

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Health Technology Evaluation

## Semaglutide for managing overweight and obesity in young people aged 12 to 17

## Draft scope

**Draft remit/evaluation objective**

To appraise the clinical and cost effectiveness of semaglutide within its marketing authorisation, in addition to healthy nutrition and increased physical activity, for managing overweight and obesity in young people aged 12 to 17.

**Background**

Overweight and obesity is a chronic condition characterised by increased body fat. Young people living with overweight or obesity are at an increased risk of developing asthma, cardiovascular disease, type 2 diabetes, cancer, osteoarthritis and chronic kidney disease. Overweight and obesity in childhood is also associated with psychological problems such as low self-esteem and depression and is also a predictor of overweight and obesity in adulthood<sup>1</sup>.

For children and young people, instead of using fixed body mass index (BMI) thresholds to indicate having overweight or obesity, variable thresholds are used. The thresholds are derived from a reference population known as a child growth reference which provides an average BMI for children and young people according to age and sex. This allows a measure of an individual's BMI according to the expected value based on their age and sex, including the centile of the population they are within<sup>2</sup>. [NICE clinical guideline 189 \(CG189\) 'Obesity: identification, assessment and management'](#) recommends using the [Royal College of Paediatrics and Child Health UK-World Health Organization \(WHO\)](#) growth chart to classify BMI centile. In line with NICE CG189, for children and young people, a BMI that is in the 91<sup>st</sup> centile of the WHO child growth reference is classified as overweight, and BMI that is in the 98<sup>th</sup> centile is classified as obese.

A 2017 UK study of 10,825 14-year-olds showed that 15% of participants were overweight (defined as BMI above the 85<sup>th</sup> centile) and 21% had obesity (above the 95<sup>th</sup> centile). Differences in the rates of overweight and obesity were seen based on ethnicity, with 48% of Black young people compared with 34.5% of White young people having overweight or obesity. Differences were also seen according to maternal education, as around 38% of participants whose mothers were educated to GCSE level or lower were overweight or obese compared with 26% of people whose mothers had a degree level education or higher<sup>1</sup>.

NICE CG189 'Obesity: identification, assessment and management' states that tailored interventions should be considered for treatment of overweight or obesity in young people. Multicomponent interventions are the treatment of choice and should 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. In young people, pharmacological treatment with orlistat is recommended only if physical comorbidities or severe psychological comorbidities are present. Orlistat should be started in a specialist paediatric setting by

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multidisciplinary teams with experience of prescribing in this age group. Treatment should continue only when prescribed by a multidisciplinary team with expertise in drug monitoring, psychological support, behavioural interventions, interventions to increase physical activity and interventions to improve diet.

### The technology

Semaglutide (Wegovy, Novo Nordisk) does not currently have a marketing authorisation in the UK for managing overweight or obesity in young people. It has been studied in a clinical trial in young people aged 12 to 17 years with a BMI in the 95<sup>th</sup> centile or higher (defined as obese), or the 85<sup>th</sup> centile or higher (defined as overweight) plus 1 or more weight-related comorbidities including hypertension, dyslipidaemia, obstructive sleep apnoea or type-2 diabetes. All participants also received talks about healthy food choices, how to be more physically active and what they can do to help lose weight.

Semaglutide does have marketing authorisations in the UK as an adjunct to diet and exercise for managing overweight and obesity in adults. It also has a marketing authorisation in the UK for managing insufficiently controlled type 2 diabetes mellitus, either as monotherapy when metformin is considered inappropriate due to intolerance, or in combination with other medicinal products for the treatment of diabetes.

<b>Intervention</b>	Semaglutide
<b>Populations</b>	Young people aged 12 to 17 years who on a recognised child growth reference adjusted for age and sex, have a BMI: <ul style="list-style-type: none"> <li>• equal to or above the 95<sup>th</sup> centile or,</li> <li>• equal to or above the 85<sup>th</sup> centile plus at least 1 weight-related comorbidity</li> </ul>
<b>Subgroups</b>	Young people aged 12 to 17 years who on a recognised child growth reference adjusted for age and sex have overweight or obesity in line with NICE CG189, with BMI: <ul style="list-style-type: none"> <li>• equal to or above the 98<sup>th</sup> centile or,</li> <li>• equal to or above the 91<sup>st</sup> centile and less than the 98<sup>th</sup> centile</li> </ul>
<b>Comparators</b>	For young people aged 12 to 17 years who have overweight or obesity: <ul style="list-style-type: none"> <li>• standard management without semaglutide (including a reduced calorie diet and increased physical activity)</li> <li>• orlistat (in the presence of physical comorbidities or severe psychological comorbidities only)</li> </ul>

<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• BMI</li> <li>• change in BMI percentage on gender and age specific growth charts</li> <li>• weight loss</li> <li>• waist circumference</li> <li>• incidence of type 2 diabetes</li> <li>• glycaemic status</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>	<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>
<b>Other considerations</b>	<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>
<b>Related NICE recommendations</b>	<p><b>Related Technology Appraisals:</b>  <a href="#">Liraglutide for managing overweight and obesity</a> (2020). NICE technology appraisal 664.</p> <p><b>Related appraisals in development:</b>  <a href="#">Semaglutide for managing overweight and obesity</a> NICE technology appraisal guidance [ID3850]. Publication date to be confirmed.</p> <p><b>Related Guidelines:</b>  <a href="#">Obesity: identification, assessment and management</a> (2014, updated 2022). NICE guideline CG189.</p> <p><b>Related Interventional Procedures:</b></p>

	<p><a href="#">Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity</a> (2016). NICE interventional procedures guidance 569.</p> <p><a href="#">Implantation of a duodenal–jejunal bypass sleeve for managing obesity</a> (2013). NICE interventional procedures guidance 471.</p> <p><a href="#">Laparoscopic gastric plication for the treatment of severe obesity</a> (2012). NICE interventional procedures guidance 432.</p> <p><b>Related Public Health Guidance/Guidelines:</b></p> <p><a href="#">Weight management: lifestyle services for overweight or obese children and young people</a> (2013). NICE public health guideline 47. Update ongoing; publication due March 2024.</p> <p><b>Related Quality Standards:</b></p> <p><a href="#">Obesity in children and young people: prevention and lifestyle weight management programmes</a> (2015). NICE quality standard 94.</p>
<p><b>Related National Policy</b></p>	<p>The NHS Long Term Plan, 2019. <a href="#">NHS Long Term Plan</a> NHS England (2018/2019) <a href="#">NHS manual for prescribed specialist services (2018/2019)</a> Section 139A</p>

**Questions for consultation**

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

In which setting would you expect semaglutide to be used? If it will be prescribed in specialist care what are the criteria for referring young people with overweight or obesity for specialist care in NHS clinical practice?

What is standard management of overweight or obesity in young people in the NHS? Please define standard management for different populations according to BMI centile and the presence of a comorbidity, if appropriate.

Is orlistat used to manage overweight and obesity in some young people? If so, who?

Would semaglutide be a candidate for managed access?

Do you consider that the use of semaglutide 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 semaglutide 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. We welcome comments on the appropriateness of appraising this topic through this 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 Fitzsimmons and Pongiglione; [Prevalence and trends in overweight and obesity in childhood and adolescence - Findings from the Millennium Cohort Study](#), with a focus on age 14; Centre for longitudinal studies; 2017

2 National Obesity Observatory, [A guide to classifying body mass index in children](#) (2011)