

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Liraglutide for managing overweight and obesity

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of liraglutide within its marketing authorisation, in addition to a reduced calorie diet and increased physical activity, for the management of people with obesity or overweight with risk factors.

Background

Overweight and obesity is a chronic condition characterised by increased body fat. People who are overweight or obese 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. BMI scores of 30 kg/m² to <35 kg/m² are defined as Obesity class I, scores of 35 kg/m² to <40kg/m² as Obesity class II and scores of ≥40 kg/m² as Obesity class III. Some ethnic groups may be at increased risk of some ill health conditions at lower BMI than people of European family origin.

In England, an estimated 26% of adults are obese and a further 35% are overweight. Around one in ten obese adults are morbidly obese, with a BMI above 40. People aged 55-64 years are the most likely to be obese, while people aged 16-24 years are the least likely¹. The percentage of adults with overweight and obesity in England has risen from 53% in 1993 to 61% in 2016¹.

Standard management of overweight and obesity includes dietary and lifestyle advice, behaviour modification, pharmacological treatments and surgical intervention. Specialist multi-disciplinary weight management interventions (known as tier 3 interventions) are also used in current practice. Tier 3 interventions include dietary, lifestyle and behaviour modification with or without drug therapy. These interventions can be delivered in either primary or secondary care. NICE clinical guideline 189 'Obesity: identification, assessment and management' recommends that drug therapy with orlistat should only be considered after dietary, physical activity and behavioural approaches have been started and evaluated. It recommends orlistat for the management of obesity in people with a BMI of 30 kg/m² or more, and in

people with a BMI of 28 kg/m² or more and significant comorbidities. If dietary and lifestyle advice, behaviour modification and drug treatments are unsuccessful, the NICE clinical guideline recommends bariatric surgery for people with: a BMI of 40 kg/m² or more; a BMI of between 35 kg/m² and 40 kg/m² with significant comorbidities, 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 origin who have recent-onset type 2 diabetes at a lower BMI than other populations).

The technology

Liraglutide (Saxenda, Novo Nordisk Limited) is a glucagon-like peptide-1 (GLP-1) analogue produced by recombinant DNA technology in *saccharomyces cerevisiae*. It is administered by subcutaneous injection.

Liraglutide has a marketing authorisation in the UK as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial BMI of ≥30 kg/m² (obese), or ≥27 kg/m² to <30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

Intervention(s)	Liraglutide
Population(s)	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) in the presence of at least one weight-related comorbidity
Comparators	<ul style="list-style-type: none"> • Standard management without liraglutide (including a reduced calorie diet and increased physical activity) • Orlistat (prescription dose) • Bariatric surgery

Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • BMI • weight loss • percentage body fat • waist circumference • incidence of type 2 diabetes • cardiovascular events • idiopathic intracranial hypertension • non-alcoholic fatty liver disease • mortality • adverse effects of treatment • health-related quality of life.
Economic analysis	<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>
Other considerations	<p>If the evidence allows the following subgroups will be considered. These include:</p> <p>The committee will consider how its recommendations may have a differential impact on people with mental illness or learning disability and the relevance of ethnicity when considering BMI thresholds.</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>
Related NICE recommendations and NICE Pathways	<p>Related Technology Appraisals:</p> <p>‘Naltrexone–bupropion for managing overweight and obesity’ (2017). NICE Technology Appraisal 494. Review date: December 2020.</p> <p>Related Guidelines:</p>

	<p>‘Preventing excess weight gain’ (2015). NICE guideline NG7. Review ongoing; publication date to be confirmed.</p> <p>‘Obesity: identification, assessment and management’ (2014). NICE guideline CG189. Review ongoing; publication date to be confirmed.</p> <p>‘Obesity prevention’ (2006). NICE guideline CG43. Review ongoing; publication date to be confirmed.</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 Evidence Summary:</p> <p>‘Obese, overweight with risk factors: liraglutide (Saxenda)’ (2017). NICE evidence summary ES14.</p> <p>Related Public Health Guidance/Guidelines:</p> <p>‘Weight management: lifestyle services for overweight or obese adults’ (2014). NICE guideline PH53.</p> <p>‘BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups’ (2013). NICE guideline PH46.</p> <p>‘Weight management before, during and after pregnancy’ (2010). NICE guideline PH27.</p> <p>Related Quality Standards:</p> <p>‘Promoting health and preventing premature mortality in black, Asian and other minority ethnic groups’ (2018). NICE quality standard 167.</p> <p>‘Obesity: clinical assessment and management’ (2016). NICE quality standard 127.</p> <p>‘Obesity in adults: prevention and lifestyle weight management programmes’ (2016). NICE quality standard 111.</p> <p>Related NICE Pathways:</p> <p>‘Lifestyle weight management services for overweight or obese adults’ (2016). NICE Pathway</p> <p>‘Obesity’ (2018). NICE Pathway.</p>
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	Obesity: working with local communities overview (2016). NICE Pathway.
Related National Policy	<p>The NHS Long Term Plan, 2019. NHS Long Term Plan</p> <p>NHS England (2017) Commissioning guidance to support devolution to CCGs of adult obesity surgical services in 2016/17</p> <p>NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 139A</p> <p>NHS England (2017) Report of the working group into: Joined up clinical pathways for obesity.</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017 (published 2016): Domains 1-2 https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</p>

References

1 Baker C. (2018). [House of Commons Library Briefing Paper: Obesity Statistics](#). Accessed April 2019 .