

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Liraglutide for managing overweight and obesity

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of liraglutide within its marketing authorisation, in addition to diet and 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). The most common method for measuring obesity is body mass index (BMI) which is calculated as the ratio of weight to height squared. In adults of European family origin, 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 (an appropriate adjustment of BMI for other ethnic groups is necessary).

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.

Current 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. 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.

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| 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 • Orlistat (prescription dose) |
| Outcomes | The outcome measures to be considered include: <ul style="list-style-type: none"> • BMI • weight loss • percentage body fat • waist circumference • incidence of type 2 diabetes • cardiovascular events • mortality • adverse effects of treatment • health-related quality of life. |

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| 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>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> |

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| | <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> <p>Obesity: working with local communities overview (2016). NICE Pathway.</p> |
| <p>Related National Policy</p> | <p>NHS England (2017) Next steps on the five year forward view</p> <p>NHS England (2017) Commissioning guidance to support devolution to CCGs of adult obesity surgical services in 2016/17</p> <p>NHS England (2017) Manual for prescribed specialised services 2017/18 Chapter 139A</p> <p>NHS England (2017) Report of the working group into: Joined up clinical pathways for obesity.</p> <p>NHS England (2014) NHS Five year forward view</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> |

Questions for consultation

Have all relevant comparators for liraglutide been included in the scope?
Which treatments are considered to be established clinical practice in the NHS for overweight and obesity?

How should 'standard care without liraglutide' be defined?

Are the outcomes listed appropriate?

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

Where do you consider liraglutide will fit into the existing NICE pathway, Obesity?

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 liraglutide is 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.

Do you consider liraglutide to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of liraglutide can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at <http://www.nice.org.uk/article/pmg19/chapter/1-Introduction>).

References

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