



## **A decision-making framework to assist review of GLP-1 applications for management of obesity in the public hospital sector**

There is a high unmet need for effective treatment options for the management of obesity. Glucagon-like peptide-1 (GLP-1)\* therapy offers a promising approach, however, there are challenges in identifying the patient cohorts most likely to benefit and overall cost effectiveness of GLP-1 therapy due to their expected long-term use.

### **PURPOSE**

The decision-making framework below was developed by the Council of Australian Therapeutic Advisory Groups (CATAG), with the assistance of an expert working group, to support Medicines and Therapeutics Committees (MTCs) in decision-making related to the quality use and funding of GLP-1 therapy, when use falls outside the clinical criteria specified in the Pharmaceutical Benefits Scheme (PBS) schedule. The framework draws on insights from recent reviews of GLP-1 therapies in specific populations, including consideration of individual patient use (IPU) / individual patient approval (IPA) applications and formulary requests, to support the translation of the best available evidence into practice.

This framework aims to support consistent, transparent, and evidence-based decision-making by outlining specific factors to consider for GLP-1 IPU/IPA and formulary applications for weight loss in obesity – including clinical efficacy, safety, and cost-effectiveness.

The framework aims to strengthen medicines governance and decision-making for Australian health service organisations, MTCs, and health professionals. As for all medicines, quality use of medicines (QUM) principles should apply when considering these medicines.

This decision-making framework is the result of collaborative input from multiple contributors, aiming to summarise shared understanding and agreement. However, it should not be interpreted as fully reflecting the personal views of every individual involved.

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\* For this document, the term GLP-1s includes both glucagon-like peptide-1 receptor agonists (GLP-1 RAs) such as liraglutide and semaglutide, as well as dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 receptor agonists such as tirzepatide.

## **DECISION MAKING FRAMEWORK TO ASSIST MTC AND FORMULARY COMMITTEE REVIEW OF GLP-1 THERAPY APPLICATIONS FOR MANAGEMENT OF OBESITY**

Requests for the use of glucagon-like peptide-1 (GLP-1) therapy to support weight loss in obesity outside of existing PBS listings requires consideration of the efficacy, safety, cost-effectiveness, place in therapy, equity of access and affordability to support an equitable and sustainable healthcare system.

### **1. GLP-1s should not be considered first line for management of obesity.**

- First-line management for individuals who would benefit from weight loss is comprehensive lifestyle intervention: a combination of diet, exercise, and behavioural modification.
- Initial management should involve an assessment of current medicines that may be associated with weight gain and optimisation of medicines to prioritise the use of medicines that are weight-neutral or support weight reduction, where clinically appropriate.<sup>1</sup>

### **2. The selection of weight-loss therapy should be based on efficacy, safety, and cost-effectiveness, while incorporating patient-specific factors, preferences, adherence considerations, and alignment with evidence-based guidelines.** Comorbidities, risks and contraindications for this treatment should be considered concurrently.

### **3. For use outside of the approved PBS criteria, GLP-1s should only be considered in settings where published evidence demonstrates clinically meaningful and sustainable health benefits in a cost-effective manner.**

- While many individuals may benefit from GLP-1s there is limited information to support cost-effectiveness at a population-level when used outside PBS criteria.
- Obesity is a chronic disease and likely requires chronic management. The long-term health benefits of GLP-1s are known in some but not all circumstances. Evidence suggests maximum weight loss occurs within the first 6-9 months with the subsequent impact on weight loss impact diminishing over time. Cessation of GLP-1 therapy will likely result in rebound weight gain and loss of cardiovascular benefits, within 12 months.
- If GLP-1 therapy is commenced, consider the logistical and financial implications for the individual of maintaining long-term access to GLP-1s .
- In selected individuals where GLP-1s are prescribed, therapeutic objectives should be predefined, including explicit criteria for an adequate treatment response (and continuation) and for treatment failure (and cessation). At treatment initiation and throughout the course of therapy, clinicians should incorporate planning for treatment de-escalation and implement strategies to minimise loss of lean muscle mass. Treatment should be reviewed at prespecified time points to assess ongoing clinical effectiveness and appropriateness.
- Currently public hospital funding for broad or unrestricted use of GLP-1s for ongoing, long-term management of weight loss in obesity is expected to be unsustainable for delivery through the acute hospital sector. It is recommended that access is limited to IPU/IPA approval at a local health service level in exceptional and unique circumstances that clearly define specific, niche patient cohorts where this approach is able to be sustainable and effectively resourced.

### **4. Where possible, GLP-1 pharmacotherapy for the management of obesity should be accompanied by intensive behavioural therapy (IBT) to optimise treatment outcomes and to support consumers with weight maintenance following cessation of the medicine** (consistent with the approaches taken in clinical trials).

- When possible, pharmacotherapy should be accompanied by IBT, through multidisciplinary team support. We note however, that not all areas will have access to multidisciplinary support.

- IBT incorporates setting structured goals for diet and exercise, regular counselling, and routine progress assessments. IBT may also be delivered with the support of online programs and telehealth where local resources are limited.
  - It is important to understand that the clinical trials for these medicines were accompanied by intensive behavioural therapy. The Pharmaceutical Benefits Advisory Committee (PBAC) noted the importance of weight loss to support people's ability to adhere to other cardiac health improving interventions such as exercise and dietary changes.<sup>2</sup>
5. **Further evaluation and research are needed to define those population groups most likely to benefit most from GLP-1 treatment in a cost-effective and sustainable manner.**

## BACKGROUND

Obesity is a significant and growing public health issue in Australia, currently affecting around one-third of adults.<sup>3</sup> It impacts both adults and children, contributes to numerous chronic health conditions, and requires long-term management to sustain weight loss. The World Health Organisation defines obesity in adults as a Body Mass Index (BMI) greater than or equal to 30.<sup>4</sup> Clinical obesity is a chronic, systemic illness characterized by alterations in the function of tissues, organs or the individual, due to excessive and/or abnormal adiposity.<sup>5</sup> For children aged 5–19 years obesity is greater than 2 standard deviations above the WHO Growth Reference median.<sup>6</sup>

GLP-1s have demonstrated efficacy as a pharmacological option for weight loss, particularly as an adjunct to lifestyle and behavioural interventions for people living with obesity. When used appropriately, these medicines can support clinically meaningful weight reduction and improvements in obesity-related health outcomes. CATAG supports evidence-based access to GLP-1s in a manner that prioritises patient safety, clinical appropriateness, cost-effectiveness and long-term sustainability within the health system.

Falster et al reported that since May 2020, total sales of GLP-1s in Australia have increased nearly tenfold. It estimated that 1.8% of Australians were accessing GLP-1s at a standard maintenance dose, with approximated one-third accessing the medicines privately.<sup>3</sup> This surge reflects growing demand for GLP-1s to manage obesity and cardiometabolic conditions.

To support Australians in accessing this important treatment, a consistent quality use of medicines approach for reviewing applications to access GLP-1s is required to support equity of access, particularly for indications outside the Pharmaceutical Benefits Scheme (PBS) listing. It is recognised that GLP-1s may offer significant benefits, including improved glycaemia in type 2 diabetes (T2DM), reduced cardiovascular events, improved outcomes in heart failure and chronic kidney disease, and clinically meaningful weight loss.

In the absence of long-term cost-effectiveness studies, and a PBS subsidy for individuals with obesity for all patients who may benefit from GLP-1s, MTCs have expressed concerns about the financial cost and sustainability of ongoing therapy, continuity of care post-discharge, access to multidisciplinary services that support appropriate use, risk of adverse events and poor long-term data on clinical outcomes. Given their role in chronic disease management, these medicines are commonly managed within primary care that support continuity over time. When hospitals are involved in initiating or continuing long-term therapies such as GLP-1s, it is helpful to consider the associated resource requirements in the context of broader service demands. However, if there is an agreed framework for provision of these medicines equitably across Australia, then hospital and health services are well placed to participate in a coordinated national approach.

At the November 2025 meeting, the PBAC acknowledged the need for obesity treatments and noted evidence supporting GLP-1s for weight-related comorbidities. However, uncertainty remains regarding which individuals derive the greatest benefit, raising equity challenges in prioritising access to medicines, supportive services and complementary interventions across Australia.<sup>2</sup> In March 2026, PBAC identified priority populations for GLP-1 obesity treatments for consideration in any future PBS listing. At the time of writing, no GLP-1s were included on the PBS for obesity management.

The therapeutic landscape continues to evolve, with new formulations and patent changes—such as oral semaglutide (Rybelsus®), approved for weight management by the U.S. FDA in October 2025.<sup>7</sup>

## CURRENT ACCESS IN AUSTRALIA

In Australia, medicines are evaluated by the Therapeutic Goods Administration (TGA) for safety, quality, and efficacy, and a product can only be supplied once it has been granted market authorisation and included on the Australian Register of Therapeutic Goods (ARTG). The following GLP-1s have marketing authorisation in Australia.

This is a rapidly changing space with multiple pending applications to the TGA. As of April 2026, the following information was correct.

TGA-approved indications for GLP-1 RAs on the ARTG:

- **semaglutide** (Ozempic®) and **dulaglutide** (Trulicity®) for the management of adults with type 2 diabetes mellitus (T2DM).
- **liraglutide** (Saxenda® and biosimilars) and **semaglutide** (Wegovy®) for chronic weight management in adolescents and adults who are obese or overweight.
- **semaglutide** (Plosbrio) as an adjunct to standard of care therapy to reduce the risk of sustained decline of kidney function and to reduce the risk of cardiovascular death in adults with type 2 diabetes and chronic kidney disease.

TGA-approved indications for dual glucose-dependent insulinotropic polypeptide (GIP) /GLP-1 RA on the ARTG:

- **tirzepatide** (Mounjaro®) for T2DM or chronic weight management in adults, and for moderate-to-severe obstructive sleep apnoea in adults with obesity.

### Pharmaceutical Benefits Scheme (PBS) listings (April 2026)

- **semaglutide** (Ozempic®) and **dulaglutide** (Trulicity®) are listed on the PBS for the treatment of T2DM. Individuals must not be undergoing concomitant PBS-subsidised treatment for T2DM with any of a sodium-glucose cotransporter-2 (SGLT2) inhibitor (unless prescribed for a different PBS indication), a dipeptidyl peptidase 4 (DPP4) inhibitor, another GLP-1 receptor agonist.
- **Other semaglutide** products and **tirzepatide** (Mounjaro®) are not listed on the PBS.
- **liraglutide** (Saxenda®) is not listed on the PBS.

In 2022 and 2023, the PBAC did not recommend listing semaglutide (Wegovy®) for the treatment of severe obesity due to a lack of strong clinical rationale for the obesity comorbidities selected for inclusion in the proposed PBS listing. The PBAC acknowledged the unmet clinical need for effective weight loss strategies for severe obesity; however, it considered that semaglutide was not cost-effective at the price proposed.

In response to a petition for semaglutide to be listed on the PBS for weight loss in March 2025, the Federal Health Minister requested PBAC provide advice on equitable access to medicines for the treatment of obesity and on the optimal duration of subsidisation, noting the limited long term safety data.

At the November 2025 meeting, PBAC recommended semaglutide (Wegovy®) be subsidised through the PBS for adults with established cardiovascular disease with obesity (i.e. in the secondary prevention setting). Individuals must have already experienced a cardiovascular event such as a heart attack, stroke, or have symptomatic peripheral arterial disease, with limits for access to people with a BMI of 35 kg/m<sup>2</sup> or higher, or 32.5 kg/m<sup>2</sup> or higher for people of Asian, Aboriginal, or Torres Strait Islander ethnicity.

Due to the significant risk that people would access subsidy for semaglutide outside of the proposed PBS criteria, PBAC advised that a risk sharing arrangement with the sponsor was required to adequately manage the expenditure by the Commonwealth.<sup>2</sup>

In July 2025, the PBAC deferred making a recommendation on listing **tirzepatide** on the PBS for the treatment of adults with T2DM and blood glucose levels above target range. The PBAC considered the additional costs were overestimated and disproportionate to the modest additional benefits that tirzepatide might deliver over semaglutide. The PBAC was also concerned that if listed on the PBS, there was high likelihood that tirzepatide would be used for purposes other than for the treatment of T2DM. In March 2026, the PBAC recommended listing tirzepatide on the PBS<sup>8</sup> and requested that arrangements for managing financial risks be progressed separately between the sponsor and the Department of Health, however it is reported that Lilly have withdrawn from pricing negotiations so will not pursue PBS-listing.<sup>9</sup>

On the 17 March 2026, the PBAC released advice on equitable access to GLP-1 obesity treatments.<sup>10</sup> The PBAC determined that PBS subsidy through a single-funder model is the most appropriate approach to support equitable access to GLP-1 obesity treatments in Australia and identified priority populations for consideration in any future PBS listing.

Based on current evidence, the PBAC considered the priority populations to be:

- people with established cardiovascular disease
- Aboriginal and Torres Strait Islander patients with obesity-related comorbidities
- people with syndromic obesity
- people with medication-induced obesity
- patients requiring weight loss to be eligible for surgery.

For further information please see [Pharmaceutical Benefits Advisory Committee \(PBAC\) advice on equitable access to GLP-1 obesity treatments](#).

Whilst the PBAC recommendation is welcomed, it is acknowledged that there are many patient cohorts who may benefit from this treatment but will not be eligible for access under the proposed recommendations. These PBAC recommendations may be useful to consider when reviewing individual patient use (IPU/IPA) applications.

For a summary of [recommendations from international organisations](#) see Appendix 1.

## **INDICATIONS PREVIOUSLY REVIEWED FOR JURISDICTIONAL APPLICATIONS FOR OBESITY**

GLP-1s are widely recognised as an evidence-based pharmacological option for weight management in people living with obesity. Refer to Appendix 2, [Summary of Key Evidence for Weight Loss with GLP-1s](#), for an overview of the supporting evidence.

The information below has been provided to assist in the review of future MTC applications. It is a summary of information that has been shared with CATAG by some participating CATAG jurisdictions and MTCs and is current at the time of publication. It is not an exhaustive list of applications considered by health services nor a comprehensive literature review of all possible indications. As the evidence base continues to evolve, MTCs should conduct their own reviews and deliberations, with the following serving as a preliminary guide.

- **Management of acquired hypothalamic obesity**

Hypothalamic obesity secondary to craniopharyngioma is a relatively rare condition and there is limited evidence for the use of semaglutide in this condition. There is currently no consensus in Australian or

international guidelines on the management of acquired hypothalamic obesity and no head-to-head trials with semaglutide and conventional treatments.

Two case studies<sup>11, 12</sup> and two case series<sup>13, 14</sup> were published over 2023-24, which showed that initiation of **semaglutide** was associated with weight loss of greater than 10% over 6-10 months.

Roth et al led a double-blind RCT, where 42 participants with hypothalamic obesity were randomly assigned to once weekly **exenatide** (2 mg/week; n=23) or placebo (n=19), for 36 weeks.<sup>15</sup> The study failed to demonstrate a significant difference in percentage change in BMI between groups, although there was significant reduction in body fat mass and waist/height ratio in the exenatide group. Further research may help identify ideal timing and populations to achieve the best outcomes.

- **Management of obesity in adolescents**

Obesity is an increasing concern impacting long term health outcomes for children and adolescents and is one of the most common paediatric chronic diseases. In addition to physical and metabolic consequences, obesity in childhood and adolescence is associated with poor psychological and emotional health, increased stress, depressive symptoms, and low self-esteem.<sup>16</sup>

The American Academy of Paediatrics published "[Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity, January 2023](#)" in which the authors recommend paediatricians and other primary health care providers (PHCP), 'may offer children ages 8 through 11 years of age with obesity weight loss pharmacotherapy, according to medicine indications, risks, and benefits, as an adjunct to health behaviour and lifestyle treatment.'<sup>17</sup> No current evidence supports weight loss medicine use as a monotherapy; thus, paediatricians and other PHCPs who prescribe weight loss medicine to children should provide or refer to intensive behavioural interventions for individuals and families as an adjunct to pharmacological therapy.

The Canadian Medical Association published [Managing obesity in children: a clinical practice guideline, 2025](#) which suggests that GLP-1s be considered, in combination with behavioural and psychological interventions, for managing obesity in children aged 12 years and older. There may be a small increased risk in mild to moderate adverse effects with these medicines, but the risk appeared to vary. Most of the evidence supporting this recommendation was derived from children aged 12 years and older. Studies that examined the effects of GLP-1s included concurrent behavioural and psychological interventions, which varied study to study.<sup>18</sup>

A multinational, randomised, double-blind, two-armed, placebo-controlled trial (Weghuber D et al) studied a population of 201 pubertal adolescents, ages 12 to less than 18 years with obesity or overweight and 1 or more weight-related comorbidity.<sup>19</sup> The intervention was weekly injections of semaglutide 2.4 mg versus weekly placebo injections. The trial included a 12-week run-in period of non-pharmacological lifestyle intervention before randomisation for both placebo and intervention groups. The estimated change in BMI percentage from baseline to week 68 was greater with semaglutide 2.4 mg (-16.4%) compared to placebo (0.61%). The estimated proportion of subjects with a 5% or greater reduction in BMI from baseline to week 68 (secondary endpoint) was greater with semaglutide 2.4 mg (77.1%) compared to placebo (19.7%), odds ratio 13.75 (6.31; 30.02) favouring semaglutide.

There is currently no medicine available that can be used as a cost comparator.

- **Management of cardiometabolic adverse effects of antipsychotics**

People with severe mental illness have a reduced life expectancy of between 7-24 years. They are three times more likely to live with obesity and two to three times more likely to die from cardiovascular

disease compared with the general population.<sup>20</sup> Management of cardiometabolic adverse effects of antipsychotics aim to reduce the risk of premature death and weight management may improve compliance with antipsychotic medicines and reduce hospital admissions associated with antipsychotic treatment disruption. Clozapine and olanzapine are noted to have the worst metabolic side effect profiles.<sup>21,22</sup>

The current first line pharmacological recommendation for the prevention and management of antipsychotic-associated weight gain is metformin<sup>22,23</sup>; however, weight loss is modest (approximately 3 kg).<sup>24</sup> Early commencement of metformin with antipsychotic therapy may also reduce the amount of weight gain experienced by 4kg.<sup>23</sup> One multisite RCT (n=148) showed only approximately 17% of overweight people with schizophrenia lost 5% or more of their body weight with metformin.<sup>25</sup>

Evidence is emerging for the use of GLP-1s for the management of antipsychotic-associated weight gain. One observational study for **liraglutide** demonstrated a mean weight loss of approximately 5.3 kg at the end of 16 weeks. This study noted 63.8% of trial participants developed normal glucose tolerance compared with 16% of placebo participants and liraglutide also produced reductions in weight circumference, blood pressure and visceral fat.<sup>26</sup>

There is limited evidence for **semaglutide** in this population group. People with active major depressive disorder, bipolar disorder, or schizophrenia were excluded from the pivotal semaglutide (STEP) trials.

The Australian COaST trial is the only RCT published at this time in individuals treated with antipsychotics. In this small RCT, participants were included if they had stable weight, a BMI above 25 kg/m<sup>2</sup> and were stabilised on clozapine. Sixteen individuals were treated with **semaglutide** up to 2 mg per week compared with 15 control individuals. At 36 weeks, the semaglutide group had a mean body weight reduction of approximately 14% with almost all individuals (93%) achieving more than 5% weight loss within the 36 weeks and 67% achieving more than 10% weight loss from baseline. No meaningful secondary outcomes were reported. No serious adverse events occurred, and low rates of constipation were noted (an important consideration for people taking clozapine).<sup>27</sup>

In the recent INTEGRATE international guidelines for the algorithmic treatment of schizophrenia, it recommended cardiometabolic management in schizophrenia should start with early and proactive monitoring of weight, BMI, waist circumference, blood pressure, fasting glucose, and lipids at treatment initiation and regularly thereafter. Care should be integrated across psychiatry, primary care, and endocrinology, with structured lifestyle interventions such as diet, exercise, and smoking cessation offered from the outset. When adjustments to pharmacological therapy are needed, clinicians should prioritise antipsychotics with lower metabolic risk, however PBS clinical criteria may limit community-based access to some antipsychotic medicines. Clinicians should also consider adjunctive agents like metformin for weight gain or insulin resistance. The INTEGRATE guidelines recommend GLP-1s as an effective option for weight reduction and metabolic improvement for individuals with persistent obesity or high cardiometabolic risk despite first-line strategies.<sup>22</sup>

- **Management of obesity prior to surgery**

Weight loss treatment options for obesity other than bariatric surgery are limited and surgery for these individuals carries clinical risks. In addition, uncontrolled diabetes and severe obesity may lead to ineligibility for transplant surgery.<sup>28,29</sup> GLP-1s may offer promise in this population as they have been shown to reduce weight, central adiposity, HbA1c, and risk of cardiovascular outcomes.<sup>28</sup>

- i) **Bariatric surgery**

Bariatric surgery provides an effective pathway for long-term weight control and can help sustain benefits previously achieved through GLP-1 therapy.

Since 2017, studies have examined the role of GLP-1s prior to bariatric procedures. AbuHasan et al analysed outcomes in 2,169 individuals with a mean BMI of 45 kg/m<sup>2</sup>.<sup>30</sup> The study found no significant differences in 30-day postoperative outcomes between individuals who used GLP-1s preoperatively and those who did not. However, a BMI of 50 kg/m<sup>2</sup> or more is widely recognised as a threshold where surgical risk increases substantially. Reducing body fat and liver size before surgery can improve technical feasibility and reduce complications.

Individuals with BMI above 50 kg/m<sup>2</sup> face higher surgical risks during bariatric surgery, often requiring preoperative weight reduction. This retrospective study reviewed 31 such individuals, comparing those who received GLP-1s preoperatively to those who did not. GLP-1 use led to significantly greater BMI reduction (5.5 vs. 2.9 points; p=0.026) without delaying surgery or increasing complications. No adverse effects from GLP-1 therapy were reported.<sup>31</sup>

There are no cost effectiveness reviews in this cohort to guide selection of one medicine over another or to indicate which option could be chosen for a particular individual.

There is insufficient evidence to support routine use of these medicines for weight loss before surgery.<sup>32</sup>

## ii) **Kidney transplant surgery**

Obesity is increased amongst candidates for kidney transplant and may hinder access to eligibility for transplant waitlists, due to the higher incidence of postoperative complications (such as impaired wound healing, bacterial infections, delayed graft function and prolonged warm ischemia time).<sup>29</sup> One small study, of 23 individuals, demonstrated a weight loss of 11.4 kg after 12 months of semaglutide. Semaglutide enabled waitlisting and transplantation of otherwise ineligible obese transplant candidates, with 56.5% of individuals initially rejected for transplantation, waitlisted for transplant.<sup>29</sup> Data about efficacy and safety of semaglutide in kidney transplant candidates is limited to a few case reports and studies with small sample sizes. This limits the ability to generalise findings and the relatively short follow-up periods do not allow for assessment for long-term metabolic and transplant outcomes. (Unlike bariatric surgery as a weight-loss intervention, which can sustain more than 25% weight loss after 10 years<sup>33</sup>). Outside of live donor options there is a finite number of deceased donor organs; more people being eligible for waitlisting does not equate to more transplants.

## **CESSATION OF GLP-1s**

Treatment for weight management in obesity is likely to be needed long-term to maintain weight loss benefits. However, long-term adherence to GLP-1s can be challenging, with discontinuation rates as high as 80% after two years.<sup>34</sup> The risk of weight regain upon cessation of GLP-1s remains a significant issue.

The STEP 4 clinical trial began with participants receiving open-label, once-weekly semaglutide for 20 weeks, during which participants achieved a mean weight loss of 10.6%. This was followed by a 48-week, double-blind phase in which participants either continued semaglutide or switched to placebo. Those who remained on semaglutide experienced a further 7.9% reduction in body weight, resulting in a total mean loss of 18.5% by week 68. In contrast, participants who transitioned to placebo regained 6.9% of their weight, leaving them with a total mean weight loss of just 3.7%.<sup>35</sup> The SURMOUNT 4 study involving tirzepatide found a 14% body weight regained after stopping tirzepatide for one year. In contrast, participants who continued tirzepatide lost an additional 5.5% and maintained their prior weight loss. Only 16.6% of those who stopped tirzepatide maintained at least 80% of their initial weight loss, compared with 89.5% who stayed on treatment.<sup>36</sup>

Additionally, STEP 1-extension<sup>37</sup> and SURMOUNT-1 extension<sup>38</sup> studies indicate that the cardiovascular benefits and progression to diabetes (respectively) are also lost within 6 months to 1 year of ceasing the medicine. Those who remain on a GLP-1 appear to have a peak weight loss and then plateau at approximately 60–68 weeks for semaglutide<sup>35</sup> and 72 weeks for tirzepatide.<sup>39</sup>

A meta-analysis published in 2026 determined that after discontinuing weight-management medicines, individuals tend to regain weight at an average pace of about 0.4 kg per month, which estimates a return to pre-treatment weight within approximately 1.7 years. Improvements achieved during therapy and subsequent weight loss, including reductions in HbA1c, fasting glucose, cholesterol levels, triglycerides, and both systolic and diastolic blood pressure, also gradually fade, with most measures returning to baseline approximately 1.4 years after stopping treatment. Notably, the rebound in weight following cessation of medicine occurs more rapidly than the weight regain typically seen after ending behavioural weight-management programs, regardless of how much weight was initially lost.<sup>40</sup>

Emerging observational evidence is establishing less intensive GLP-1 therapy options for weight maintenance following initial weight loss e.g. reduced frequency dosing (every 2 weeks),<sup>41</sup> that may maintain the clinical benefits at a reduced long-term cost.

A major concern with the GLP-1 medicines is the loss of skeletal muscle during treatment underscoring the importance of accompanying strength training and the tendency for that lost muscle to be replaced by fat once the medicine is discontinued.<sup>34</sup> This shift in body composition could weaken pelvic floor muscles, contributing to problems such as incontinence and prolapse—significant drawbacks that must be carefully considered. Ongoing follow-up is also important to identify treatment cessation, nutritional issues, and excessive fat regain.<sup>34</sup>

Given these risks, the harm: benefit ratio places this therapy outside the scope of first-line therapy, and their use should be accompanied by exercise ideally with access to an exercise physiologist or physiotherapist to help preserve muscle mass.<sup>34</sup>

## **CONSIDERATIONS FROM AN ECONOMIC PERSPECTIVE**

This review explores key considerations for hospital MTCs evaluating GLP-1s for overweight and obesity indications. While these medicines show strong evidence for weight loss, diabetes control, and cardiovascular benefits in randomised trials, translating these results into real-world effectiveness and long-term outcomes remains complex.

Cost-effectiveness is a critical factor for consideration. GLP-1s are subsidised through the PBS for type 2 diabetes in Australia under strict conditions. Weight-loss indications have only just been recommended by the PBAC (although not yet listed on the PBS) for a select group of individuals. Economic evaluations suggest that significant price reductions are required for cost-effectiveness in high-risk cardiovascular populations.<sup>10,42</sup> Affordability poses a major challenge given the prevalence of obesity and the long-term nature of treatment.

Equity and access also require attention. While utilisation controls can help manage affordability, they risk creating inequities in care. Hospital committees often face requests for the use of GLP-1s outside trial populations, such as pre-surgical patients, where evidence is limited. Decisions need to balance clinical benefit, cost, and fairness, aiming for transparent processes that minimise inequitable impacts.

Given the need for long-term use to maintain weight loss, community-based access is required. For this access to be equitable across patient cohorts and geographic regions, this is best achieved through the PBS. To prioritise the most cost-effective use, any hospital funded access should clearly define, at the time of approval, criteria for treatment success and therefore continuation of therapy, and criteria for treatment cessation.

## CONCLUSION

This document provides guidance for considerations in reviewing GLP-1 applications for IPU/IPAs or formulary submissions. It emphasises prioritising evidence-based clinical benefit, defining clear therapeutic objectives, and ensuring sustainability through regular review and cessation criteria. Decisions must balance individual patient outcomes with broader cost-effectiveness and financial sustainability considerations.

Challenges remain for the hospital sector in approving broad or unrestricted use of GLP-1s for chronic weight management, as their requirement for long-term use to sustain weight loss makes public hospital funding for ongoing treatment through the acute care setting likely to be unsustainable. Access through hospitals via IPU/IPA approval at a local health service level may be justified in exceptional and unique circumstances for a very small, clearly-defined group of individuals, as a short-term bridge to more definitive therapy, where clinical need is unequivocal, or for a clearly defined, time-limited period, where this approach is able to be sustainable and effectively resourced. However, there is currently limited evidence on cost-effectiveness studies for key priority populations and further information is needed to clearly establish a sustainable approach in some populations.

The therapeutic landscape for these medicines continues to evolve, with new product formulations and patent changes influencing availability and cost.

Application of the recommended principles, supports transparent, consistent, and responsible decision-making across jurisdictions, aligned with clinical service priorities, fiscal sustainability, and equity of access.

## APPENDIX 1: RECOMMENDATIONS FROM LEADING INTERNATIONAL HEALTH ORGANISATIONS

When interpreting the following recommendations from leading international health organisations, it is important to consider that some funding approvals have only been supported where jurisdictional funding negotiations with the pharmaceutical company have resulted in significant price reductions resulting in more cost-effective treatment with an improved cost-benefit ratio.

### • World Health Organisation (WHO)

The WHO issued [global guideline the use of glucagon-like peptide-1 for the treatment of obesity in adults](#) on 1 December 2025.<sup>43,44</sup>

The guidance emphasises the importance of fair access to GLP-1 therapy and preparing health systems for use of these medicines. This requires a capacitated health system to ensure adequate resources are in place, including supporting governance, comprehensive training of health workers, monitoring and evaluation, referral systems, procurement, supply chain and financial coverage. The guidance contains two key conditional recommendations:

- GLP-1 therapy may be used by adults, but excluding pregnant women, for the long-term treatment of obesity. While the efficacy of this therapy in treating obesity and improving metabolic and other outcomes was evident, the recommendation is conditional due to limited data on their long-term efficacy and safety, maintenance and discontinuation, their current costs, inadequate health-system preparedness, and potential equity implications.
- Intensive behavioural interventions, including structured interventions involving healthy diet and physical activity, may be offered to adults living with obesity prescribed GLP-1s. This is based on low-certainty evidence suggesting it may enhance treatment outcomes.

### • UK: National Institute for Health and Care Excellence (NICE)<sup>†</sup>

Access to the newer GLP-1s, **semaglutide** and **tirzepatide**, has recently been approved by NICE in the UK. The NICE technology appraisals are not yet published; however, some information is available.

**Semaglutide** is recommended for adults with at least one weight-related condition and BMI of 30 kg/m<sup>2</sup> or above. Individuals must be treated by a specialist weight-management service, and prescriptions are for a maximum of two years. The stipulation for specialised weight management services is because it aligns with the clinical trials and the 2 years is because those services only allow 2-year participation.<sup>45</sup>

In April 2026, it was reported that an independent NICE committee has recommended semaglutide for use in adults with a BMI of 27 kg/m<sup>2</sup> or higher who have a history of major cardiovascular events, including heart attack, stroke, or significant peripheral arterial disease affecting the legs. A BMI of 27 kg/m<sup>2</sup> falls within the overweight category.<sup>46,47</sup>

Funded **tirzepatide** is capped at 220,000 individuals over 3 years in the UK. How these individuals will be selected is unknown given that it has been recommended for adults with an initial BMI of at least 35 kg/m<sup>2</sup> and at least one weight-related comorbidity. Individuals do not need to be involved in a specialist weight management service for tirzepatide. Price agreements are commercial in confidence therefore it is unknown how much these medicines cost the government in the UK.<sup>48</sup>

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<sup>†</sup> The NICE guidelines are intended for all settings where health and social care is provided, including hospitals, community health services, primary care (GPs), social care and care homes, and integrated or transitional care between settings.

**Liraglutide** is only funded for adults with an initial BMI of 35 kg/m<sup>2</sup> or more and non-diabetic hyperglycaemia and a high risk of cardiovascular disease. The medicine is ceased after 12 weeks on the 3 mg/day dose if at least 5% of the initial body weight has not been lost.<sup>45</sup>

- **Scottish Medicines Consortium**<sup>49</sup>

**Semaglutide** (Wegovy®), **tirzepatide** (Mounjaro®) and **liraglutide** (Saxenda®) are approved as adjuncts to a reduced-calorie diet and increased physical activity for weight management (weight loss and maintenance) in adults with:

- BMI 30 kg/m<sup>2</sup> or above (obesity), or
- BMI 27-29.9 kg/m<sup>2</sup> (overweight) with at least one weight-related comorbidity (e.g., hypertension, dyslipidaemia, sleep apnoea, cardiovascular disease, prediabetes, or type 2 diabetes).

**In addition, semaglutide** (Wegovy®) and **tirzepatide** (Mounjaro®) are

- Restricted to BMI 30 kg/m<sup>2</sup> or above with at least one weight-related comorbidity.
- Must be prescribed within a specialist weight management service.
- A lower BMI threshold may apply for minority ethnic groups at equivalent obesity risk.

**In addition, liraglutide** (Saxenda®) has a more stringent restriction:

- BMI 35 kg/m<sup>2</sup> or above with the addition of:
- non-diabetic hyperglycaemia (prediabetes) at high risk of type 2 diabetes, and
- high cardiovascular risk (e.g., high cholesterol, low HDL, or high systolic BP).

- **Canada's Drug Agency (CDA-AMC)**

Canada's Drug Agency recommends that **semaglutide** (Wegovy®) should be considered for reimbursement by public drug plans for chronic weight management if certain conditions are met, which includes a satisfactory price reduction from the marketed price.

Indication: As an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m<sup>2</sup> or greater (obesity), or
- 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, dyslipidaemia, or obstructive sleep apnoea.

**Liraglutide** is not recommended for reimbursement for chronic weight management in adults.

**Tirzepatide** is currently under review (as of April 2026).

## APPENDIX 2: SUMMARY OF KEY EVIDENCE FOR WEIGHT LOSS WITH GLP-1s

This is not intended to be a comprehensive literature review of evidence for weight loss, but rather a consolidation of information already collated and reviewed by participating CATAG jurisdictions and considered by MTCs. As the evidence base continues to evolve, MTCs should conduct their own reviews and deliberations, with the following serving as a preliminary guide.

For information on the comparative weight-loss efficacy of injectable medicines used for weight management, CATAG recommends the *Australian Prescriber* article “**Injectable drugs for weight management**” .<sup>50</sup>

It is important to note for all the GLP-1s discussed, that the clinical trials demonstrating benefit were funded by the sponsoring pharmaceutical company. This raises concerns about potential bias. To fully understand the long-term safety and broader clinical impact of GLP-1s in weight management, additional independent research and extended follow-up studies are warranted.

- **Semaglutide**

In STEP-1, a randomised controlled trial (RCT) comparing semaglutide 2.4 mg to placebo in adults with a BMI greater than 30, Wilding et al found that semaglutide once weekly plus lifestyle intervention was associated with sustained, clinically relevant reduction in body weight.<sup>51</sup> The mean change in body weight from baseline to week 68 was -14.9% in the semaglutide group vs -2.4% with placebo.<sup>51</sup>

In STEP-2, a large, double-blind trial of adults with overweight or obesity and type 2 diabetes, weekly semaglutide 2.4 mg led to substantially greater weight loss than both placebo and the lower 1 mg dose. Over 68 weeks, participants receiving 2.4 mg lost about 9.6% of their body weight compared with 3.4% in the placebo group, and more than two-thirds achieved at least a 5% reduction. Although gastrointestinal side effects were common, they were mostly mild to moderate. Overall, the higher semaglutide dose produced a clinically meaningful weight loss benefit in this population.<sup>52</sup>

In the STEP-8 RCT, semaglutide was shown to be more effective for weight loss than **liraglutide** when comparing semaglutide 2.4 mg vs liraglutide 3 mg vs placebo in adults with a BMI greater than 30. The mean weight change from baseline was -15.8% with semaglutide vs -6.4% with liraglutide. Proportions of participants discontinuing treatment for any reason were 13.5% with semaglutide and 27.6% with liraglutide.<sup>53</sup>

The SELECT RCT demonstrated cardiovascular benefit in overweight participants without diabetes with a high cardiovascular risk profile. A reduction in death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke was identified at a mean follow-up of 39.8 months.<sup>54</sup> In STEP-HFpEF<sup>#</sup>, a trial of 529 adults with HFpEF and obesity, weekly semaglutide 2.4 mg for 52 weeks led to greater improvements in heart failure related symptoms and physical limitations, as measured by the KCCQ-CSS<sup>‡</sup>, and produced substantially more weight loss (-13.3%) compared with placebo (-2.6%). Semaglutide also improved exercise capacity, reduced inflammation, and outperformed placebo in a composite endpoint of clinical outcomes. Serious adverse events occurred less frequently with semaglutide than with placebo.<sup>55</sup>

In the STEP-HFpEF DM trial, weekly semaglutide 2.4 mg produced consistent improvements in heart failure related symptoms, physical function, and weight in people with obesity-related HFpEF and type 2 diabetes, regardless of their starting HbA1c level. Across all glycaemic subgroups, semaglutide led to substantially greater weight loss, in the order of 9-11% at 52 weeks, compared to placebo, with no

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<sup>#</sup> HFpEF - Heart Failure with Preserved Ejection Fraction

<sup>‡</sup> KCCQ CSS - Kansas City Cardiomyopathy Questionnaire Clinical Summary Score

evidence that baseline HbA1c modified the treatment effect. Rates of hypoglycaemia were low and comparable between groups. Overall, semaglutide delivered meaningful clinical benefits in this population independently of glycaemic control.<sup>56</sup>

In the STEP-teens RCT, Weghuber et al found semaglutide plus lifestyle intervention resulted in a 16.1% reduction in BMI at 68 weeks, compared to 0.6% with placebo.<sup>19</sup> Reductions in body weight and improvement with respect to cardiometabolic risk factors (waist circumference and levels of glycated haemoglobin, lipids [except high-density lipoprotein cholesterol], and alanine aminotransferase) were also greater with semaglutide than with placebo.

- **Tirzepatide**

In SURMOUNT-1, tirzepatide was shown to be effective for weight loss in an RCT comparing tirzepatide (5 mg, 10 mg, or 15 mg) to placebo for 72 weeks in adults with a BMI above 30. The mean percentage change in body weight from baseline to week 72 was -15% with 5 mg, -19.5% with 10 mg and -20.9% with 15 mg in the tirzepatide groups vs -3.1% with placebo (P<0.001 for all comparisons with placebo).<sup>57</sup>

In a large cardiovascular outcomes trial of people with type 2 diabetes and established atherosclerotic cardiovascular disease, weekly tirzepatide (up to 15 mg) was compared with dulaglutide, a GLP-1 agonist already shown to reduce cardiovascular risk.<sup>58</sup> Among more than 13,000 participants, tirzepatide was found to be noninferior to dulaglutide for the composite outcome of cardiovascular death, myocardial infarction, or stroke. Although tirzepatide did not demonstrate statistical superiority, event rates were slightly lower in the tirzepatide group, and safety profiles were generally similar apart from more gastrointestinal side effects with tirzepatide.<sup>58</sup>

In a head-to-head clinical trial comparing semaglutide (Wegovy®) vs tirzepatide (Mounjaro®) for treatment of obesity (SURMOUNT-5) in participants without diabetes, tirzepatide (at 5 mg, 10 mg and 15 mg) was reported to be more efficacious than semaglutide 1 mg. Tirzepatide use led to greater weight loss than for those taking semaglutide. On average, tirzepatide led to 1.9 kg, 3.6 kg, and 5.5 kg more weight loss (depending on the dose, P<0.001 for all comparisons. and waist circumference reduction (-18.4 cm) compared to semaglutide use(-13.7% and -13.0 cm, respectively) at 72 weeks.<sup>59</sup>

- **Liraglutide**

A recent 2025 Cochrane review concluded that while liraglutide appears effective for weight loss, its long-term safety profile and impact on clinically meaningful outcomes require further investigation.<sup>60</sup>

It found in medium-term trials (26–68 weeks), liraglutide demonstrated modest benefits for weight management compared with placebo, with an average reduction of approximately 4.7% in body weight and a higher likelihood of achieving at least 5% weight loss (relative risk (RR) 2.10; moderate-certainty evidence). However, the certainty of evidence for mean weight change was very low, and safety concerns were notable. Compared to placebo, liraglutide use may have an increased risk of adverse events, including serious events (such as gastrointestinal complications, biliary disorders, and psychiatric events) Withdrawals due to adverse effects was common in the reviewed clinical trials. Liraglutide demonstrated little to no clinically meaningful improvement in major adverse cardiovascular events or quality of life. Mortality outcomes remain highly uncertain.

Over longer durations (104–162 weeks), liraglutide continued to provide modest weight reduction (mean 4.3% weight loss) and likely improved the proportion of participants achieving 5% weight loss, but adverse events persisted, and evidence for cardiovascular and mortality outcomes remained very uncertain.

### APPENDIX 3: SAFETY OF GLP-1s

The evidence on adverse drug reactions (ADRs) associated with GLP-1s continues to evolve, and current understanding remains uncertain as new data emerges. It is not possible to include all ADRs in this document. Refer to recent literature for the most up to date information.

It is important to consider other comorbidities, risks, contraindications when considering these medicines.

The common side effects for GLP-1s are mostly minor gastrointestinal side effects, as listed in the product information for each medicine.<sup>61-64</sup>

Other more concerning side effects have been reported.

- **Potential risk of suicidal thoughts or behaviours**

The Therapeutic Goods Administration (TGA) on 1<sup>st</sup> December 2025 published an alert noting that warnings about the potential risk of suicidal thoughts or behaviours across the GLP-1s class of medicines have been aligned. Evidence available was not sufficient to support an association between GLP-1s and suicidal or self-harming behaviours, however the TGA advised health professionals to monitor for the emergence or worsening of depression, suicidal thoughts or behaviours, or any unusual changes in mood or behaviour. The Advisory Committee on Medicines noted there was a complex interplay between mental illness and chronic endocrine disorders for which GLP-1s may be used for treatment, and the potential relationship between weight loss and suicidal/self-injurious ideation.<sup>65</sup>

For the general population, no psychiatric adverse events are noted in the product information for GLP-1s. “A post hoc analysis of the STEP 1, 2, 3, and 5 trials found that semaglutide, 2.4 mg, did not increase the risk of developing symptoms of depression, suicidal ideation, or suicidal behaviour relative to placebo in people with overweight or obesity without known major psychopathology.”<sup>66</sup> The studies reviewed indicate no new psychiatric or worsening psychiatric adverse events in this population but these studies are too small to be definitive. A WHO database analysis on semaglutide and liraglutide on suicidality indicated a very low number of reports (213 of 36,172,078 total reports) but did conclude a disproportionality signal of suicidal ideation with semaglutide among those who also took antidepressants.<sup>67</sup> Please also refer to safety of GLP-1 RA information below as per the 2025 TGA alert on potential risk of suicidal thoughts or behaviours below.

- **Gastrointestinal effects**

Other uncommon but serious complications include gallbladder issues (e.g., cholelithiasis) and ileus.<sup>68</sup> Due to post-marketing reports of ileus, the FDA has issued warnings for semaglutide and tirzepatide. However, long-term studies assessing this risk are lacking.

- **Acute pancreatitis**

Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotising pancreatitis, have been observed in people treated with GLP-1s.

- **Risk of thyroid c-cell tumours**

Studies in rodents have shown that semaglutide can cause thyroid C-cell tumours at clinically relevant doses. It is not known whether semaglutide increases the risk of thyroid C-cell tumours, including medullary thyroid carcinoma in humans, as the relevance of these findings to humans has not been established. Semaglutide should not be used in those with a personal or family history of medullary thyroid carcinoma or those diagnosed with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).<sup>41</sup>

- **Eye health concerns**

A retrospective study of 16,827 individuals found a potential link between semaglutide and non-arteritic anterior ischemic optic neuropathy (NAION), but more research is needed to confirm causality.<sup>69</sup>

In a two-year study involving individuals with type 2 diabetes and elevated cardiovascular risk, complications related to diabetic retinopathy occurred more frequently in those receiving semaglutide (3.0%) compared to those on placebo (1.8%).<sup>70</sup> The absolute increase in risk was greater among participants who had diabetic retinopathy at baseline (semaglutide 8.2%, placebo 5.2%) than among those without a prior history (semaglutide 0.7%, placebo 0.4%). Rapid improvements in blood glucose control have been linked to temporary worsening of retinopathy. The long-term impact of semaglutide on retinopathy progression remains unknown.<sup>68</sup>

- **Loss of muscle**

Research shows that as much as one-third of the weight lost during treatment may come from lean body mass, including muscle and bone. When treatment is stopped, people commonly regain a significant portion of the weight they lost, often up to two-thirds, and much of this rebound weight may consist of fat rather than muscle. To reduce the risk of malnutrition and unhealthy changes in body composition, GLP-1s should be started only alongside a structured, supervised exercise program and tailored dietary support.<sup>34</sup>

## APPENDIX 4: HOW THIS GUIDANCE WAS DEVELOPED

This document provides short, summarised guidance to hospital and statewide MTCs developed through a structured and iterative process between July 2025 and May 2026, incorporating input from a dedicated working group and broader CATAG membership. This document is a consensus statement, reflecting an effort to bring together a range of views and perspectives into a single, cohesive statement. While it represents collective agreement, it may not necessarily reflect the views of any individual member.

In June 2025, CATAG called for expressions of interest for experienced professionals to join a working group to review the use of GLP-1s in Australian hospitals. A working group was established from across Australia, comprised of individuals reflecting a range of geographies and specialisations.

Three working groups meetings were held.

- **July 2025 (Working Group Meeting 1):**

The working group established the scope, purpose and overall direction of the document. Key themes and priority areas for inclusion were identified.

- **October 2025 (Working Group Meeting 2):**

An initial draft was reviewed. Members provided detailed feedback on content, identified gaps, and refined key messages. Additional points for inclusion were agreed, and revisions were progressed.

- **December 2025 (Working Group Meeting 3):**

A revised draft was presented for further review. The working group consolidated content, clarified guidance, and reviewed alignment with the intent of the document.

Members of the working group reviewed the evidence, agreed on principles, reviewed feedback and drafts of the document and approved the final document. Draft versions of the document were circulated to CATAG members following key development stages. Feedback from members was incorporated iteratively, supporting broader input and alignment across jurisdictions.

The final version of the document was presented at the CATAG meeting in May 2026, where it was supported by members.

This guidance was developed in consultation with the CATAG member organisations listed below:

- ACT Health
- Clinical Excellence Commission, NSW Health
- NSW Therapeutic Advisory Group (NSW TAG)
- Northern Territory Health Medicines and Therapeutics Committee (NTMTC)
- Queensland Health Medicines Advisory Committee (QHMAC)
- South Australian Medicines Advisory Committee (SAMAC)
- Tasmanian Medicines Access and Advisory Committee (TMAAC)
- Victorian Therapeutics Advisory Group (Vic TAG)
- Western Australian Therapeutics Advisory Group (WATAG)

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