

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Tirzepatide for managing overweight and obesity

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of tirzepatide within its marketing authorisation for managing obesity or overweight with risk factors.

Background

Overweight and obesity is a chronic condition characterised by increased body fat. People living with overweight or obesity are at an increased risk of developing cardiovascular disease, type 2 diabetes, atherosclerosis (the presence of fatty deposits in the arteries), hypertension and dyslipidaemia (abnormal levels of fats in the blood). Other conditions associated with obesity are non-alcoholic fatty liver disease, non-diabetic hyperglycaemia, subfertility, osteoarthritis, dyslipidaemia, obstructive sleep apnoea and idiopathic intracranial hypertension. The most common method for measuring obesity is body mass index (BMI) which is calculated as the ratio of weight to height squared. Overweight is typically defined by a BMI of 25 kg/m² to <30 kg/m² and obesity by a BMI of 30 kg/m² or more. Some ethnic groups may be at increased risk of some ill health conditions at lower BMI than people of European family background.

Obesity affects approximately 1 in 4 adults in the UK, with 67% of men and 60% of women in England living with overweight or obesity.^{1,2} In 2019/20 there were 10,780 hospital admissions directly attributable to obesity, a decrease of 3% on 2018/19 (11,117 admissions).³

[NICE clinical guideline \(CG\) 189 'Obesity: identification, assessment and management'](#) states multicomponent interventions are the treatment of choice. Weight management programmes include behaviour change strategies to increase people's physical activity levels or decrease inactivity, improve eating behaviour and the quality of the person's diet, and reduce energy intake. Pharmacological treatments are usually considered only after dietary, exercise and behavioural approaches have been started and evaluated. NICE CG189 recommends orlistat for managing obesity in adults with a BMI of 30 kg/m² or more, and in people with a BMI of 28 kg/m² or more with associated risk factors. If dietary and lifestyle advice, behaviour modification and drug treatments are unsuccessful, NICE CG189 recommends bariatric surgery for people with: a BMI of ≥40 kg/m²; a BMI of between 35 kg/m² and 40 kg/m² and other significant disease, a BMI between 30 kg/m² and <35 kg/m² and with recent-onset of type 2 diabetes (surgery can be considered for people of Asian family background who have recent-onset type 2 diabetes at a lower BMI than other populations).

[NICE technology appraisal \(TA\) 664](#) recommends liraglutide as an option for managing overweight and obesity alongside a reduced-calorie diet and increased activity in adults with a BMI of at least 35 kg/m² (or at least 32.5 kg/m² 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), non-diabetic hyperglycaemia and a high risk of cardiovascular disease.

The technology

Tirzepatide (brand name unknown, Eli Lilly) does not currently have a marketing authorisation in the UK for managing overweight and obesity. It has been studied in a clinical trial compared with placebo in adults with a BMI of ≥ 30 kg/m² or ≥ 27 kg/m² and at least 1 weight-related comorbidity including hypertension, dyslipidaemia, obstructive sleep apnoea or cardiovascular disease.

Tirzepatide as a monotherapy or in combination with other medicinal products is licensed in the UK for treating type 2 diabetes as an adjunct to diet and exercise.

Intervention	Tirzepatide
Population	Adults who have a BMI of: <ul style="list-style-type: none"> • ≥ 30 kg/m² (obese) or • ≥ 27 kg/m² to < 30 kg/m² (overweight) and at least one weight-related comorbidity
Comparators	<ul style="list-style-type: none"> • Standard management without tirzepatide (including a reduced calorie diet and increased physical activity) • Liraglutide (for the population for whom liraglutide is recommended in TA664) • Orlistat (prescription dose) • Semaglutide (subject to NICE evaluation)
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none"> • BMI • weight loss • waist circumference • incidence of type 2 diabetes • glycaemic status • cardiovascular events • mortality • adverse effects of treatment • health-related quality of life.

<p>Economic analysis</p>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
<p>Other considerations</p>	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<p>Related NICE recommendations</p>	<p>Related technology appraisals:</p> <p>Liraglutide for managing overweight and obesity (2020) NICE technology appraisal guidance 664</p> <p>Naltrexone–bupropion for managing overweight and obesity (2017) NICE technology appraisal guidance 494</p> <p>Related technology appraisals in development:</p> <p>Semaglutide for managing overweight and obesity. NICE technology appraisal guidance [ID3850]. Publication date to be confirmed</p> <p>Semaglutide for managing overweight and obesity in young people aged 12 to 17. NICE technology appraisal guidance [ID6139]. Publication date to be confirmed</p> <p>Related NICE guidelines:</p> <p>Obesity: identification, assessment and management (2014, updated September 2022) NICE guideline CG189</p> <p>Obesity: working with local communities (2012, updated 2017) NICE guideline PH42</p> <p>Preventing excess weight gain (2015) NICE guideline 7</p> <p>Obesity prevention (2006, updated 2015) NICE guideline CG43</p> <p>Weight management: lifestyle services for overweight or obese adults (2014) NICE guideline PH53</p>

	<p>Weight management: lifestyle services for overweight or obese children and young people (2013) NICE guideline PH47</p> <p>Related NICE guidelines in development:</p> <p>Obesity: Surgical interventions – update. NICE guideline. Publication expected July 2023</p> <p>Weight Management: preventing, assessing and managing overweight and obesity (update) NICE guideline. Publication expected March 2024</p> <p>Related interventional procedures:</p> <p>Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity (2016) NICE interventional procedures guidance 569</p> <p>Implantation of a duodenal–jejunal bypass sleeve for managing obesity (2013) NICE interventional procedures guidance 471</p> <p>Laparoscopic gastric plication for the treatment of severe obesity (2012) NICE interventional procedures guidance 432</p> <p>Related quality standards:</p> <p>Obesity in adults: prevention and lifestyle weight management programmes (2016) NICE quality standard 111</p> <p>Obesity: clinical assessment and management (2016) NICE quality standard 127</p> <p>Obesity in children and young people: prevention and lifestyle weight management programmes (2015) NICE quality standard 94</p>
<p>Related National Policy</p>	<p>NHS England (2022) Enhanced service specification: weight management programme 2022/23</p> <p>The NHS Long Term Plan (2019) NHS Long Term Plan</p> <p>NHS England (2018) NHS manual for prescribed specialist services (2018/2019) Chapter 139A</p> <p>NHS England (2017/18). NHS Standard Contract for Severe and Complex Obesity (Adults). A05/S/a.</p> <p>Department of Health and Social Care (2016) NHS outcomes framework 2016 to 2017: Domains 1-2</p> <p>NHS England (2013). Clinical Commissioning Policy: Complex and Specialised Obesity Surgery. NHSCB/A05/P/a.</p>

Questions for consultation

Which treatments are considered to be established clinical practice in the NHS for overweight and obesity?

Is bariatric surgery a relevant comparator for adults with a BMI of ≥ 30 kg/m² or ≥ 27 kg/m² to < 30 kg/m² and at least one weight-related comorbidity?

Where do you consider tirzepatide will fit into the existing care pathway for managing overweight and obesity?

Are there any other subgroups of people in whom tirzepatide is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Would tirzepatide be a candidate for managed access?

Do you consider that the use of tirzepatide can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which tirzepatide will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation>).

References

1. NHS (2019). [Obesity](#). Accessed December 2022.
2. NHS Digital (2020). [Statistics on Obesity, Physical Activity and Diet, England 2020](#). Accessed December 2022.
3. NHS Digital (2021). [Statistics on Obesity, Physical Activity and Diet, England 2021](#). Accessed December 2022.