

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Liraglutide for managing obesity in people aged 12 to 17

Draft scope (pre-referral)

**Draft remit/appraisal objective**

To appraise the clinical and cost effectiveness of liraglutide within its marketing authorisation, for managing obesity in people aged 12 to 17.

**Background**

Obesity is a chronic condition characterised by increased body fat. People who are 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, obesity is typically defined by a BMI of 30 kg/m<sup>2</sup> or more. But BMI in childhood changes substantially with age, so obesity is usually defined as a BMI at or above the 95th percentile for children and teens of the same age and sex.

In 2017, the Health Survey for England (HSE) found 30% of children aged 2 to 15 in England were overweight or obese, including 17% who were obese<sup>1</sup>. Various diseases or conditions are associated with obesity in childhood. Of these, type 2 diabetes is a particular concern, usually occurring in middle aged and older people but increasingly being diagnosed in younger people and children (some as young as 7) over the past decade<sup>2</sup>. Being overweight as a child has also been associated with other cardiovascular risk factors in childhood or early adulthood<sup>3,4</sup>. Other conditions associated with childhood obesity include non-alcoholic fatty liver disease<sup>5</sup>; gall stones<sup>6</sup>; asthma and sleep-disordered breathing, including sleep apnoea<sup>7</sup>; and musculoskeletal conditions<sup>8,9</sup>.

NICE clinical guideline 189 ([CG189](#)) '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. For children aged 12 years and older treatment with orlistat is recommended only if physical comorbidities (such as orthopaedic problems or sleep apnoea) or severe psychological comorbidities are present. Treatment should be started in a specialist paediatric setting, by multidisciplinary teams with experience of prescribing in this age group. Surgical interventions are not generally recommended in children and young people.

**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 does not currently have a marketing authorisation in the UK for managing obesity in people aged 12 to 17. It is being studied in a clinical trial of obese people aged 12 to 17 with an initial BMI equal to or above 30 kg/m<sup>2</sup> for adults by international cut-off points and equal or above the 95th percentile for age and sex with a history of failure to control their weight through lifestyle and diet modification.

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/m<sup>2</sup> (obese), or ≥27 kg/m<sup>2</sup> to <30 kg/m<sup>2</sup> (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.

<b>Intervention(s)</b>	Liraglutide
<b>Population(s)</b>	People aged 12 to 17 who have a BMI of: <ul style="list-style-type: none"> <li>• ≥ 30 kg/m<sup>2</sup>, or</li> <li>• ≥ the 95th percentile for age and sex</li> </ul>
<b>Comparators</b>	Standard management without liraglutide Orlistat (for people aged 12 to 17 with physical comorbidities or severe psychological comorbidities)
<b>Outcomes</b>	The outcome measures to be considered include: <ul style="list-style-type: none"> <li>• BMI</li> <li>• weight loss</li> <li>• percentage body fat</li> <li>• waist circumference</li> <li>• incidence of type 2 diabetes</li> <li>• cardiovascular events</li> <li>• mortality</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>
<b>Economic analysis</b>	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.  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.  Costs will be considered from an NHS and Personal Social Services perspective.

<p><b>Other considerations</b></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><b>Related NICE recommendations and NICE Pathways</b></p>	<p>Related Technology Appraisals:</p> <p><a href="#">Naltrexone–bupropion for managing overweight and obesity</a> (2017). NICE Technology Appraisal 494. Review date: December 2020.</p> <p>Appraisals in development:</p> <p><a href="#">Liraglutide for managing overweight and obesity</a> [ID740]. Publication expected March 2020</p> <p>Related Guidelines:</p> <p><a href="#">Preventing excess weight gain</a> (2015). NICE guideline NG7.</p> <p><a href="#">Obesity: identification, assessment and management</a> (2014). NICE guideline CG189.</p> <p><a href="#">Obesity prevention</a> (2006). NICE guideline CG43.</p> <p>Related Evidence Summary:</p> <p><a href="#">Obese, overweight with risk factors: liraglutide (Saxenda)</a> (2017). NICE evidence summary ES14.</p> <p>Related Public Health Guidance/Guidelines:</p> <p><a href="#">Weight management: lifestyle services for overweight or obese children and young people</a> (2013). NICE guideline PH47.</p> <p><a href="#">Obesity: working with local communities</a> (2012). NICE guideline PH42.</p> <p><a href="#">Weight management: lifestyle services for overweight or obese adults</a> (2014). NICE guideline PH53.</p> <p><a href="#">BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups</a> (2013). NICE guideline PH46.</p> <p><a href="#">Weight management before, during and after pregnancy</a> (2010). NICE guideline PH27.</p> <p>Related Quality Standards:</p> <p><a href="#">Obesity in children and young people: prevention and lifestyle weight management programmes</a> (2015). NICE quality standard 94.</p> <p><a href="#">Promoting health and preventing premature mortality in black, Asian and other minority ethnic groups</a> (2018). NICE quality standard 167.</p> <p><a href="#">Obesity: clinical assessment and management</a> (2016). NICE quality standard 127.</p>

	<p><a href="#">Obesity in adults: prevention and lifestyle weight management programmes</a> (2016). NICE quality standard 111.</p> <p>Related NICE Pathways:</p> <p><a href="#">Lifestyle weight management services for overweight or obese adults</a> (2016). NICE Pathway</p> <p><a href="#">Obesity</a> (2018). NICE Pathway.</p> <p><a href="#">Obesity: working with local communities overview</a> (2016). NICE Pathway.</p>
<b>Related National Policy</b>	<p>The NHS Long Term Plan, 2019. <a href="#">NHS Long Term Plan</a></p> <p>NHS England (2018/2019) <a href="#">NHS manual for prescribed specialist services (2018/2019)</a> Chapter 139A. Specialist morbid obesity services for (children)</p> <p>NHS England (2017) <a href="#">Commissioning guidance to support devolution to CCGs of adult obesity surgical services in 2016/17</a></p> <p>NHS England (2014) <a href="#">Report of the working group into: Joined up clinical pathways for obesity</a></p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 1 and 2</p> <p><a href="https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017">https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</a></p> <p>Department of Health and Social Care (2018) <a href="#">Childhood obesity: a plan for action, chapter 2</a></p> <p>Public Health England (2018) <a href="#">Promoting healthy weight in children, young people and families</a></p> <p>Public Health England (2017) <a href="#">Child weight management: short conversations with families</a></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 obesity in this population?

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

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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 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.

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. Health Survey for England (2017). [Overweight and obesity in adults and children](#). [online]
2. Diabetes UK (2011) [Diabetes in the UK 2011/2012: key statistics on diabetes](#). [online]
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4. Logue J, Sattar N (2011) Childhood obesity: a ticking time bomb for cardiovascular disease? *Nature* 90: 174–8

5. Wei C, Ford A, Hunt L et al. (2011) Abnormal liver function in children with metabolic syndrome from a UK based obesity clinic. *Archives of Disease in Childhood* 96: 1003–7
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9. Taylor ED, Theim KR, Mirch MC et al. (2006) Orthopedic complications of overweight in children and adolescence. *Pediatrics* 117: 2167–74