

## National Institute for Health and Care Excellence

## Health Technology Evaluation

## Semaglutide for managing overweight and obesity in young people aged 12 to 17 ID6139

## Response to stakeholder organisation comments on the draft remit and draft scope

**Please note:** Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

**Comment 1: the draft remit and proposed process**

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Novo Nordisk	<p>An STA is appropriate.</p> <p>Novo Nordisk is aware that NICE is exploring several new processes with the aim of taking a proportionate approach to technology appraisals. Semaglutide already has a draft positive recommendation for weight management, including weight loss and weight maintenance, alongside a reduced-calorie diet and increased physical activity in adults.<sup>1</sup> The weight loss demonstrated in children and young people in the STEP TEENS clinical trial is greater than in the adult population.<sup>2</sup> For this reason, it is Novo Nordisk's view that this appraisal is a suitable topic for a proportionate response. Therefore, Novo Nordisk is open to engagement with NICE on any new processes which are appropriate for this technology appraisal.</p>	Thank you for your comment. This appraisal will follow the standard STA process.

Section	Stakeholder	Comments [sic]	Action
	Sheffield Children's Hospital	Important & timely evaluation given limited pharmaceutical options to manage weight in young people	Thank you for your comment.
	NHS England	NHS England supports the NICE Technology Appraisal on the use of Semaglutide for managing overweight and obesity in young people aged 12 to 17.	Thank you for your comment.
Wording <i>Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider?</i>	Novo Nordisk	Yes  For clarity, the STEP TEENS clinical trial enrolled patients enrolled adolescents (12 to <18 years of age).	Thank you for your comment.
	Sheffield Children's Hospital	Yes	Thank you for your comment.
	NHS England	Wording reflects the issues in the most part however would recommend articulating that semaglutide should be used within a wider context of providing a biopsychosocial approach.	Thank you for your comment. The committee will consider the context within which semaglutide should be considered. No update to the remit needed.

## Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Novo Nordisk	<p>Novo Nordisk has the following comments on the background information.</p> <p>Current wording: “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”</p> <p>Suggested new wording (changes in <b>bold</b>): “Young people living with overweight or obesity are at an increased risk of developing <b>weight-related comorbidities including but not limited to</b>; asthma, cardiovascular disease, type 2 diabetes, cancer, osteoarthritis and chronic kidney disease”</p> <p>Rationale: The list of weight related comorbidities is not exhaustive. For example, non-alcoholic fatty liver disease, polycystic ovarian syndrome and sleep apnoea, mobility issues and psychological distress about obesity are also comorbidities associated with overweight and obesity and sometimes used as part of referral criteria. Weight related comorbidities may persist into adulthood if obesity remains untreated.</p> <p>Current wording: “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.”</p> <p>Suggested new wording (changes in bold): “In line with NICE CG189, for children and young people, a BMI that is in the 91<sup>st</sup> centile of the <b>RCPCH UK-WHO child growth chart</b> is classified as overweight, and BMI that is in the 98<sup>th</sup> centile is classified as obese.</p>	Thank you for your comment. The background section has been updated.

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		<p>Rationale: The RCHPCH-WHO growth chart is a combination of the WHO growth standard (for children up to 4 years of age) and the RCPCH UK growth reference (for children 4 years and older). The suggested correction ensures the correct terminology is used in relation to the growth chart.</p> <p>Current wording: “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).”</p> <p>Suggested new wording (changes in bold): “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 <b>and below the 95<sup>th</sup> centile</b>) and 21% had obesity (above the 95<sup>th</sup> centile).”</p> <p>Rationale: To clarify that the overweight category does not also include patients in the obesity category.</p>	
	Sheffield Children’s Hospital	Fine	Thank you for your comment.
	NHS England	<p>The NHS has committed in the Long-Term Plan to improving care for children and young people (CYP) with complications related to severe obesity.</p> <p>The prevalence of CYP with complications from severe obesity is currently unknown and there is limited evidence of the causes of severe obesity in this cohort at a national level.</p>	Thank you for your comment. Semaglutide will be considered within its marketing authorisation.

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		<p>NHS England has commissioned 21 Complications from Excess Weight (CEW) clinics to provide a standardise treatment offer for CYP living with complications related to sever obesity.</p> <p>We do know that taking a holistic view for managing complications related to severe obesity, that recognises that this is a long-term condition, will be the most likely model for treatment success. More emphasis is required on the psychological and social support required for this patient cohort.</p>	
Population <i>Is the population defined appropriately?</i>	Novo Nordisk	Yes.	Thank you for your comment.
	Sheffield Children's Hospital	Yes	Thank you for your comment.
	NHS England	<p>We suggest that the population definition is aligned to CEW clinic criteria.</p> <ul style="list-style-type: none"> <li>• Patients with a BMI in the 99.6 percentile with a co-morbidity <u>OR</u></li> <li>• Patients with a BMI threshold equal to or greater than 3.33 Standard Deviation<sup>1</sup> above the mean</li> </ul> <p>However, we recognise that the cost benefit will need to be considered at different obesity thresholds. Therefore, prescription of specialist obesity medicines should be based on (i) the degree of obesity and (ii) presence of comorbidities.</p>	Thank you for your comment. Semaglutide will be considered within its marketing authorisation.

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Subgroups	Novo Nordisk	The subgroups suggested in the scope are appropriate.	Thank you for your comment.
	Sheffield Children's Hospital	Type 2 diabetes – GLP-1 already licenced for weight management	Thank you for your comment. This appraisal will focus on semaglutide for management of overweight and obesity. No updates to the subgroups in the scope have been made.
	NHS England	<p>As above</p> <p>However further consideration may be need for children and young people with autism, learning disability, down syndrome or with clinical mental health needs.</p>	Thank you for your comment. The Equality Impact Assessment has noted that further consideration of children and young people with autism, learning disability, Down's Syndrome and clinical mental health should be made during this appraisal by the committee. No updates to the subgroups in the scope have been made.

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Comparators	Novo Nordisk	<p>All relevant comparators have been included.</p> <p>While orlistat is recommended as part of NICE clinical guideline 189<sup>3</sup> its use in clinical practice is limited and Novo Nordisk do not consider it an appropriate comparator. It was not included as comparator in the appraisal of semaglutide for adults.<sup>1</sup> Please see additional comments below in response to the questions for consultation.</p>	<p>Thank you for your comment. Orlistat has been kept on the comparators list. Orlistat is a potential treatment option and therefore should be considered. The appropriateness of the comparators will be considered by the committee.</p>
	Sheffield Children's Hospital	Liraglutide is not on the list of comparators but is licenced (also made by Novo Nordisk)	<p>Thank you for your comment. Liraglutide has been added to the list of comparators.</p>
	NHS England	<p>Medication such as Orlistat and Liraglutide are available for adults living with obesity. Prescription of these medications is recommended with wider lifestyle change and some medication such as Liraglutide can only be prescribed within specialist weight management services (tier three) for adults.</p> <p>It is important to note that Liraglutide can currently be prescribed 'off licence' to young people living with obesity.</p> <p>However, the appraisal of Semaglutide should be prioritised over other weight loss medications due to the effectiveness of BMI loss.</p>	<p>Thank you for your comment. Liraglutide has been added to the list of comparators.</p>

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		The role of Semaglutide in a bariatric pre-operative pathway should also be considered, we suggest medicines, CEW clinics and digital options are explored before surgery.	
Outcomes	Novo Nordisk	<p>The outcomes listed in the scope are broadly appropriate, however Novo Nordisk proposes the following change to the outcome measures listed in the scope:</p> <p>Current wording: “change in BMI percentage on gender and age specific growth charts”</p> <p>Suggested wording “change in BMI <b>centile</b> based on gender and age specific growth charts (<b>references or standards</b>)”</p> <p>Rationale: BMI centile is the correct description of this outcome as opposed to “BMI percentage” and is consistent with the terminology used elsewhere in the scope.</p> <p>The clinical trial was conducted in multiple countries and includes endpoints which use both growth references (based on historical data, such as CDC growth charts) and growth standards (such as the international WHO standard, based on expected growth). The suggested wording ensures that the totality of the evidence is considered.</p>	Thank you for your comment. The outcomes list has been updated.
	Sheffield Children's Hospital	Yes. Appropriate	Thank you for your comment.



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	NHS England	<p>The outcomes currently mentioned are narrow in scope and do not cover the range of complications CYP living with obesity related complications may experience. This should be updated to include an exhaustive list. Please find the CEW minimum core data requirements attached.</p> <p>They focus on physical health benefits and exclude mental health and psychological outcomes for example, social and emotional functioning as well as communication, worry, daily activities and family relationships. The outcome list should be updated to be more holistic.</p> <p>For example, cardiovascular events are very rare in this age group and it's unlikely that we will see this as a helpful outcome. Whereas mortality including suicide, should be considered given increased suicide rates with some anti-obesity medications.</p>	<p>Thank you for your comment. The outcomes list has been updated to include mortality, including suicide, and social and emotional functioning. The outcomes listed are not intended to be fully exhaustive and it is acknowledged that other outcomes may also be relevant.</p>
Equality	Novo Nordisk	<p><b>Protected groups</b></p> <p>Childhood obesity is strongly associated with health inequalities, for which protected groups can be disproportionately impacted. For instance, children from some Black and minority ethnic communities are more likely than White British children to have a high BMI and this inequality is growing.<sup>4</sup></p> <p>For interventions for obesity in adults lower BMI thresholds are considered for certain groups. For example, the draft NICE recommendation for semaglutide for treating adults with obesity states: "Use lower BMI thresholds (usually reduced by 2.5 kg/m<sup>2</sup>) for people from south Asian, Chinese, and Black African or Caribbean family backgrounds."</p>	<p>Thank you for your comments. The equality issues raised have been detailed in the Equality Impact Assessment for this appraisal and will be considered by the committee.</p>

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		<p>NICE CG181 notes that there is not sufficient evidence to determine whether BMI thresholds should similarly be altered for children and includes the following research recommendation “What are the most accurate and suitable measurements and boundary values to assess the health risk associated with overweight, obesity and central adiposity in children and young people of different ethnicities, particularly those from Black, Asian and minority ethnic family backgrounds?”</p> <p>The appropriateness of any BMI thresholds applied in recommendations for different ethnic groups should be considered by the committee.</p> <p><b>People with disabilities</b></p> <p>Almost 2 in 5 (37%) people with a learning disability live with obesity compared to 28% of the general population<sup>5</sup>, and there are additional challenges associated with managing obesity in people with learning difficulties. NICE clinical guideline 181 recommends to “Consider referral to an appropriate specialist for children who are living with overweight or obesity and have significant comorbidities or complex needs (for example, learning disabilities or other additional support needs).” Therefore, the committee should consider whether additional considerations are required for children and young people with learning difficulties and whether their recommendations could make their access to treatment more challenging.</p> <p>Specialised growth charts are used for children and young people for whom puberty is delayed. Therefore, committee should consider whether there are groups of people with certain disabilities where BMI should be assessed differently.</p>	

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	Sheffield Children's Hospital	Severe obesity is a diseases of poverty& deprivation disproportionately affecting minority groups. 50% referrals to our CEW service are from the poorest socioeconomic decile	Thank you for your comment. The equality issue raised has been detailed in the Equality Impact Assessment for this appraisal and will be considered by the committee.
	NHS England	<p>Consideration should be given to young people with a learning disability, autism and SEND needs and the appropriate reasonably adjusted treatment and interventions made available.</p> <p>The relationship with Learning Disabilities and obesity includes, but is not limited to:</p> <ul style="list-style-type: none"> <li>• CYP diagnosed with an Autism Spectrum Disorder can sometimes overeat and have greater likelihood of having obesity;</li> <li>• There is an association between some genetic conditions and obesity, such as Prader-Willi Syndrome;</li> <li>• CYP who present with Avoidant and Restrictive Food intake Disorder (ARFID) will need further consideration.</li> </ul> <p>We must be mindful not to over medicate young people with learning disabilities and to provide multi-disciplinary teams with the appropriate guidance to effectively communicate the purpose of medication.</p> <p>Additionally, it is well documented in clinical research that CYP from BAME backgrounds and those living in deprived communities are more likely to</p>	Thank you for your comments. The equality issues raised have been detailed in the Equality Impact Assessment for this appraisal and will be considered by the committee.

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		become severely obese. Therefore, it may be necessary to assess impact of Semaglutide on ethnicity and deprivation, adjusting remit and scope accordingly.	
Other considerations	Novo Nordisk	See details in responses to questions for consultation below.	Thank you for your comment.
Questions for consultation	Novo Nordisk	<p><b>Where do you consider semaglutide will fit into the existing care pathway for overweight and obesity?</b></p> <p>Semaglutide would be offered as an option in addition to diet and exercise for children and young people who have been referred to specialist care to manage their obesity.</p> <p><b>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?</b></p> <p>NICE guideline CG181 recommends that for treatment with orlistat (used off-label) in patients aged 12 or older “Treatment should be started in a specialist paediatric setting, by multidisciplinary teams with experience of prescribing in this age group.” Novo Nordisk anticipates that semaglutide will be used in a similar setting and that the requirement for specialist involvement in prescription is also in line with the draft recommendations for semaglutide for adults. There is limited experience with the licensed GLP-1 receptor agonist liraglutide in children and young people’s specialist obesity services.</p>	Thank you for your comment.

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		<p>NICE CG181 recommends that “Assessment of comorbidity should be considered for children with a BMI at or above the 98<sup>th</sup> centile.” but in contrast to guideline recommendations for adults makes no specific recommendations for referral criteria for specialist services. BMI criteria for referral to both specialist and non-specialist obesity services are highly variable across the NHS. Several obesity services include referral criteria relating to BMI at the 98<sup>th</sup> centile, which corresponds to patients defined as clinically obese in the NICE guideline.</p> <p>Children and young people in a very high BMI centile and with a significant comorbidity burden may be referred to Complications of Excess Weight (CEW) clinics.<sup>6</sup> This is a relatively new service offering which is within a 2-year pilot phase, therefore availability of and referral criteria to these clinics is variable across England.</p> <p>As noted previously NICE clinical guideline 181 recommends considering different referral criteria for children with learning disabilities or conditions which affect growth, however this is rarely clearly defined as part of referral criteria.</p> <p><b>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.</b></p> <p>The obesity services and referral criteria offered to patients in the NHS are variable depending on location.</p>	

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		<p>There is no standard referral and management approach for children and young people with obesity. They may receive initial advice on diet and exercise in primary care. When their obesity can't be managed by diet and exercise alone, they may be treated by dietitians, specialists in childhood obesity or general paediatricians. Service offerings can be variable.</p> <p><b>Is orlistat used to manage overweight and obesity in some young people? If so, who?</b></p> <p>Orlistat is rarely prescribed in general practice. An analysis of 2 years of data from the THIN database (covering 6% of the UK population) identified only 55 children and young people who were prescribed orlistat.<sup>7</sup> Of these prescriptions 89% were initiated independent of specialist advice (in contrast to the recommendations of CG181 for orlistat to be prescribed only by specialists). Adherence to orlistat was low with 45% of patients only having a single prescription and median supply being 2 months.<sup>7</sup></p> <p>A survey of adolescent's experiences using orlistat indicated that most patients stopped treatment due to a combination of side effects and lack of efficacy.<sup>8</sup></p> <p>In HST21 of setmelanotide for treating obesity caused by LEPR or POMC deficiency<sup>9</sup> the population under consideration included young children and adolescents. The committee concluded that "orlistat, methylcellulose and bariatric surgery are not relevant comparators for setmelanotide."</p>	

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		<p>Due to the limited use of orlistat in clinical practice and precedent from previous NICE appraisals, Novo Nordisk does not consider orlistat an appropriate comparator for semaglutide.</p> <p><b>Would semaglutide be a candidate for managed access?</b></p> <p>No</p> <p><b>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.</b></p> <p>Novo Nordisk considers that the following benefits of semaglutide may not be fully captured by the QALY calculation.</p> <p><b>1) Improvements in quality of life</b></p> <p>The UK government's plan for action for childhood obesity<sup>10</sup> highlights that children and young people who are obese or overweight are more likely to experience bullying, low-esteem and a lower quality of life. Analysis of the UK's Millennium Birth Cohort Study (MCS) found that obese children as young as three years for boys, and five years for girls have significantly greater peer relationship problems than healthy weight children of the same age.<sup>11</sup> Compared with children of a healthy weight, children with obesity are 32% more likely to have depression.<sup>12</sup> For girls, the risk of developing social anxiety increases with BMI.<sup>13</sup> A survey of the UK general public identified</p>	

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		<p>several aspects of health that were not adequately captured by EQ-5D.<sup>14</sup> Identified aspects relevant to obesity include mental health, emotional wellbeing/self-esteem, personal and social relationships and general effects of the absence/presence of a chronic illness.</p> <p>Improvements in psychological well-being by alleviating people with obesity's distress over their obesity may help to improve the odds of success of interventions aiming to manage obesity.<sup>15</sup></p> <p>The STEP TEENS trial included a disease specific measure of quality of life (IWQOL kids) which provides evidence of improvement in quality of life across a range of subscales, including body esteem, social life and family relations.</p> <p>In the draft guidance for semaglutide in the adult population the committee concluded that there were likely some uncounted benefits not included in the QALY calculation.<sup>1</sup> These included:</p> <ul style="list-style-type: none"> <li>• a decreased risk of adverse events associated with respiratory infections such as COVID-19</li> <li>• a reduction in social isolation and stigma associated with obesity, and related improvement in career prospects</li> </ul> <p><b>2) Improvement of obesity services</b></p> <p>As noted previously in these comments, the availability of paediatric obesity services is not uniform across the NHS. In the draft guidance for semaglutide</p>	



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		<p>in the adult population the committee noted that “the system for obesity management is not ideal. It suggested that this system, including the referral criteria for people with severe mental illness, should be reconsidered. It welcomed any review of NHS services for overweight and obesity, which is not uniform.”</p> <p>The availability of a well-tolerated, effective treatment for obesity for children and young people may provide additional benefits to the NHS by supporting both the NHS Long Term Plan and the Plan for Action on Childhood Obesity’s national ambitions to halve childhood obesity rates by 2030 and significantly reduce the health inequalities that persist.<sup>10,16</sup></p> <p><b>3) Reduction of health Inequalities</b></p> <p>Reducing health inequalities is a key priority for the NHS, exemplified through various long-standing strategies – such as the NHS Long Term Plan<sup>16</sup> – as well as recently launched policies including CORE20PLUS5, and formation of the Innovation for Healthcare Inequalities Programme.<sup>17</sup> Recent research by the King’s Fund has found that the gap in overweight and obesity rates between children from the least and most affluent families in the UK is larger than any EU country (26 points compared to the EU average of 8 percentage points).<sup>18</sup> Indeed, the National Child Measurement Programme, England – 2021-22 report published by NHS digital found that the prevalence of year 6 children living with severe obesity was over four times as high for children living in the most deprived areas (9.4%) compared with those living in the least deprived areas (2.1%).<sup>19</sup></p> <p>The National Institute for Health and Care Research (NIHR) has recently announced funding for local government to introduce interventions aimed at</p>	

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		<p>reducing health inequalities, with childhood obesity identified as one of the priority areas.<sup>20</sup></p> <p>Due to the disproportionate impact of obesity on children and young people from low-income families, the availability of new interventions such as semaglutide may help to reduce health inequalities by ensuring these children can receive effective treatments to manage and maintain their weight loss.</p> <p><b>References</b></p> <p>1) <a href="#">Semaglutide for managing overweight and obesity</a> NICE technology appraisal guidance [ID3850]. Publication date to be confirmed.</p> <p>2) Weghuber D, et al. Once-Weekly Semaglutide in Adolescents with Obesity, <i>NEJM</i>, 2022, DOI: 10.1056/NEJMoa2208601</p> <p>3) <a href="#">Obesity: identification, assessment and management</a> (2014, updated 2022). NICE guideline CG189.</p> <p>4) <a href="#">The Parliamentary Office of Science and Technology: POSTNOTE 640 April 2021 Childhood Obesity</a></p> <p>5) <a href="#">Public Health England: Obesity and weight management for people with learning disabilities: guidance (updated 2020)</a></p>	

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		<p>6) <a href="https://www.england.nhs.uk/get-involved/cyp/specialist-clinics-for-children-and-young-people-living-with-obesity/">https://www.england.nhs.uk/get-involved/cyp/specialist-clinics-for-children-and-young-people-living-with-obesity/</a> (accessed, Dec 2022)</p> <p>7) White B, et al. Survey of antiobesity drug prescribing for obese children and young people in UK primary care, <i>BMJ Paediatrics Open</i>, 2017;<b>1</b>:e000104. DOI: 10.1136/bmjpo-2017-000104</p> <p>8) White B, et al. Adolescent experiences of anti-obesity drugs, <i>Clinical Obesity</i>, 2015, <b>5</b>(3), 116–126</p> <p>9) <a href="#">Setmelanotide for treating obesity caused by LEPR or POMC deficiency</a> (2022). NICE highly specialised technology guidance 21.</p> <p>10) <a href="#">Childhood obesity: a plan for action, chapter 2</a>, Department of Health and Social Care (2018)</p> <p>11) <a href="#">Public Health England: Reducing social isolation across the lifecourse</a> (2015)</p>	

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		<p>12) Sutaria et al. Is Obesity Associated with Depression in Children? Systematic Review and Meta-analysis. <i>Arch. Dis. Child.</i>, 2019, <b>104</b>(1), 64–74.</p> <p>13) Anderson et al. Adolescent Obesity and Risk for Subsequent Major Depressive Disorder and Anxiety Disorder: prospective evidence. <i>Psychosom. Med.</i>, 2007, <b>69</b>(8), p740–747.</p> <p>14) Shah K, et al. Views of the UK General Public on Important Aspects of Health Not Captured by EQ-5D. <i>Patient</i>, 2017, <b>10</b>, 701–709</p> <p>15) Vallis M, Quality of life and psychological well-being in obesity management: improving the odds of success by managing distress. <i>Int J Clin Pract</i>, 2016, <b>70</b>(3), 196–205</p> <p>16) <a href="#">NHS Long Term Plan Chapter 2: More NHS action on prevention and health inequalities - Obesity</a> (2019)</p> <p>17) <a href="#">NHS Accelerated Access Collaborative » Innovation for Healthcare Inequalities Programme</a> (accessed December 2022)</p>	

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		<p>18) <a href="#">Tackling obesity: The role of the NHS in a whole-system approach</a> The King's Fund (2021)</p> <p>19) <a href="#">National Child Measurement Programme, England, 2021/22 school year - NDRS</a> (2022)</p> <p>20) <a href="https://www.nihr.ac.uk/news/50-million-awarded-to-local-government-to-tackle-interventions-for-health-inequalities-through-research/31654">https://www.nihr.ac.uk/news/50-million-awarded-to-local-government-to-tackle-interventions-for-health-inequalities-through-research/31654</a> (accessed Dec 2022)</p>	
	NHS England	<p><b>Questions for consultation</b></p> <p><b>Where do you consider semaglutide will fit into the existing care pathway for overweight and obesity?</b></p> <p>The NHS Long Term Plan committed to providing a treatment offer for CYP living with complications from severe obesity and developing a tier three service.</p> <p>The long term health impacts of severe obesity in children are considerable on an individual and societal level. Emerging data on children with severe obesity suggests increased mortality in early adulthood, reduced economic activity and increased morbidity in all organ systems including mental health resulting in increased healthcare utilisation.</p>	Thank you for your comment.

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		<p>The aim of the clinics is three-fold:</p> <ol style="list-style-type: none"> <li>1. Identify the factors involved in the development of severe obesity. Assessment should be holistic with equal consideration for mental health, physical health and social needs.</li> <li>2. Treat complications associated with severe obesity and coordinate / refer onto other services where required.</li> <li>3. Consider an individualised holistic plan that considers biopsychosocial needs. This may include interventions such as family-based therapy, behavioural coaching, dietary planning, and mental health treatment. This approach will aim to address health inequalities by considering culturally appropriate factors and a personalised approach.</li> </ol> <p>Working with regional and local commissioners, 21 CEW clinics have been mobilised across the country and over 700 patients have started their treatment journey. CEW Clinics are also a world first in providing a national infrastructure to provide a standardised treatment offer for CYP living with complications from severe obesity.</p> <p>CEW clinics are providing the mechanism for prescription of 'off licence' medicines and they provide the infrastructure required by NICE for prescribing obesity medications – are tier three services, include a biopsychosocial model and have links to tertiary hospitals.</p> <p><b>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?</b></p> <p>Semaglutide should be provided under the consultation of a multi-disciplinary team that provides biopsychosocial support.</p>	

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		<p>For example, the CEW Clinic infrastructure provides the specialist weight management environment with a multi-disciplinary team required by the NICE TA for other weight management medicines such as liraglutide for adult use.</p> <p>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.</p> <p>Children and young people living with excess weight are mostly treated in the community through tier one and tier 2 services. These are commissioned by local authorities.</p> <p>The NHS commissions tier three services (CEW clinics as described above) and tier four services for surgical interventions.</p> <p><b>Is orlistat used to manage overweight and obesity in some young people? If so, who?</b></p> <p>As above.</p> <p>Orlistat is the only licenced medication for obesity in CYP. It is rarely used due to an unfavourable side-effect profile and very modest benefits.</p> <p>Currently no effective obesity medications have been appraised by NICE. GLP1 agonists (liraglutide and semaglutide) are the group of drugs that currently have best outcomes for weight loss, with trial data showing far greater weight loss with semaglutide over liraglutide.</p> <p><b>Would semaglutide be a candidate for managed access?</b></p>	

Section	Consultee/ Commentator	Comments [sic]	Action
		<p>As above, Semaglutide should be provided in Tier 3 obesity services under the consultation of a multi-disciplinary team.</p> <p><b>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?</b></p> <p><b>Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.</b></p> <p>Benefits of rapid weight loss may include BMI reduction, reversing complications, psychological and social benefits (i.e. school attainment). However further research is needed to understand long term benefits.</p> <p><b>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:</b></p> <p>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 medications. This is because people from deprived communities are less likely to access secondary services.</p> <p><b>Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.</b></p>	



Section	Consultee/ Commentator	Comments [sic]	Action
		<p>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 <a href="https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation">https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation</a>).</p>	
	NHS England Specialised	<p><b>Where do you consider semaglutide will fit into the existing care pathway for overweight and obesity?</b></p> <p><b>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?</b></p> <p>Tier 3 services for children and young people with obesity are the responsibility of ICSs'. Tier 4 services, providing medical management and bariatric surgery for eligible children, are the commissioning responsibility of NHS England Specialised Commissioning. NHS England has a published service specification for Tier 4 services (<a href="#">170014s-specialised-complex-obesity-surgery-children.pdf (england.nhs.uk)</a>)</p> <p>In order to access treatment and management in a Tier 4 service, including bariatric surgery, it is anticipated that children and young people will have completed clinical assessment and management/treatment within a commissioned Tier 3 service prior to referral. This would include relevant non-surgical/pharmacological treatments. The NHS England Clinical</p>	Thank you for your comment.

Section	Consultee/ Commentator	Comments [sic]	Action
		<p>Commissioning policy on Obesity Surgery in Children and Young people (<a href="#">16053p-obesity-surgery-children-severe-complex-obesity.pdf (england.nhs.uk)</a>) outlines criteria for children and young people accessing obesity surgery.</p> <p>As such, if recommended, semaglutide should be also available in both Tier 3 and Tier 4 services, to ensure that Tier 4 services have the capability to manage severely obese adolescents for whom surgical intervention is not appropriate, but who have significant comorbidities, as outlined in the NHS England service specification (<a href="#">170014s-specialised-complex-obesity-surgery-children.pdf (england.nhs.uk)</a>).</p> <p><b>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.</b></p> <p><b>Is orlistat used to manage overweight and obesity in some young people? If so, who?</b></p> <p><b>Would semaglutide be a candidate for managed access?</b></p> <p><b>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?</b></p> <p>It is anticipated that the use of semaglutide may lead to a reduction in the number of children referred to Tier 4 services and, as such, potentially a reduction in bariatric surgery cases.</p>	

Section	Consultee/ Commentator	Comments [sic]	Action
Additional comments on the draft scope	Sheffield Children's Hospital	Looks fine	Thank you for your comment.

**The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope**

None