered indications of T2DM, OSA and reduction in CV risk, GLP-1s are being investigated for use in a variety of other indications. The US FDA approved semaglutide (Wegovy) for the treatment of metabolic-dysfunction-associated

[96] Ji L et al (2025), '743-P: Efficacy and safety of VCT220 in Chinese adults with overweight or obesity', *Diabetes*, 74(S1).
[97] Hanmi Pharmaceutical, Efocipegtrutide ([LAPS]triple agonist), accessed 17 October 2023.
[98] Dahl K et al (2025), 'Amycretin, a novel, unimolecular GLP-1 and amylin receptor agonist administered subcutaneously: results from a phase 1b/2a randomised controlled study', 406(10499):149-162.
[99] IP Australia, Albumin-binding derivatives of therapeutic peptides, accessed 9 October 2025.
[100] IP Australia, GIP and GLP-1 co-agonist compounds, accessed 9 October 2025.
[101] Heaney C, NewsGP, Wegovy launches in Australia, 2 August 2024, accessed 1 October 2025.
[102] Chemist Warehouse, Wegovy 2.4mg/Dose FlexTouch Pen 3mL – Semaglutide, accessed 1 October 2025.

steatohepatitis (MASH) in adults with moderate-to-advanced fibrosis in August 2025.[103] GLP-1s are being investigated for use in CKD, hypertension, neurodegenerative disorders such as Alzheimer's and Parkinson's disease, allergic airways disease, psoriatic arthritis, and substance use disorders, among other conditions.[104] Liraglutide has been investigated as a treatment for unresponsive high-frequency or chronic migraine in patients with obesity.[105]

For more detail on PBAC's view, see Section 10. PBAC outcome.

6 Australian GLP-1 obesity treatment private market estimation

6.1 To estimate the extent of private use of GLP-1s, the number of units of liraglutide, semaglutide and tirzepatide supplied by wholesalers to retail pharmacies between January 2019 and July 2025, was obtained from the Australian Pharmacy Index (API) dataset sourced by IQVIA.

6.2 Monthly PBS prescriptions supplied of semaglutide (Ozempic) between January 2019 and July 2025 was obtained from Services Australia data.[106] PBS-subsidised prescriptions supplied for semaglutide were subtracted from the wholesaler pharmacy sell-in data to determine the likely private market for semaglutide. As pharmacies may hold stock of medicines, and supply dates to pharmacies and PBS dispensing dates may be different, these monthly analyses should be considered indicative estimates of the private market only.

6.3 Figure 1 shows annual wholesaler pharmacy units for liraglutide, semaglutide and tirzepatide between 2019 and 2024, while Figure 2 shows the same data excluding the PBS semaglutide units supplied over this period. In 2024, excluding PBS supplied Ozempic, there were around 4.1 million units of Ozempic (1.2 million), Wegovy (800,000), tirzepatide (1.6 million) and liraglutide (500,000) supplied to pharmacies. This would be sufficient supply for continuous 12 months use for around 340,000 people (4.1 million units/12 months). The actual number of patients supplied one of these medicines privately is likely to be substantially larger due to patients commencing treatment during the period, extending the time between dosages, microdosing, or ceasing therapy after a short time period, e.g. due to adverse events or cost.

[103] US FDA, FDA Approves Treatment for Serious Liver Disease Known as 'MASH', 15 August 2025, accessed 1 October 2025.
[104] Drucker D (2025), 'GLP-1-based therapies for diabetes, obesity and beyond', *Nature Reviews*, 24:631-650.
[105] Braca S et al (2025), 'Effectiveness and tolerability of liraglutide as add-on treatment in patients with obesity and high-frequency or chronic migraine: A prospective pilot study', *Headache*, 17 July 2025.
[106] Services Australia, Pharmaceutical Benefits Schedule Item Reports, accessed 15 September 2025.

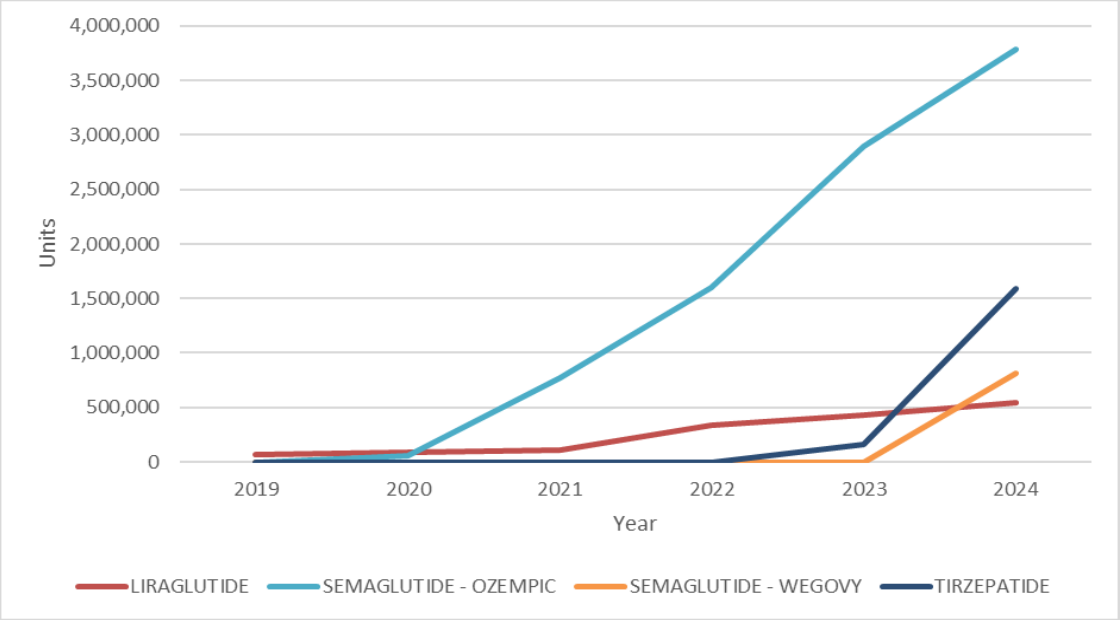

Figure 1: Annual wholesaler pharmacy 'sell-in' packs for semaglutide, liraglutide and tirzepatide (2019-2024)

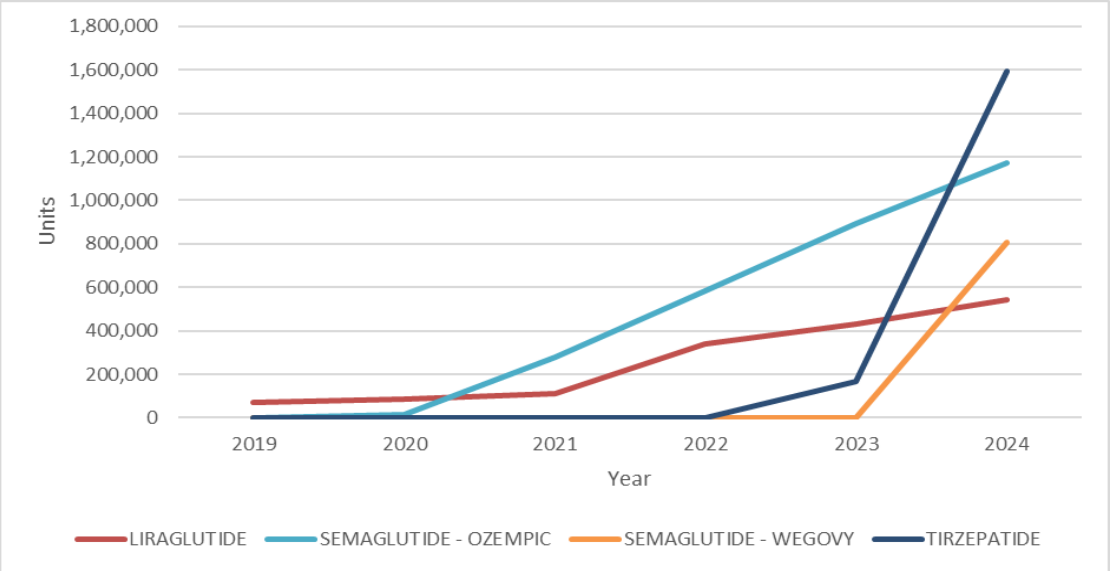

Figure 2: Annual wholesaler pharmacy 'sell-in' packs for semaglutide, liraglutide and tirzepatide, excluding PBS supplied semaglutide (Ozempic) (2019-2024)

6.4 Figure 3 shows monthly wholesaler pharmacy sell-in data for the different semaglutide doses between January 2023 and July 2025, excluding PBS supplies. In late 2024 to early 2025 around 300,000 units per month of semaglutide (total of all strengths) were likely being supplied to Australians on the private market. There appears to be a reduction in use of semaglutide from April 2025, down to around 220,000 units in July 2025, due primarily to a reduction in private market use of 1 mg Ozempic (Figure 4). There also appears to be a reduction in PBS supplied semaglutide over this time period (data not shown).

6.5 Due to shortages of GLP-1s throughout the period, there are some months where PBS supplied semaglutide units exceeded the pharmacy sell-in units (Figures 3 and 4).

6.6 Figure 5 shows the monthly pharmacy sell-in data for tirzepatide between January 2023 and July 2025. In July 2025, around 200,000 units were supplied (total of all strengths).

6.7 Taken together, these data indicate that around 420,000 people received a private market supply of semaglutide or tirzepatide in July 2025.

6.8 Figures 6 and 7 show the wholesaler pharmacy sell-in data dosage breakdown for semaglutide (excluding PBS supplies) for January 2025 to July 2025 for Ozempic and Wegovy (Figure 6), and Wegovy only (Figure 7). The 1 mg dose is the most frequently supplied, followed by the 0.25/0.5 mg dose. This may indicate that few people are titrating up to the higher doses (i.e. maintenance therapy on low dose), that many people are initiating therapy, or that people are ceasing therapy early.

6.9 Figure 8 shows the dose breakdown for wholesaler pharmacy sell-in data for tirzepatide between January 2025 and July 2025. Similarly to semaglutide, low doses are the most used, with the 5 mg dose being most supplied followed by the 2.5 mg dose.

6.10 In Australia, private market data indicate that many people may be using doses of Wegovy and Mounjaro that are below the doses recommended for maintenance weight management therapy. This may be due to cost, tolerability, or because patients are achieving therapeutic goals with lower doses.

6.11 An analysis of a digital weight loss service operating in Australia found that mean program adherence was around 172 days (5-6 months). The most common reasons for discontinuation were: inadequate supply of a patient's desired GLP-1 (43.7%), cost (26.2%), result dissatisfaction (9.9%), and service dissatisfaction (7.2%). BMI was not associated with adherence, but age was positively correlated with adherence. Adherence was higher for people with Caucasian than non-Caucasian ethnicity, which may indicate barriers for equitable access.[107]

6.12 In the US, a retrospective cohort study of adults with overweight/obesity, without T2DM, initiated on semaglutide or tirzepatide between 2021 and 2023, found that around 80% of patients were on low maintenance doses. Around 20% of patients discontinued early (i.e. within 3 months of commencing therapy).[108]

For more detail on PBAC's view, see Section 10. PBAC outcome.

[107] Talay L and Vickers M (2024), 'Patient adherence to a real-world digital, asynchronous weight loss program in Australia that combines behavioural and GLP-1 RA therapy: A mixed methods study', *Behav Sci*, 14(6):480.
[108] Gasoyan et al. (2025), 'Changes in weight and glycaemic control following obesity treatment with semaglutide or tirzepatide by discontinuation status', *Obesity,* 33(9):1657-1667.

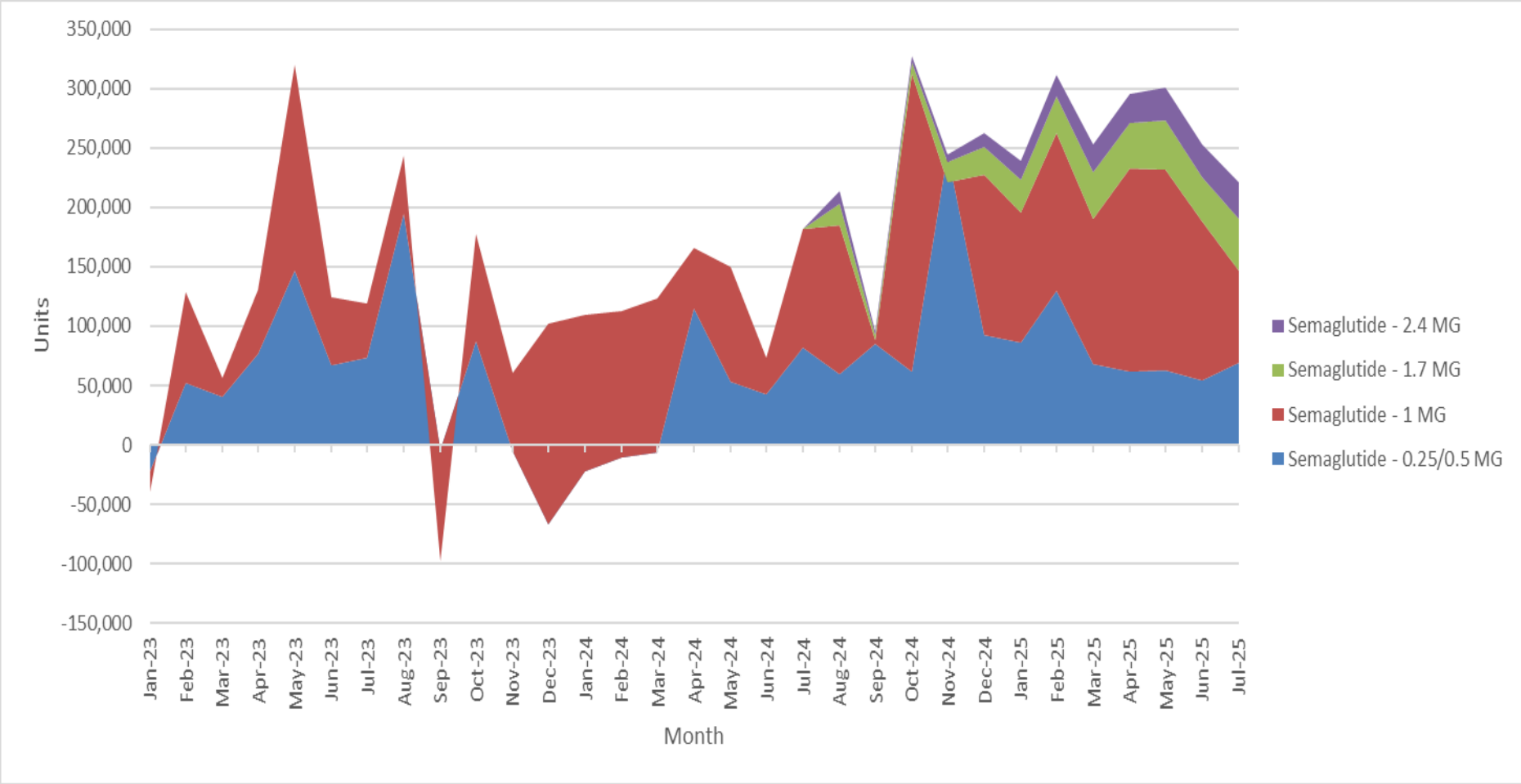

Figure 3: Stacked graph of monthly wholesaler pharmacy sell-in data for semaglutide (Ozempic and Wegovy combined) excluding PBS semaglutide supplied (Jan 2023 to July 2025)

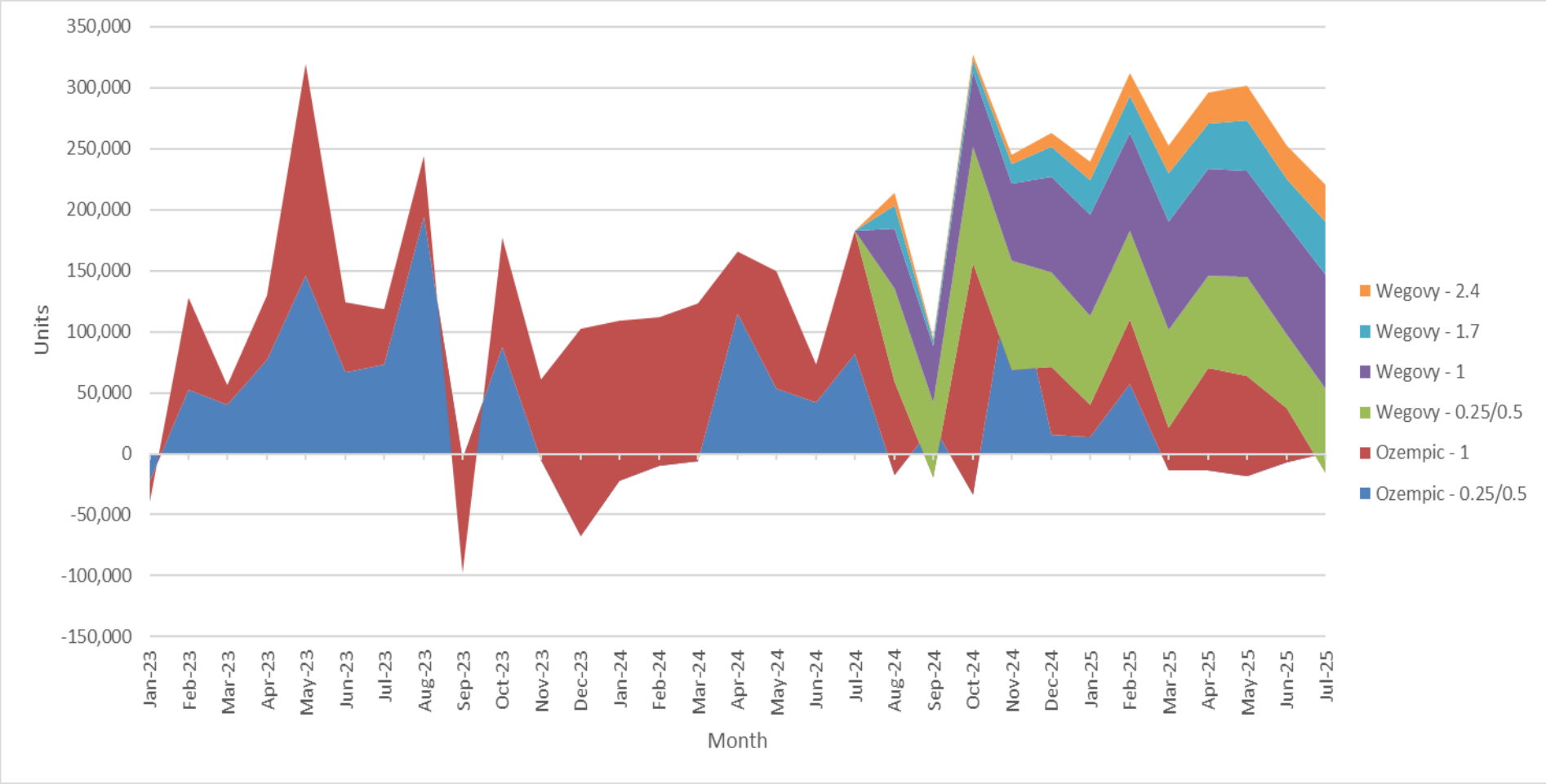

Figure 4: Stacked graph of monthly wholesaler pharmacy sell-in data for semaglutide (Ozempic and Wegovy) excluding PBS semaglutide supplied (Jan 2023 to July 2025)

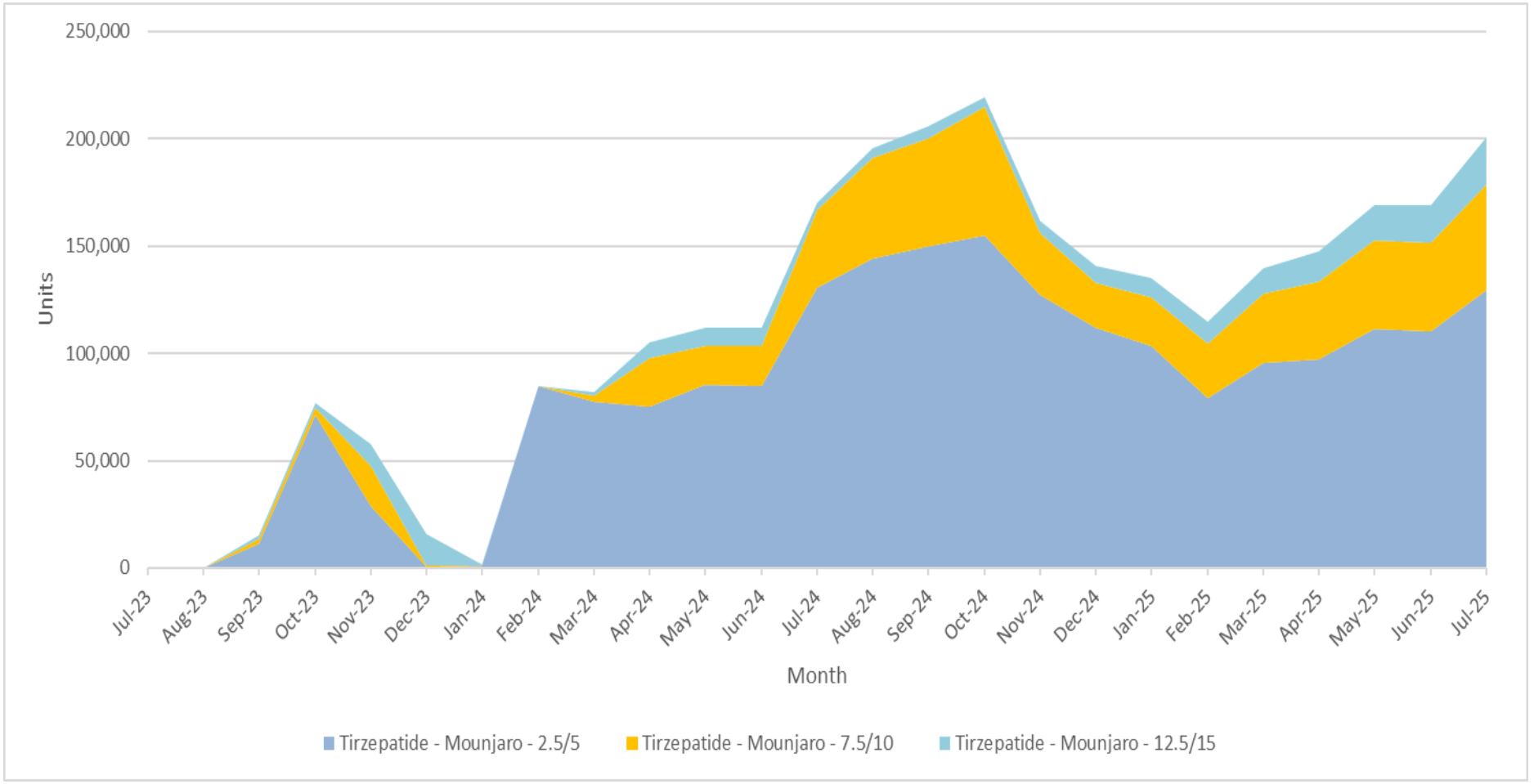

Figure 5: Stacked graph of monthly wholesaler pharmacy sell-in data for tirzepatide (Jan 2023 to July 2025)

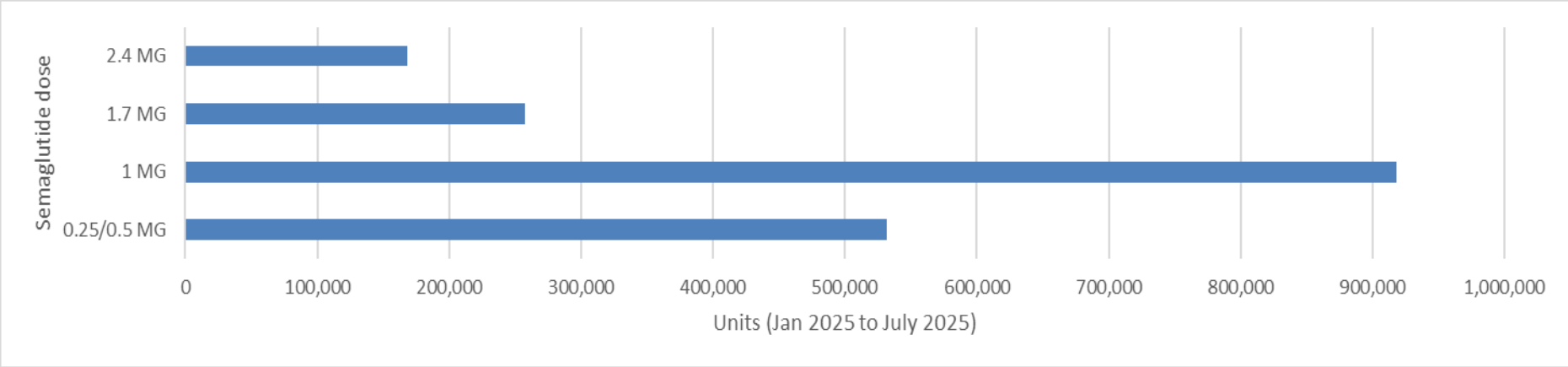

Figure 6: Wholesaler pharmacy sell-in data for semaglutide (Ozempic and Wegovy) by dose (excluding PBS supplies) (Jan 2025 to July 2025)

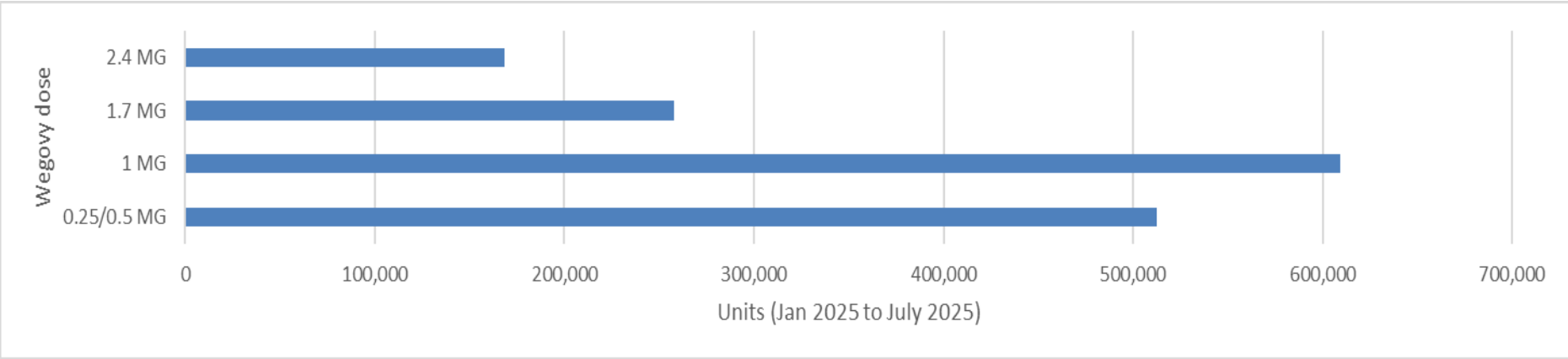

Figure 7: Wholesaler pharmacy sell-in data for semaglutide (Wegovy) by dose (Jan 2025 to July 2025)

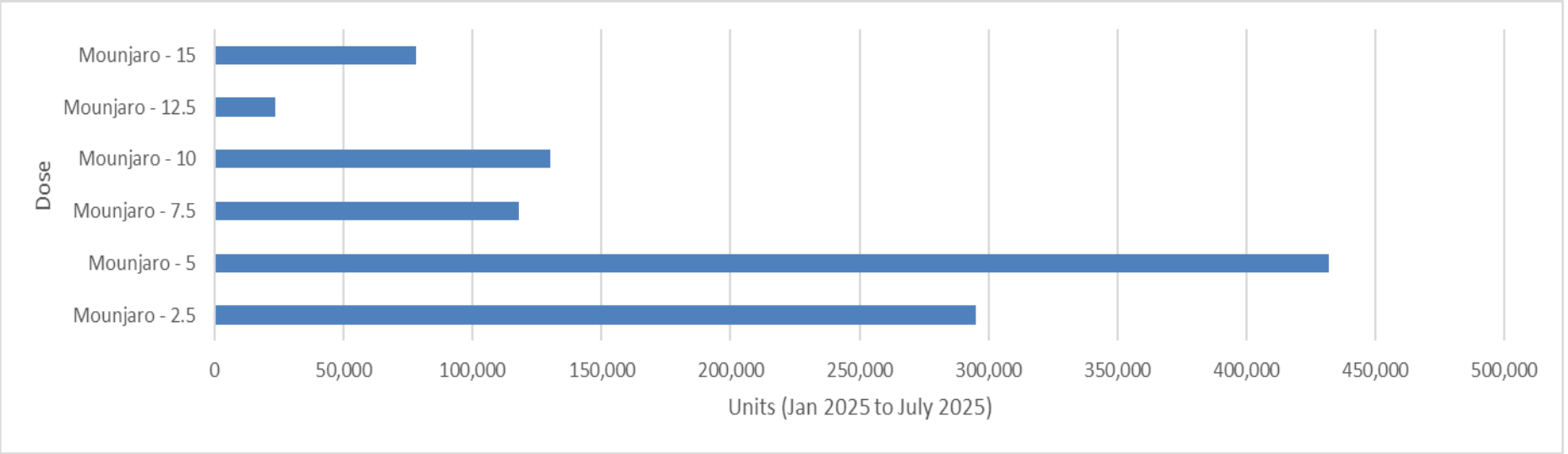

Figure 8: Wholesaler pharmacy sell-in data for tirzepatide by dose (Jan 2025 to July 2025)

7 Stakeholder consultation process

7.1 An item on equitable access to GLP-1 medicines for the treatment of obesity through the PBS was added to the published PBAC agenda on 5 September 2025, with consultations open to 24 September 2025 (2.5 weeks). A PBS News item was published on the PBS website on 5 September 2025, to raise awareness of the public consultation. On 19 September 2025, the Department also wrote to several stakeholders, including consumer and clinical groups, some sponsors of continuous glucose monitoring devices, and weight management service providers to inform them of the public consultation. Some stakeholders without public email addresses were not contacted. The Department provided extensions to stakeholders where requested.

7.2 540 public submissions were received; Table 3 provides a summary of respondents.

Table 3. Public submissions to November 2025 PBAC item on equitable access to GLP-1 obesity treatments

Category	No. of inputs received
Health professional working in the area	25
Individual who has used this medicine for own health condition	459
Individual who would like to access the medicine to treat own health condition, but has never used the medicine	31
Parent or partner of an individual from above two groups	1
Other interested individual (including family members, friends, or members of the public)	1
Medical/other organisation	17
Consumer group/organisation	6
Total	**540**

Note:

1. The number of inputs received per category reflects how contributors have classified themselves.

2. The tally does not include input where only the 'Contact Details' section of the survey was completed.

3. The tally does not include inputs received for item 7.04 (semaglutide for established cardiovascular disease).

7.3 Organisations that provided a response (listed alphabetically) include:

- Aboriginal Medical Services Alliance Northern Territory (AMSANT)
- Amgen Australia Pty Ltd
- Australasian Sleep Association
- Australia and New Zealand Society for Paediatric Endocrinology and Diabetes (ANZSPED) Incorporated
- Australian College of Nurse Practitioners
- Australian Diabetes Society
- Australian and New Zealand Society for Vascular Surgery

- Cancer Council Australia
- Commonwealth Scientific and Industrial Research Organisation (CSIRO)
- Council of Therapeutic Advisory Groups (CATAG)
- Dexcom AMSL
- Diabetes Alliance (representing Diabetes Australia, the Australian Diabetes Educators Association, the Australian Diabetes Society, Breakthrough T1D, the Australasian Diabetes in Pregnancy Society, and the Australian and New Zealand Society for Paediatric Endocrinology and Diabetes)
- Dietitians Australia
- Digital Wellness
- Eli Lilly Pty Ltd
- National Aboriginal Community Controlled Health Organisation (NACCHO)
- National Paediatric Medicines Forum
- Novo Nordisk Pty Ltd
- NT Health
- Patients Australia Limited
- Prader Willi Research Foundation Australia (PWRFA)
- Rural Doctors Association of Australia
- The Obesity Collective (jointly developed with the National Association of Clinical Obesity Services (NACOS), the Australian and New Zealand Metabolic and Obesity Surgery Society (ANZMOSS), the Australian and New Zealand Obesity Society (ANZOS), and the Weight Issues Network (WIN)).

7.4 Due to the large number of submissions, the Department contracted Biotext Pty Ltd to prepare a summary of inputs received via the Office of Health Technology Assessment Consultation Hub for the PBAC. Some members of the PBAC Working Group also considered the unsummarised inputs.

7.5 The Department met with the following stakeholders between April and October 2025 to discuss equitable access to GLP-1 obesity treatments:

- Central Australian Aboriginal Congress
- RACGP Obesity Specific Interest Group
- Canada's Drug Agency L'Agence des medicaments du Canada (CDA-AMC)
- UK National Institute for Health and Care Excellence (NICE)
- Dietitians Australia

- Eucalyptus (telehealth provider operating in Australia and globally)
- Eli Lilly Pty Ltd (sponsor of tirzepatide)
- Novo Nordisk Pty Ltd (sponsor of semaglutide)
- Amgen (sponsor of maridebart cafraglutide).

7.6 Several organisations were provided with a copy of the PBAC Overview paper on 21 October 2025 and invited to provide a pre-PBAC response by 29 October 2025 (1 week), including sponsors of TGA-registered GLP-1 obesity treatments, pharmaceutical representative groups, and peak clinical groups.

8 Consumer inputs

8.1 The PBAC noted and welcomed the input from individuals who have used GLP-1s (459), other individual consumers (33), health care professionals (25) and organisations (23) via the Office of Health Technology Assessment Consultation Hub. The PBAC also noted and welcomed the pre-PBAC inputs received from sponsors (2), pharmaceutical representative groups (1), and peak clinical groups (2).

8.2 The PBAC noted that amongst the inputs received from those who had used these medicines there were four broad categories of consumers:

- People with inherited and genetic causes of obesity.
- People whose obesity was secondary to treatment for another condition (including use of steroids or anti-psychotics, or cancer treatment).
- People who find it difficult to exercise due to their obesity.
- People with comorbidities that reduce their ability to exercise, such as various disabilities and autoimmune diseases that affect joints, such as rheumatoid arthritis and systemic lupus erythematosus (SLE).

8.3 Consumers had a wide range of comorbidities, including CVD, CKD, T2DM, fatty liver disease, endocrine disorders, autoimmune disease, musculoskeletal conditions, OSA and mental health conditions.

8.4 The PBAC noted that some consumers indicated that they had struggled with obesity since childhood, while others associated hormonal changes due to life stage (such as childbirth, and peri- and post-menopause) with more difficulty in managing weight gain and obesity.

8.5 The PBAC noted that reasons cited by consumers and health professionals for using GLP-1 obesity treatments to lose weight included:

- To be eligible for surgery (reduce anaesthesia risk) or to have better outcomes from surgery (improve prehabilitation and rehabilitation).

- To improve physical health and reduce the risk of poor outcomes from comorbidities related to obesity, including prevention of cancer or recurrence of cancer.
- To improve mental health by reducing stigma, anxiety and depression.
- To improve quality of life, by enhancing engagement with family, community, society and work.

8.6 Consumers generally considered GLP-1 obesity treatments more effective for weight loss than their previous diet and exercise regimens. A number who had previously had metabolic bariatric surgery said these medications were effective after their surgical weight loss either plateaued or reversed. Most people talked about benefits to both their physical and mental health with some considering the drugs to be 'life changing'. They noted improvements in blood pressure, cholesterol levels, sleep, breathing and pain, with some able to reduce use of other medications. Consumers also noted psychological benefits including improved mood and a reduction in 'food noise'.

8.7 The PBAC noted that cost was a barrier to accessing GLP-1s for obesity treatment. Some noted that stigma and weight discrimination by healthcare professionals was an issue for access to medication. Consumers noted that there were cost barriers for access to other weight loss measures, such the high cost of healthy food, gym memberships and wraparound support services. Cost and access issues, for both GLP-1s and wraparound supports, may be exacerbated in regional and remote areas. Consumers noted concerns about the potential effects of supply shortages on access to therapy. The cost burden was felt by whole households, particularly where more than one person was accessing these medications, where household sacrifices had to be made to pay for them or people had to continue to work to fund others' access to these medications.

8.8 Several people who had used these medicines talked about cost resulting in them altering their doses in various ways. These included not going onto higher doses as recommended, 'counting clicks' in pre-filled devices to 'microdose' at lower levels and using a syringe to draw off lower doses from larger dosed devices to spread out the interval between prescriptions and reduce cost. Others discussed stopping taking the medications for periods of time when they could not afford it resulting in weight gain. The PBAC noted important quality use of medicines issues associated with these practises in terms of dosing, efficacy, and safety with one input specifically stating that by prolonging their use of each device in this way they were using their medication beyond its shelf-life.

8.9 The PBAC noted that while some consumers mentioned the importance of wraparound support services and a clinical support team, such as a GP, nurse practitioner, dietitian, exercise physiologist or physiotherapist, the majority did not seem to have access to wraparound supports or multidisciplinary care. Some consumers mentioned the use of telehealth and digital weight loss clinics.

8.10 Most consumers noted the gastrointestinal side effects of GLP-1s when starting or changing dose but considered that these were manageable and usually subside. Consumers also noted suicidal ideation and cholecystectomy as adverse effects experienced.

8.11 The PBAC noted the following inputs from health professionals, medical/other organisations and consumer organisations:

- Healthy nutrition and physical activity remain the first-line treatment for overweight and obesity, and it is important to embed the use of GLP-1s within multidisciplinary care models.
- Obesity medications should be prescribed alongside clinically proven lifestyle programs.
- There is a need for action on the social determinants of health, such as poverty, food insecurity, and the high cost of food in remote areas.
- GLP-1 obesity treatments show favourable effects on cardiometabolic risk factors, including waist circumference, glycated haemoglobin, insulin sensitivity, cholesterol, blood pressure, lipid profiles, and may improve liver and kidney health. GLP-1 treatment may therefore lead to a reduction in polypharmacy.
- There are potential long-term benefits to patients and the health care system from subsidised GLP-1 use that results in a reduction in CV events, hospitalisations, complex surgeries, amputations, cancer care, and use of dialysis and specialist services, but it may take several years for these benefits to be realised.
- Obesity is a chronic relapsing condition. GLP-1 treatment would therefore generally need to be long-term, particularly given that cessation of GLP-1 therapy in clinical trials has been associated with weight regain.
- Use of GLP-1s in individuals with overweight/obesity and OSA can reduce treatment complexity, cardiometabolic risk, and pressure on public sleep services, and improve work and road safety outcomes.
- Weight loss associated with GLP-1 use can allow people to live a more active and enjoyable life. Other benefits included improvements in mental health, and increased engagement in employment, education and the community.
- There is limited evidence on long-term efficacy and safety outcomes for GLP-1s used to treat overweight/obesity, particularly for adolescents.
- Gastrointestinal side effects from GLP-1s are usually transient and tolerable, but rare, serious side effects include pancreatitis and gall bladder disease. Patients using GLP-1s may require counselling regarding pregnancy and the potential teratogenic risk.

- Use of GLP-1s may increase anaesthetic risk due to delayed gastric emptying. There is a need to develop guidelines for the management of GLP-1 use prior to surgery or procedures that require fasting.
- Subsidy of GLP-1s should be needs-based with targeted measures to increase access for Aboriginal and Torres Strait Islander people, and other disadvantaged groups.
- If subsidised, there would be a need for clear guidance on patient prioritisation, eligibility and monitoring criteria, and continuation rules to ensure appropriate, equitable and sustainable use of GLP-1 obesity treatments.
- A suggestion to prioritise subsidised access for people who need to lose weight to access life-saving surgery, such as organ transplant, as well as those with very high BMI and either a single life-threatening obesity-related health impairment, or at least three serious obesity-related health impairments.
- A suggestion to prioritise access for Aboriginal or Torres Strait Islander people with BMI ≥ 37 kg/m^2 (or waist circumference ≥ 90 cm for men or ≥ 80 cm for women) and either: CVD, T2DM, or at least two related risk factors.
- For adolescents, it was suggested to restrict access to GLP-1s to people 12 years or over, with initiation restricted to paediatricians or endocrinologists with expertise in obesity management. A national paediatric GLP-1 registry could be established to collect data on long-term safety and effectiveness to address evidence gaps.
- A request for subsidised access to GLP-1 treatments for people with Prader-Willi Syndrome (PWS), restricted to prescribing by an endocrinologist to manage safety concerns. The input notes the high, unmet need in this population and low financial impact of subsidised access due to the small population.
- A request that GLP-1 prescribing be only by medical professionals who have regular contact with the patient.
- A suggestion for a lower BMI threshold for access to subsidised GLP-1 therapy for people living in remote areas, and prioritisation of people with a strong family history of CVD or T2DM.
- A suggestion to follow the UK's prioritised, phased roll-out of GLP-1 obesity treatments.

9 Summary of key issues for PBS subsidy of obesity treatments

9.1 In August 2025, the PBAC Chair and Deputy Chair wrote to Minister Butler providing an update on PBAC's considerations of ongoing issues and risks associated with a potential PBS listing for obesity treatment. The PBAC Chair and Deputy Chair acknowledged that other countries are also experiencing significant challenges in developing public subsidy approaches for obesity treatments, driven by high unmet

clinical need and consumer expectation; uncertainty in the evidence; uncertainty about models of care and system capacity; equity concerns; and opportunity costs at both the population and individual level.

9.2 The PBAC Working Group identified the following key issues for consideration in providing advice on equitable access to obesity treatments:

Clinical need and equity

9.3 There is a high unmet clinical need for obesity treatments and strong consumer interest in subsidy of GLP-1s. Clinical evidence shows potential uses of GLP-1s for a range of weight-related comorbidities, but there is uncertainty on which patients may benefit the most. There are equity issues in prioritising access, as the clinical evidence may not include priority populations including children and adolescents, Aboriginal and/or Torres Strait Islander people, people with disabilities, and those using medications that result in weight gain. In addition to ensuring equitable access to pharmacotherapies, there needs to be equitable access to supportive wraparound care and alternative treatments, such as bariatric surgery, including in regional and remote areas.

Evidence uncertainty

9.4 If GLP-1s are subsidised for obesity patients through the PBS, there is a high likelihood of use outside any restrictions and difficulties with enforcing compliance that may reduce cost-effectiveness. While there are several potential comparative therapies for reducing the risk of cardiovascular events, an important outcome of the use of obesity treatments, there is lack of evidence for comparative effectiveness. Cost-effectiveness is also impacted by uncertainty regarding the dosing and duration of subsidy. Real-world evidence indicates that patients are using lower doses of GLP-1s, ceasing therapy at higher rates, and achieving less weight loss than in clinical trials, but it is unclear if this is due to tolerability or cost.

9.5 While there are some common side effects of GLP-1 use, such as gastrointestinal effects, there remains uncertainty regarding whether these medicines cause an increased risk of several serious adverse events, such as suicide and suicidal ideation, teratogenic effects, pulmonary aspiration during sedation, thyroid cancer and non-arteritic anterior ischaemic optic neuropathy.

Market dynamics and timing

9.6 Obesity medication is a very active field of research, with several new medicines likely to enter the market over the next few years that may provide better outcomes. A potential PBS listing may reduce future opportunities for price competition and negotiation. A PBS listing for a small population cohort may drive prices higher in future, but a broader PBS listing may have a large opportunity cost for the health system. Research indicates that GLP-1s may have a role in treating several other conditions including autoimmune and inflammatory conditions. The potential population for future subsidy may be substantially larger than currently anticipated.

Subsidy mechanism

9.7 High subsidy levels may reduce personal efforts at weight loss, but a means-tested arrangement for higher patient contributions is not available through the PBS. It is unclear if the PBS is the most effective subsidy mechanism, but an alternative subsidy scheme may set a precedent of funding non-cost-effective therapies and would have high set-up costs.

Service delivery models and wraparound care

9.8 There is uncertainty regarding the level of wraparound care, such as diet and exercise counselling, required to achieve cost-effective use of GLP-1s. There are also potential issues with workforce availability, scalability, and equity of access to, and quality assurance of, wraparound care models. There may be potential quality use of medicines issues associated with digital care delivery models that are currently operating in Australia with a focus on prescribing obesity treatments, including fragmentation of care and conflict of interest in prescribing.

Need to capture actionable, real-world data

9.9 There is a need to collect and analyse real-world data on GLP-1 use and outcomes to address evidence uncertainty, and to use this information to inform models of care and subsidy. It would be useful to collect data on: indication, usage (e.g. dose, duration), health outcomes (e.g. weight loss, comorbidities, biomarkers), side effects and adverse events, models of service provision, and total costs and service use.

For more detail on PBAC's view, see section 10 PBAC outcome.

10 PBAC outcome

The PBAC agreed that the following could provide the basis of the advice to be provided to Minister Butler on equitable access to GLP-1 obesity treatments in response to the Minister's questions.

Which Australian cohorts are most likely to benefit from potential availability of obesity medicines through the PBS?

10.1 The PBAC considered that the following population groups should be prioritised for potential future PBS subsidy of GLP-1 obesity treatments and invited submissions from sponsors for these populations:

1. People with established CVD.
2. People with syndromic obesity.
3. Aboriginal and/or Torres Strait Islander people with BMI ≥ 32.5 kg/m^2, and at least one of the following comorbidities: established CVD, OSA, CKD, or T2DM.
4. People with BMI ≥ 35 kg/m^2 using obesogenic medicines, such as anti-psychotics or steroids.

5. People who cannot have safe surgery, or cannot be waitlisted for surgery, due to weight, including renal transplant, hip and knee replacement, or bariatric surgery.

10.2 The PBAC noted that the first of these groups was considered at the November 2025 meeting (patients with established CVD and overweight/obesity).

10.3 The PBAC considered that access to GLP-1 obesity treatments for Aboriginal and/or Torres Strait Islander people meeting the BMI and comorbidity requirements detailed above should be prioritised to assist in meeting Closing the Gap targets. The PBAC also noted that many Aboriginal and Torres Strait Islander people experienced barriers to accessing healthcare, wraparound support services and healthy food in remote areas. The PBAC also noted that epidemiological modelling indicated that this was a relatively small population (**redacted text**).

10.4 The PBAC noted the importance of providing GLP-1 treatments for patients with syndromic obesity, noting the high burden of disease in this patient group and potential benefits to patient and carer quality of life due to reductions in food seeking behaviours. The PBAC noted that this was a relatively small population (estimated 21,000 people based on preliminary Department estimates).

10.5 Regarding prioritisation of GLP-1 access for people requiring weight loss to be eligible or waitlisted for surgery, the PBAC considered that GLP-1 treatment would integrate into existing models of care and that the benefits of treatment were likely to outweigh any potential adverse effects. Estimating this population may be challenging, as patients may not be waitlisted for surgery until they meet BMI thresholds, which may vary by surgeon and procedure.

10.6 The PBAC noted that individuals with schizophrenia and bipolar disorder are at increased risk of cardiometabolic disease. The PBAC considered that some individuals with a mental illness may experience impacts on executive functioning that can make it harder to follow dietary and physical activity plans and/or engage with allied health services. The use of obesogenic antipsychotic medications in these individuals can then further exacerbate weight gain and increase cardiometabolic risk.

10.7 The PBAC noted that the priority populations for access to GLP-1 obesity treatments may need to be revised as new evidence emerges regarding their clinical and cost-effectiveness.

10.8 The PBAC noted that any PBS listing would be subject to the legislative requirements to demonstrate clinical and cost-effectiveness.

Are obesity medicines effective as standalone therapies or best used in combination with other interventions, along with supporting models of care?

10.9 The PBAC noted that all randomised controlled trials (RCTs) included some form of diet and physical activity advice or support for both arms. The PBAC considered that wraparound support services, such as diet and exercise support, and multidisciplinary

care models were an important component of obesity care and that there was a need to address issues affecting access to these services, such as cost and availability.

10.10 The PBAC considered that dietary and physical activity interventions consistent with the TGA-registered indications for these medicines should be encouraged but there should not be any mandatory requirements for use of specific wraparound services for PBS-subsidised access to GLP-1s, as this would create a barrier to accessing therapy. Any such barriers may particularly impact people who were already at higher risk of obesity and its associated comorbidities, such as Aboriginal and/or Torres Strait Islander people, those socioeconomically disadvantaged, and those living in regional and remote areas.

10.11 The PBAC noted that patients are able to access MBS-rebated allied health services through GPCCMPs, however this may attract out-of-pocket fees and has limits on the number and types of services that can be accessed. The PBAC noted that the eligible MBS-rebated allied health services available under the GPCCMP were currently being reviewed by MRAC, and that there were also broader reforms underway for GP practice incentives for patients with chronic conditions to move from fee-for-service to patient-centric funding models.

10.12 The PBAC noted that digital delivery could assist in providing low-cost, scalable wraparound care. The PBAC noted that several private digital wraparound care options were available, but that there was a need to validate the effectiveness of these services. The PBAC considered that PBS subsidy of GLP-1s should not be reliant on the availability of digital wraparound care but considered that if these services were made more widely available, they may help patients to adhere to therapy and maintain the benefits of medicine use. The PBAC considered that funding for these services could be provided through tendering arrangements outside of the PBS/MBS and noted that data collected from these services could potentially be used to inform future subsidy considerations.

10.13 The PBAC noted that several states were already providing free health coaching tailored to the individual, with some offering in-person, telephone or group-based options.

Are they most effectively used as the sole intervention, in association with bariatric surgery, or combination of options?

10.14 The PBAC noted that while bariatric surgery was currently more effective for weight loss, newer obesity treatments in development may be similarly effective. The PBAC considered that there were major barriers to accessing bariatric surgery in Australia including cost and availability.

10.15 The PBAC considered that prior bariatric surgery should not preclude a person from accessing PBS-subsidised GLP-1 treatment, as some patients with sub-optimal responses to bariatric surgery may benefit from treatment.

10.16 The PBAC noted that patients with BMI ≥ 40 kg/m^2 may benefit from GLP-1 treatment prior to bariatric surgery to reduce surgery risks.

What is the optimal duration of subsidisation?

10.17 The PBAC considered that the optimal duration of subsidy was currently unknown and that there was no long-term trial data on use beyond a few years. The PBAC noted that trial data demonstrated weight regain following cessation of therapy, with patients often returning to baseline weight by around two years post-cessation.

10.18 The PBAC considered that it was unresolved whether patients may be able to maintain weight loss on lower doses, or with intermittent dosing (e.g. every two weeks) following achievement of goal weight. The PBAC noted that real-world data indicated that patients tend to use lower doses of GLP-1s than in clinical trials, but it is unclear if this is due to cost, tolerability, or because patients are achieving therapeutic goals at lower doses.

Additional advice – Market dynamics and subsidy mechanism

10.19 The PBAC noted obesity treatments are a very active therapeutic market with several medicines in phase 3 clinical trials and many more in earlier stages of development. The PBAC expressed concern that a PBS listing in the near future may benchmark prices for future listings and this may lead to higher total costs to the PBS if newer medications are listed on a superiority basis. The PBAC also noted the potential for PBS prices to be higher than future private market prices if market competition leads to a reduction in prices.

10.20 The PBAC considered that the PBS, or a single-funder model, was the most appropriate mechanism for subsidy of GLP-1 obesity treatments in Australia. The PBAC considered that subsidy through other mechanisms, such as state-based programs, may lead to more complex and inequitable access.

10.21 The PBAC advised that, if listed, a slow and managed roll-out of access to PBS-subsidised GLP-1 treatments in the Australian health care system would help to manage leakage and uncertainties around long-term use, outcomes and emerging adverse events.

10.22 The PBAC considered that there was a need to develop a model on the cost-effectiveness of preventive therapies that considered societal benefits and productivity, and for incremental cost-effectiveness ratios (ICERs) to be applied consistently across preventive therapies, including vaccines. The PBAC considered that it was important to carefully consider the economic modelling of obesity treatments due to the multiple interacting impacts of treatment and potential for double-counting of benefits.

10.23 The PBAC considered that there may be merit in broader subsidy of GLP-1 medicines for early intervention and prevention of obesity-related comorbidities. However, the PBAC concluded that such a subsidy would need to be established as a program outside of the PBS as it was unlikely that sponsors would agree a cost-effective price

for providing obesity medicines through the PBS for these broader purposes at this time.

10.24 The PBAC considered that if there was future expansion of access to PBS-subsidised GLP-1 obesity treatments from any initial listing, this should be coupled with significant price reductions, particularly when moving to a broader early intervention and/or prevention population.

Additional advice – Potential PBS restrictions

10.25 The PBAC considered that an Authority Required (telephone/electronic) listing would be appropriate for patients receiving their first PBS-prescription for GLP-1 obesity treatments, with subsequent access via an Authority Required (streamlined) listing. The PBAC considered that it would be impractical for Services Australia to process subsequent PBS-prescriptions for semaglutide via an Authority Required (telephone/electronic) listing, due to the likely high volume of requests. **Redacted text.** The PBAC therefore reiterated that there would be a very high risk of leakage outside any potential PBS restrictions for obesity treatments.

10.26 The PBAC noted that while BMI is not a precise measure of excess adiposity and cardiometabolic risk, overestimating it in athletes and underestimating it in people with reduced muscle mass, it remains the most practical measure for assessment of patients in clinical practice. The PBAC considered that the use of BMI in any potential PBS restrictions for GLP-1s may need to be reviewed as clinical practice evolves.

10.27 The PBAC considered that for any future submissions for GLP-1s for obesity treatment, the use of a lower BMI threshold for Aboriginal and Torres Strait Islanders was appropriate to support meeting Closing the Gap targets and address health inequalities for this population.

Additional advice – Data analysis and adverse events

10.28 The PBAC noted that as more people are treated with GLP-1 obesity treatments, there may be an increased number of cases of rare, serious adverse events. The PBAC considered that it would be useful to monitor these medicines for emerging safety signals.

10.29 The PBAC considered that there was a need to collect and analyse real-world data on GLP-1 use to address evidence uncertainty and inform models of care and subsidy.

Outcome:
Advice provided.