

## Integrated Impact Assessment Report for Service Specification

<b>Reference Number</b>	A05 S02		
<b>Service Specification Title</b>	Obesity surgery for children with severe complex obesity		
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<b>Section K - Activity Impact</b>			
<b>Theme</b>	<b>Questions</b>	<b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)	
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	<p>K1.1 This service specification describes the service model to support the proposed policy to <b>routinely commission</b> obesity surgery for children (up to 18 years) with severe and complex obesity.<sup>i</sup></p> <p><b>Severe obesity in children</b> is a major health problem that is associated with a number of different illnesses.<sup>ii</sup> Although there is limited data on the prevalence and incidence of severe obesity in children, it can be deduced that the prevalence of severe obesity is c. 0.14% of the population.<sup>iii</sup> Based on this estimation, there may be c. 4,360 children<sup>iv</sup> with severe obesity in England in 2014/15.<sup>v</sup></p>	

	<p>K1.2 What is the number of patients currently eligible for the treatment under the proposed specification?</p> <p>K1.3 What age group is the treatment indicated for?</p> <p>K1.4 Describe the age distribution of the patient population taking up treatment?</p> <p>K1.5 What is the current activity associated with currently routinely</p>	<p>K1.2 The population <b>eligible for treatment</b> is a subset of the prevalent population. To be eligible for obesity surgery a patient must have either:</p> <ul style="list-style-type: none"> <li>• severe obesity (a BMI <math>\geq 35\text{kg/m}^2</math>) and significant associated comorbidities; or</li> <li>• very severe obesity (BMI <math>\geq 40\text{kg/m}^2</math>)</li> </ul> <p>A number of other factors are also considered; varying from social, psychometric, lifestyle, mental and physical health factors.<sup>vi</sup> It is estimated that around 20-25 patients per year would meet these criteria.<sup>vi</sup></p> <p>K1.3 There is no strict age group for which bariatric surgery is indicated for in children. The eligibility criteria for surgical intervention, instead, are determined by whether a child has reached skeletal maturity (Tanner Stage 4)<sup>viii</sup>. It can therefore be inferred that the approximate age group would be those aged around 13 or over.<sup>ix</sup></p> <p>K1.4 Although the policy is indicated for patients aged under 18, the age distribution is estimated to range from 13-17 years.<sup>x</sup> The majority of patients having undergone bariatric surgery in childhood in the past were aged 16-17.<sup>xi</sup></p> <p>K1.5 Around 6-8 patients are estimated to receive obesity surgery each year but this may be an underestimate and further analysis and</p>
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commissioned care for this group?

K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new specification) in 2, 5, and 10 years?

K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2, 5 and 10 years?

validation is taking place.<sup>xi</sup> The remaining 14-17 patients eligible for obesity surgery under the policy may currently be:<sup>xiii</sup>

- receiving orlistat<sup>xiv</sup>;
- having other non-surgical or non-pharmacological care;<sup>xv</sup> or
- receiving no further treatment.<sup>xi</sup>

K1.6 It is estimated that in the UK between 1993 and 2011, obesity rates almost doubled.<sup>xii</sup> In children, it has been acknowledged that national surveys and measurement programmes suggest the prevalence continues to rise each year, but that levelling off has been indicated in more recent studies.<sup>xiii</sup>

Based on this, no change to the future prevalence of severe childhood obesity is anticipated given the prevalence of childhood obesity has remained stable over recent years.<sup>xiv</sup> The prevalent population identified in K1.1 could grow in line with population growth and is estimated to be<sup>xv</sup>:

- ~ 4,330 in 2016/17 (year 1)
- ~ 4,320 in 2017/18 (year 2)<sup>xvi</sup>
- ~ 4,410 in 2020/21 (year 5)

K1.7 Under a do nothing position, it is assumed that activity will remain broadly constant over time – with around 6 to 8 patients per annum receiving complex obesity surgery and the other eligible patients receiving one of the other interventions listed in K1.5.

	<p>K1.8 How is the population currently distributed geographically?</p>	<p>K1.8 The incidence of obesity for both adults and children has been found to be greater in the North and Central parts of England than in the South of England; with the highest incidence levels in the North-East and the lowest incidence levels by the South Coast.<sup>xxi</sup> The regional variation in childhood obesity could be attributed to the differences in prevalence by socioeconomic status<sup>xxiii</sup> and ethnicity.<sup>xxiv</sup></p>
<p>K2 Future Patient Population &amp; Demography</p>	<p>K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?</p> <p>K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).</p>	<p>K2.1 The policy proposes the <b>routine commissioning</b> of obesity surgery for the target group identified in K1.2.<sup>xxv</sup></p> <p>K2.2 The factors that affect the prevalence of obesity include:<sup>xxvi</sup></p> <ul style="list-style-type: none"> <li>• attitudes, habits and beliefs ;</li> <li>• food and drink access and availability;</li> <li>• the price of food and drink;</li> <li>• food marketing;</li> <li>• opportunities for physical activity;</li> <li>• technological advancements;</li> <li>• income growth.</li> </ul> <p>The factors above are difficult to quantify; and as mentioned in K1.6, prevalence of childhood obesity has remained fairly stable over recent years.</p>

	<p>K 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details.</p> <p>K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?</p>	<p>K2.3 The prevalence of childhood obesity has been found to vary with socioeconomic status and ethnicity, as described in K1.8. These factors may therefore drive changes in the geographical distribution.</p> <p>K2.4 Under a <b>routine commissioning position</b>, the 20 – 25 eligible patients (as identified in K1.2) would receive bariatric surgery. This represents a <b>net increase</b> in the number of patients receiving the procedure of <b>14 to 17<sup>xxvii</sup></b> each year, as 6 to 8 per year are estimated to currently receive the procedure.</p> <p>As described in K2.2, over the next five years, even after applying the demographic growth projections, the number of patients receiving the procedure could remain broadly flat given the low volume.</p>
K3 Activity	<p>K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.</p> <p>K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.</p>	<p>K3.1 Current annual activity is identified in K1.5.</p> <p>K3.2 Under the <b>routine commissioning position</b>, activity is expected to be equal to the annual target population of 20-25 patients as identified in K1.2.</p> <p>Activity related to treating the co-morbidities from obesity may be lower for the target population under the specification when compared to the 'do-nothing'. Patients who undergo bariatric surgery and achieve significant weight reduction may reduce the need for support: including<sup>xxviii</sup>:</p>

	<p>K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet.</p>	<ul style="list-style-type: none"> <li>• Home education;</li> <li>• Overnight continuous positive airway pressure (CPAP) ventilation costs; and</li> <li>• Treating diabetes (such as the cost of insulin).</li> </ul> <p>It has been shown that bariatric surgery has the potential to improve patients' comorbidities, including amongst others: type 2 diabetes, hypertension and sleep apnoea.<sup>xxx</sup> Furthermore it has been demonstrated in adults that there could be significant reductions in medication use after bariatric surgery of:<sup>xxx</sup></p> <ul style="list-style-type: none"> <li>• 76% reduction in diabetes medication;</li> <li>• 51% reduction in hypertension medication; or</li> <li>• 59% reduction in hyperlipidaemia medication.</li> </ul> <p>Therefore, although there is expected be an increase in the number of procedures, there could be a reduction in activity relating to treating co-morbidities and the use of medication following surgery.</p> <p>K3.3 If the policy is <b>not adopted</b>, it is expected that activity would be equal to the 'do nothing' identified in K1.5.</p>
<p>K4 Existing Patient Pathway</p>	<p>K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.</p>	<p>K4.1 Obesity is managed through a tiered service:</p> <ul style="list-style-type: none"> <li>• Tier 1 - Primary Care and Community Advice</li> <li>• Tier 2 - Primary Care with Community Interventions.</li> </ul>

	<p>K4.2. What are the current treatment access criteria?</p> <p>K4.3 What are the current treatment stopping points?</p>	<ul style="list-style-type: none"> <li>• Tier 3 - A specialist multi-disciplinary team (MDT) to provide an intensive level of input to patients</li> <li>• Tier 4 - Specialised Complex Obesity Services (including both medical management, obesity surgery and other elements of specialised MDT care)</li> </ul> <p>There is currently no routinely commissioning surgical treatment for children in Tier 4.</p> <p>K4.2 N/A</p> <p>K4.3 N/A</p>
<p>K5 Comparator (next best alternative treatment) Patient Pathway</p>	<p>K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.</p>	<p>K5.1 Alternative routinely commissioned treatments include lifestyle interventions and pharmacological treatments. These treatments are managed by Tier 3 services, which are currently commission by CCGs and are highly variable across the country.</p> <p>Lifestyle interventions should be multicomponent interventions. Weight management programmes should include behaviour change strategies to increase physical activity levels or decrease inactivity, improve eating behaviour and the quality of the diet, and reduce energy intake (NICE CG189).</p> <p>In children aged 12 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 for this age group (NICE CG189).</p>

	<p>K5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p>	<p>K5.2 N/A</p>
<p>K6 New Patient Pathway</p>	<p>K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.</p>	<p>K6.1 Obesity surgery will be recommended for a small number of children that have completed assessment and treatment within a commissioned Tier 3 service, and all non-surgical avenues have been adequately explored and found to be unsuccessful. It is expected that the Tier 3 service will have identified, investigated and managed the associated comorbidities prior to referral for surgical assessment to a Tier 4 service. The adequacy of intensity and duration will be determined by specialist MDT.</p> <p>Adolescents indicated for obesity surgery should have a comprehensive psychological, educational, family and social assessment by an appropriate multi-disciplinary team before undergoing surgery. This includes a full medical evaluation, and genetic screening or assessment to exclude rare, treatable causes of obesity.</p> <p>Primarily three types of obesity surgery are being commonly performed in the paediatric/adolescent population: laparoscopic Roux-en Y gastric bypass (RYGB); laparoscopic adjustable gastric banding (LAGB); and more recently sleeve gastrectomy (LSG). The adolescent and their family need to commit to long-term follow-up. Specialist Tier 4 services will be responsible for follow up for a</p>



	<p>K6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p>	<p>period of 5 years post-surgery and transition to an adult service. The Tier 4 service will develop shared care models of follow up with specialist Tier 3 services to facilitate local access for the individual and their family.</p> <p>K6.2 N/A</p>
<p>K7 Treatment Setting</p>	<p>K7.1 How is this treatment delivered to the patient?</p> <ul style="list-style-type: none"> <li>○ Acute Trust: Inpatient/Daycase/ Outpatient</li> <li>○ Mental Health Provider: Inpatient/Outpatient</li> <li>○ Community setting</li> <li>○ Homecare delivery</li> </ul> <p>K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? <i>e.g. service capacity</i></p>	<p>K7.1 This is an acute inpatient or day case procedure with a length of stay of typically between 0 and 3 days.<sup>xxx</sup></p> <p>K7.2 No</p>

<p>K8 Coding</p>	<p>K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?</p> <p>K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)</p>	<p>K8.1 As this is an inpatient procedure; activity would be recorded in SUS. Activity may also be recorded in the National Bariatric Surgery Registry.<sup>xxxii</sup></p> <p>K8.2 New activity may be identified through the relevant ICD10 codes<sup>xxxiii</sup> for Obesity and OPCS codes<sup>xxxiv</sup> for obesity surgery.</p>
<p>K9 Monitoring</p>	<p>K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?</p> <p>K9.2 If this treatment is a drug, what pharmacy monitoring is required?</p> <p>K9.3 What analytical information /monitoring/ reporting is required?</p> <p>K9.4 What contract monitoring is required by supplier managers? What</p>	<p>K9.1 The new service specification complements the policy proposition.</p> <p>K9.2 N/A</p> <p>K9.3 Mandatory compliance by obesity surgery providers with National Bariatric Surgery Registry (NBSR) requirements, including 100% provision of required data, and publication of long term follow up data.</p> <p>Given the relative lack of evidence relating to adverse effects (e.g. nutritional deficiencies) in the adolescent population, it would be beneficial for specific outcome requirements to be included in the NBSR dataset and published, to support longitudinal study.</p> <p>K9.4 None</p>

	<p>changes need to be in place?</p> <p>K9.5 Is there linked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?</p> <p>K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?</p> <p>K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. See also linked question in M1 below</p>	<p>K9.5 No</p> <p>K9.6 No quality standards identified.</p> <p>K9.7 N/A</p>
<b>Section L - Service Impact</b>		
<b>Theme</b>	<b>Questions</b>	<b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	L1.1 The Working Group identified four providers that considered they offered a paediatric service: Bristol Children's Hospital, Sheffield Children's Hospital, University College London Hospital and King's College Hospital but this requires further validation as it is expected that small volumes of surgery may be occurring at other sites

	L1.2 How will the proposed service specification change the way the commissioned service is organised?	L1.2 No change.
L2 Geography & Access	<p>L2.1 Where do current referrals come from?</p> <p>L2.2 Will the new service specification change / restrict / expand the sources of referral?</p> <p>L2.3 Is the new specification likely to improve equity of access?</p> <p>L2.4 Is the new specification likely to improve equality of access / outcomes?</p>	<p>L2.1 Patients referred by Tier 3 services.</p> <p>L2.2 Yes the approach to commissioning should include formal selection of providers and confirmation of the limited number of providers that should be commissioned for the adolescent age range.</p> <p>L2.3 Yes, through a consistent commissioning position across the country.</p> <p>L2.4 Yes</p>
L3 Implementation	<p>L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?</p> <p>L3.2 Is there a change in provider physical infrastructure required?</p>	<p>L3.1 Yes</p> <p>L3.2 Possibly</p>

	<p>L3.3 Is there a change in provider staffing required?</p> <p>L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?</p> <p>L3.5 Are there changes in the support services that need to be in place?</p> <p>L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p> <p>L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?</p> <p>L3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g.</p>	<p>L3.3 Possibly</p> <p>L3.4 No.</p> <p>L3.5 Tier 3 services for adults and children are currently commission by CCGs and highly variable across the country.</p> <p>L3.6 No.</p> <p>L3.7 No.</p> <p>L3.8 New service specifications for obesity surgery in children supported by a commissioning process.</p>
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	publication and notification of new policy, competitive selection process to secure revised provider configuration)	
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	L4.1 No (however obesity surgery for adults will no longer be commissioned by NHS England from 2016)
<b>Section M - Finance Impact</b>		
<b>Theme</b>	<b>Questions</b>	<b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which?	<p>M1.1 Obesity surgery falls under national tariff, however, there have been significant changes to the how this is reimbursed in the 2014/15, 2015/16 and proposed 2016/17 national tariffs.</p> <p>The HRGs used to reimburse this activity, as well as the combined day case / ordinary elective tariff, including a Market Forces Factor and children's specialised service top up<sup>xxxv</sup>, are presented below for each of the three procedures.</p> <ol style="list-style-type: none"> <li>In the 2014/15 national tariff, obesity procedures were reimbursed through HRG codes that included a variety of activity. <ul style="list-style-type: none"> <li><b>Sleeve gastrectomy / gastric bypass.</b> HRG FZ04A-B: <i>Very Major Stomach or Duodenum Procedures: c. £10,165 to £16,345.</i></li> <li><b>Gastric band.</b> HRG FZ05A-B: <i>Major Stomach or Duodenum Procedures 2 years and over: c. £3,935 - £6,600.</i></li> </ul> </li> <li>In the 2015/16 national tariff, new HRGs were proposed specifically for bariatric surgery:</li> </ol>

	<p>M1.2 Is this treatment excluded from national prices?</p> <p>M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?</p>	<ul style="list-style-type: none"> <li>• <b>Sleeve gastrectomy / gastric bypass.</b> HRG FZ84Z: <i>Stomach Bypass Procedures for Obesity</i>: c. <b>£8,350.</b></li> <li>• <b>Gastric band.</b> HRG FZ85Z: <i>Restrictive Stomach Procedures for Obesity</i>: c. <b>£5,010.</b></li> </ul> <p>3. In the draft 2016/17 national tariff, the HRGs from 2015/16 remain, however the tariffs increase to:</p> <ul style="list-style-type: none"> <li>• <b>Sleeve gastrectomy / gastric bypass.</b> HRG FZ84Z: <i>Stomach Bypass Procedures for Obesity</i>: c. <b>£11,895.</b></li> <li>• <b>Gastric band.</b> HRG FZ85Z: <i>Restrictive Stomach Procedures for Obesity</i>: c. <b>£9,465.</b></li> </ul> <p>As can be seen above, there is significant variation across each of the years in how these procedures are reimbursed. Given the 2014/15 tariffs do not specifically split out obesity surgery and that the 2015/16 tariffs are considered to under-reimburse providers<sup>xxxvi</sup>, the draft 2016/17 tariffs are used for the estimates further in this document.<sup>xxxvii</sup></p> <p>M1.2 No</p> <p>M1.3 No</p>
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	<p>M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes?</p> <p>M1.5 is VAT payable (Y/N) and if so has it been included in the costings?</p> <p>M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?</p>	<p>M1.4 Not applicable.</p> <p>M1.5 VAT would be recoverable under certain specific conditions<sup>xxxxiii</sup>. It is assumed here that VAT would not be recoverable.</p> <p>M1.6 No.</p>
<p>M2 Average Cost per Patient</p>	<p>M2.1 What is the revenue cost per patient in year 1?</p>	<p>M2.1 The total cost per patient is estimated to comprise<sup>xxxxix</sup>:</p> <ul style="list-style-type: none"> <li>• <b>Pre-assessments:</b> Adolescents indicated for obesity surgery should have a comprehensive clinical, psychological, educational, family and social assessment by a specialised MDT before undergoing surgery.<sup>xi</sup> This could be in the form of 4 outpatient attendances, at c. £195<sup>xi</sup> for a first and c. £127<sup>xii</sup> for a follow-up and a <b>total cost of c. £580.</b></li> <li>• <b>The procedure</b> itself, which as identified in M1.1 has a price of: <ul style="list-style-type: none"> <li>• c. <b>£11,895</b> for the sleeve gastrectomy / gastric bypass ; or</li> <li>• c. <b>£9,465</b> for the gastric band.</li> </ul> </li> <li>• Post-surgery: 3 days in a paediatric critical care unit at c.</li> </ul>



	<p>M2.2 What is the revenue cost per patient in future years (including follow up)?</p>	<p>£1,159<sup>xiii</sup> per day, and a <b>total cost of c. £3,475.</b></p> <ul style="list-style-type: none"> <li>• <b>Follow-up costs:</b> <ul style="list-style-type: none"> <li>• Patients would be expected to be followed up once a month for the first three months then quarterly for the remainder of the first year<sup>xiv</sup>. Using the follow-up outpatient tariff above, this could cost <b>c. £765</b> in the first year.</li> <li>• In addition, radiology appointments may be required where the gastric band needs to be adjusted<sup>xv</sup>; and</li> <li>• There would also be additional follow-up care as part of the package described in M2.2.</li> </ul> </li> </ul> <p>The cost range per patient in year 1 could therefore be <b>c. £14,285 to £16,715</b>, excluding the wider care package follow-up costs. It is noted that these costs are higher than for adults as they require more assessment and investigation.<sup>xvi</sup></p> <p>The cost of surgery may be offset to some extent by lower costs in treating comorbidities in patients with obesity. The reduction in activity, outlined in K3.3, may lead to cost savings. As an example, annual per patient spend on type-2 diabetes has been estimated in the region of £1,800 to £2,500 in inpatient costs and £300 to £370 for outpatient treatment.<sup>xvii</sup></p> <p>M2.2 In the years following the procedure, patients are offered a follow-up care package for a minimum of 5 years within the Tier 4 obesity service, or through shared care follow up arrangements with more local specialist paediatric centres<sup>xviii</sup>. This should include:</p> <ul style="list-style-type: none"> <li>• Monitoring nutritional intake ;</li> <li>• Monitoring for comorbidities ;</li> <li>• Medication review ;</li> </ul>
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		<ul style="list-style-type: none"> <li>• Dietary and nutritional assessment, advice and support ;</li> <li>• Physical activity advice and support ;</li> <li>• Psychological support tailored to the individual; and</li> <li>• Information about professionally-led or peer support groups.</li> </ul> <p>As each package is tailored to each patient, there is some uncertainty around these costs and as such they have not been quantified.</p>
M3 Overall Cost Impact of this Policy to NHS England	<p>M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.</p> <p>M3.2 Where this has not been identified, set out the reasons why this cannot be measured.</p>	<p>M3.1 The policy is to <b>routinely commission</b> this treatment. The 14-17 additional patients each year identified in K2.4 would lead to an <b>annual cost pressure to NHS England</b>. This is expected to be in the range of <b>£0.2m to £0.3m</b> for the in-year costs identified in M2.1.</p> <p>In addition, follow-up costs associated with care package required would also be incurred, as discussed in M2.2.</p> <p>Although increasing the number of procedures leads to a direct cost pressure to NHS England, as identified in K3.2 and M2.1, bariatric surgery could have the potential to reduce recurrent costs elsewhere in the system. These are expected to be to CCGs and are discussed in M4.1.</p> <p>M3.2 N/A</p>
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).	M4.1 The cost pressure identified to NHS England in M3.1 could be offset by a reduction in the indirect costs incurred around these patients, as described in K3.2 and M2.1. This is, however, difficult to quantify and it is not possible to estimate the effect of the specification on these costs for the patient group, however, it is thought that costs

	<p>M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.</p> <p>M4.3 Where this has not been identified, set out the reasons why this cannot be measured.</p> <p>M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?</p>	<p>may fall.<sup>xix</sup></p> <p>M4.2 There is estimated to be a direct cost pressure to NHS England as identified in M3.1, however there is uncertainty around the extent to which this would be offset by costs no longer incurred in the system.</p> <p>M4.3 See M4.2.</p> <p>M4.4 There may potentially be costs savings for Education regarding reduced provision of special arrangements for home tuition. Many severely obese children are not in education or training.<sup>1</sup></p>
M5 Funding	<p>M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. <i>e.g. decommissioning less clinically or cost-effective services</i></p>	<p>M5.1 To be discussed by CPAG.</p>
M6 Financial Risks Associated with Implementing this Policy	<p>M6.1 What are the material financial risks to implementing this policy?</p> <p>M6.2 Can these be mitigated, if so how?</p>	<p>M6.1 No material financial risks have been identified.</p> <p>M6.2 N/A</p>

	<p>M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</p>	<p>M6.3 The range of cost pressure set out in M3.1 is based on the scenarios developed around the risks of the target population size and the price of the procedure.</p> <p>The high scenario is based on the upper estimate of patients meetings the eligibility criteria each year (17), and a year 1 cost per patient of <b>£16,715</b>.</p> <p>A low scenario is based on the lower estimate of number of patients meeting the eligibility criteria a year (14) and a procedure cost per patient of <b>£14,285</b>.</p>
<p>M7 Value for Money</p>	<p>M7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i></p> <p>M7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence</i></p>	<p>M7.1 Aikenhead at al (2011) in a systematic review identified three studies on LAGB in adolescent, that showed net cost saving per disability adjusted life year was \$AU4,400 (£2,092) (level 2+).</p> <p>Bairdain et al (2015) (level 3) evaluated cost-effectiveness (n=11) and estimated that obesity surgery was not cost effective in the first three years, but cost effective after that \$80,065 (£52,925) QALY in year four and \$36,570 (23,515) QALY in year seven (threshold of \$100,000/QALY).</p> <p>M7.2 There is lack of studies evaluating cost effectiveness of obesity surgery in children and adolescents. The US findings may not be entirely applicable to the UK population cohort. Bairdain et al (2015) was a small study and failed to include obesity specific comorbidities.</p>
<p>M8 Cost Profile</p>	<p>M8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i></p>	<p>M8.1 No.</p>

	M8.2 If so, confirm the source of funds to meet these costs.	M8.2 N/A
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<sup>i</sup> Very severe obesity is defined as a BMI  $\geq 40 \text{ kg/m}^2$  (BMI SD  $\geq 3.0$ ). Severe obesity is defined as  $\geq 35 \text{ kg/m}^2$  (BMI SD  $\geq 3.5$ ). However, only those with severe (BMI between 35 and 39.9) obesity that have significant associated comorbidities may be eligible for obesity surgery.

<sup>ii</sup> Obesity is directly linked to a number of different illnesses including type 2 diabetes, fatty liver disease, hypertension, gallstones and gastro-oesophageal reflux disease as well as psychological and psychiatric morbidities (NICE clinical guideline 189).

<sup>iii</sup> A patient has severe obesity, equivalent to a BMI of 35, when their BMI is more than three standard deviations away from the mean. Three standard deviations equate to around 0.14% of the population. Based on discussions with the policy working group.

<sup>iv</sup> Aged 13 to 17. Please refer to questions K1.3 and K1.4.

<sup>v</sup> This applies the prevalence rates to ONS (2012) population projections for 2014/15. The population demographic (13-17) of the closest cohort to target population is used.

<sup>vi</sup> According to the NICE clinical guidance 189, the following factors are assessed in children: presenting symptoms and underlying causes of being overweight or obese; willingness and motivation to change; comorbidities (such as hypertension, hyperinsulinaemia, dyslipidaemia, type 2 diabetes, psychosocial dysfunction and exacerbation of conditions such as asthma); any risk factors assessed using lipid profile (preferably done when fasting) blood pressure measurement and HbA1c measurement; psychosocial distress, such as low self-esteem, teasing and bullying; family history of being overweight or obese and comorbidities; the child and family's willingness and motivation to change lifestyle; lifestyle (diet and physical activity); environmental, social and family factors that may contribute to being overweight or obese, and the success of treatment; growth and pubertal status; any medical problems and medication; the role of family and care workers in supporting individuals with learning disabilities to make lifestyle changes.

<sup>vii</sup> Based on discussions with the policy working group.

<sup>viii</sup> Policy proposition.

<sup>ix</sup> Based on discussions with the policy working group.

<sup>x</sup> Based on discussions with the policy working group.

<sup>xi</sup> Based on discussions with the policy working group.

<sup>xii</sup> This is based on an average across the 30-40 undertaken over the last 5 years (based on discussions with the policy working group). Data from the National Bariatric Surgery Registry (2014) shows that 23 primary operations for patients aged 12 – 17 were undertaken between 2011 – 2013. This would equate to c. 8 per annum. A lower

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bound of 6 is assumed given in adults c. 76% of operations are NHS funded (NBSR). <http://www.e-dendrite.com/files/13/file/Extract%20from%20the%202nd%20NBSR%202014%20Report.pdf>

<sup>xiii</sup> NICE clinical guideline 189. Obesity: identification, assessment and management of overweight and obesity in children, young people and adults.

<sup>xiv</sup> Pharmacological interventions are only considered after dietary, exercise and behaviour approaches have been evaluated; and only if the child is over 12 years of age and has physical comorbidities or psychological comorbidities.

<sup>xv</sup> This may be in the form of behavioural, lifestyle, dietary and physical activity interventions. NICE clinical guideline 189 (2014).

<sup>xvi</sup> Patients may become disengaged and therefore be receiving no further treatment. (Source: based on discussions with the policy working group)

<sup>xvii</sup> NICE guidelines [CG189, (<https://www.nice.org.uk/guidance/cg189>)

<sup>xviii</sup> Jones Nielsen et al. (2013). Rising Obesity-Related Hospital Admissions among Children and Young People in England: National Time Trends Study.

<sup>xix</sup> 'The levels in 2013, at 16 per cent for boys and 15 per cent for girls, were not statistically significantly different from those over the last three or four years.' Lifestyles Statistics Team, HSCIC, (2015). Statistics on Obesity, Physical Activity and Diet. England 2015. [online] pp.20-21. Available at: <http://www.hscic.gov.uk/catalogue/PUB16988/obes-phys-acti-diet-eng-2015.pdf> [Accessed 25 Nov. 2015].

<sup>xx</sup> ONS (2012) population projections have been used.

<sup>xxi</sup> Please note that there is a negative population growth rate for children (adjusted for ages 13-17) in 2017/18.

<sup>xxii</sup> Jebb, S., Kopelman, P. and Butland, B. (2007). Foresight Tackling Obesity: Future Choices Project. Obesity Reviews, 8(s1), p.vi-ix.

<sup>xxiii</sup> 'Child obesity prevalence shows a close association with socioeconomic deprivation. Obesity prevalence in children living in the 10% most deprived areas of the country is more than double that of children living in the least deprived 10% of areas'. Public Health England (2014), NCMP: Changes in children's BMI between 2006/07 and 2012/13.

<sup>xxiv</sup> 'Children classed as White British have lower obesity prevalence than most other ethnic groups.' Public Health England (2014), NCMP: Changes in children's BMI between 2006/07 and 2012/13.

<sup>xxv</sup> Provided that those patients under 18 have reached stage 4 puberty.

<sup>xxvi</sup> Jebb, S., Kopelman, P. and Butland, B. (2007). Foresight Tackling Obesity: Future Choices Project. Obesity Reviews, 8(s1), p.vi-ix.

<sup>xxvii</sup> This corresponds to low target population and low current activity, and high target population and high current activity.

<sup>xxviii</sup> Based on discussions with the policy working group.

<sup>xxix</sup> Noria, S. and Grantcharov, T. (2013). Biological effects of bariatric surgery on obesity-related comorbidities. Canadian Journal of Surgery, 56(1), pp.47-57.

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<sup>xxx</sup> West Sussex NHS. Annex one. Health and quality impact assessments for deferral of bariatric surgery. [Online] Available at: [http://www.westsussex.nhs.uk/domains/westsussex.nhs.uk/local/media/publications/board-papers/28\\_April\\_2011/05a%20Bariatric%20Surgery,%20Vasectomy%20and%20Fertility%20Services.pdf](http://www.westsussex.nhs.uk/domains/westsussex.nhs.uk/local/media/publications/board-papers/28_April_2011/05a%20Bariatric%20Surgery,%20Vasectomy%20and%20Fertility%20Services.pdf) [Accessed 27/01/2016].

<sup>xxxi</sup> Based on SUS data for under 18s that have received obesity surgery (identified through the relevant OPCS codes) over the financial years from 11/12 to 15/16.

<sup>xxxi</sup> Based on discussions with the policy working group.

<sup>xxxi</sup> E66 – Obesity.

<sup>xxxi</sup> See HES publication for a full list of OPCS codes. ([http://www.hscic.gov.uk/media/13556/Statistics-on-Obesity-Physical-Activity-and-Diet-England-2014/pdf/MethChange201402\\_SOPAD.pdf](http://www.hscic.gov.uk/media/13556/Statistics-on-Obesity-Physical-Activity-and-Diet-England-2014/pdf/MethChange201402_SOPAD.pdf))

<sup>xxxi</sup> An average market forces factor across the 4 providers identified in L1.1 is used, and all of the providers are eligible for the specialised children's top up of 64%.

<sup>xxxi</sup> Based on discussions with the NHS Finance Lead.

<sup>xxxi</sup> Based on discussions with the policy working group.

<sup>xxxi</sup> Please refer to Section 3.2 of VAT Notice 701/557 (<https://www.gov.uk/government/publications/vat-notice-70157-health-professionals-and-pharmaceutical-products/vat-notice-70157-health-professionals-and-pharmaceutical-products>)

<sup>xxxi</sup> Assumptions based on costing data provided by a Trust.

<sup>x</sup> Policy proposition.

<sup>xi</sup> Based on the 2016/17 draft tariff prices for first outpatient attendance cost of £170 for Paediatric Surgery (Treatment Function 171) and uplifted for an average MFF across the 3 providers.

<sup>xii</sup> Based on the 2016/17 draft tariff prices for follow-up outpatient attendance cost of £110 for Paediatric Surgery (Treatment Function 171) and uplifted for an average MFF across the 3 providers.

<sup>xiii</sup> Based on costing data provided from a Trust.

<sup>xiv</sup> Based on discussions with the working group.

<sup>xv</sup> Based on discussions with the working group.

<sup>xvi</sup> Based on discussions with the working group.

<sup>xvii</sup> Diabetes.co.uk, (2016). Cost of Diabetes. [online] Available at: <http://www.diabetes.co.uk/cost-of-diabetes.html> [Accessed 27 Jan. 2016].

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<sup>xviii</sup> This should include: monitoring nutritional intake (including protein and vitamins) and mineral deficiencies, monitoring for comorbidities, medication review, dietary and nutritional assessment, advice and support, physical activity advice and support, psychological support tailored to the individual, and information about professionally led or peer-support groups. (Policy proposition).

<sup>xix</sup> Based on discussions with the working group.

<sup>l</sup> Based on discussions with the working group.

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