

SCHEDULE 2 – THE SERVICES

A. Service Specifications

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| Service Specification No. | 170014/S |
| Service | Specialised and complex obesity surgery for children |
| Commissioner Lead | NHS England |
| Period | |
| Date of Review | |

1. Population Needs

Obesity is a rapidly growing threat to the health of children and is replacing more traditional problems such as under nutrition and infectious diseases as one of the most significant causes of ill-health. The complex pathological processes reflect environmental and genetic interactions, and individuals from disadvantaged communities seem to have greater risks than more affluent individuals. Long term co-morbidities include coronary heart disease, hypertension and stroke, certain types of cancer, Type 2 diabetes, gallbladder disease, dyslipidaemia, osteoarthritis and pulmonary diseases, including sleep apnoea (Kelly et al 2013).

Obesity is a common problem, estimated to affect around one in every four adults and around one in every five children in the UK. In 2013/14, data from the national schools measurement programme suggested that 19.1% of all children aged 11 years were obese (HSCIC 2015). Of these approximately 2.9% of girls and 3.9% of boys have severe obesity (Ells et al. 2015).

Over a fifth of children in reception year are overweight/obese (excess weight), this increases to a third by year 6. For 2-10 year olds, the proportion obese are 15% and 20% for 11-15 year olds. These figures have been sustained over the last 4 years except for a slight dip in 2012. Obesity prevalence and excess weight prevalence at school year 6 is higher in boys. Obesity prevalence at reception and year 6 shows a direct correlation with deprivation (doubling of effect). Prevalence (reception/10-11y) also varies with ethnicity, especially with black African/Caribbean/other status and Bangladeshi (for reception boys), showing an increase of about a third to half. There is also a north-south gradient; however London shows the highest prevalence on a par with the North and West Midlands (Kelly et

al. 2013).

The most common method of measuring obesity is the Body Mass Index (BMI). BMI is calculated by dividing a person's weight (kilogram) by the square of their height (meter). BMI is the most appropriate way to measure the prevalence of obesity at the population level. No specialised equipment is needed and therefore it is easy to measure accurately and consistently across large populations (NICE 2006).

In adults, a BMI of 25 to 29.9 kg/m² is considered to be overweight and a BMI of 30 kg/m² is considered to be obese. Levels of obesity in adults are further stratified into Obesity I, Obesity II and Obesity III (morbid obesity).

Table 1: Classification of Obesity in Adults

| Classification | BMI (kg/m²) |
|-----------------------|-------------------------------|
| Healthy weight | 18.5–24.9 |
| Overweight | 25–29.9 |
| Obesity I | 30–34.9 |
| Obesity II | 35–39.9 |
| Obesity III (Morbid) | 40 or more |

Definition of obesity in Children

- 1.1 In children body mass index varies with age and unlike adult practice a single definition cannot be used. Various definitions of obesity in children have been proposed. In children in the UK a BMI >85th centile is termed overweight, and >95th centile obese, for public health monitoring purposes (HSCIC 2015), whereas a BMI >90th centile is termed overweight and >98th centile obese for the purposes of clinical assessment (Cole et al. 2000).
- 1.2 The most widely used definition of “severe” obesity is a BMI > 99th centile (Kelly et al. 2013). It has been demonstrated that a BMI > 99th centile correlates well with an adverse cardiovascular risk profile (Freedman 2007). Based on a definition of BMI >99th centile, 2.9% of girls and 3.9% of boys in the UK have severe obesity (Ells et al. 2015). It is broadly equivalent to a BMI SDS (Standard Deviation Score) of +2.5 (adult BMI equivalent 30kg/m²).
- 1.3 Alternative methods to define severe obesity in childhood have been suggested. BMI standard deviation scores or Z scores are one approach. A BMI SDS of +3.0 is approximately equivalent to an adult BMI of 35, BMI SDS score of +3.5 approximately equivalent to an adult BMI 40 kg/m² (Cole et al. 1995 & 2000). They are thought cumbersome to use in clinical practice.

- 1.4 Another alternative approach from the USA has been to express the BMI as a percentage above the 95th percentile for the population. It has been suggested that a BMI of 120% of the 95th centile is equivalent to the adult BMI of 35 kg/m² and 130% equivalent to a BMI of 40 kg/m² (Flegal et al 2009, Gulati et al. 2012).
- 1.5 Finally for post pubertal children it has been suggested that for ease of use a definition of simply BMI >35mg/m² would be easiest to use in clinical practice (Koebnick et al. 2010).
- 1.6 It is proposed that the following definitions of “severe” obesity in children be adopted for the purposes of commissioning more specialised services:

BMI SDS >3.0 for pre-pubertal children (crudely equivalent to adult BMI >35). Although cumbersome there are numerous on line calculators available and it is reliable in younger children. RCPCH growth and BMI charts include these centile cut offs and are also available on line.

BMI >35 kg/m² in post pubertal children which is in accordance with NICE guidelines in adults. This sets the “bar higher” than adopting a cut off of >99th centile (equivalent to adult BMI 30) as this would encompass approximately 3% of the childhood population.

- 1.7 The exact number of children and young people with BMI >35 kg/m² is unknown but the prevalence of childhood obesity has been increasing over the last few decades. In 2011, 3 in 10 children aged 2-15 years were found to be overweight or obese in the UK (NICE CG189) and that rate has remained static.
- 1.8 Rates of obesity surgery are also increasing in adolescents and young people although the overall number of procedures remains very small. There was 1 operation in 2000 and there were 8 obesity procedures on children and adolescents (up to 18 years) during 12 months in 2013/14 (HSCIC, 2014).
- 1.9 An evidence based review of the clinical and cost effectiveness of obesity management and surgery in children and adolescents is summarised in the NHS England policy for children’s obesity surgery which should be read in conjunction with this specification.
- 1.10 Surgical intervention is not generally recommended in adolescents or children (NICE CG189, 2014). It is considered that obesity surgery will be undertaken by designated centres in very specific cases, whose eligibility has been assessed and determined by a specialist multidisciplinary team (MDT) (Tier 4). Obesity surgery may be considered to achieve significant and sustainable weight reduction, if all the following criteria are fulfilled:

The adolescent or child has been evaluated by the specialist MDT and deemed appropriate for surgery. This team will comprise a Paediatric obesity/ endocrinology/

diabetes specialist, psychologist experienced in childhood obesity management, specialist dietitian, Paediatric surgeon. The latter surgeon will be working alongside the adult obesity surgeon or be a Paediatric surgeon with sufficient and current experience in obesity surgery and the range of procedures.

The team will have access to a Paediatric specialised medical team, including anaesthesia, radiology, psychiatry and social worker. The latter specialists will be expected to have a specialist interest, knowledge and experience in obesity surgery and obesity management.

The MDT should have sufficient cover arrangements. There will also be a clinical nurse specialist with dedicated responsibility as part of their role. The team will also be responsible for pre-operative work up and preparation and peri- and post-operative review including emergency care.

2 Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

| Domain 1 | Preventing people from dying prematurely | Target |
|----------|---|---|
| | <p>Percentage of total preoperative weight loss at 1 year post surgery</p> <p>Reduction in BMI at 1 year post procedure</p> | <p>Total weight loss of 20% of preoperative weight for gastric banding, 25% for sleeve gastrectomy and 30% for RYGB</p> <p>Percentage achieving a reduction in BMI of 10kg/m² for gastric banding, 14kg/m² for sleeve gastrectomy and 17kg/m² for RYGB</p> |
| | <p>Reduction in objective measures of identified co-morbidities e.g. no change, improvement (i.e. clinically significant change, a reduction in medication/dose or support) and in remission (i.e. no longer on any treatment for this problem).</p> <ul style="list-style-type: none"> • Type 2 diabetes • Obstructive sleep apnoea • Hypertension (<95th centile) • Hyperlipidaemia | <p>Resolution of type 2 diabetes in 80% of subjects</p> <p>Resolution of obstructive sleep apnoea in 80% patients</p> <p>Resolution of hypertension in 50% subjects</p> <p>Resolution of dyslipidaemia in 60% subjects</p> |
| Domain 2 | Enhancing quality of life for people with long-term conditions | |

| | | |
|-----------------|---|---|
| | Improved health quality of life: Peds QL and or equivalent measure such as Impact of Weight on Quality of Life-Kids (IWQOL-Kids[®]) | Improvement in PEDSQOL of 10-15 points |
| Domain 3 | Helping people to recover from episodes of ill-health or following injury | |
| | Improved school or college attendance rates Reduction in proportion of those not in education, training or employment (NEET) | Attendance rate >95% Reduction in those NEET by 50% |
| Domain 4 | Ensuring people have a positive experience of care | |
| | Annual User satisfaction survey | |
| Domain 5 | Treating and caring for people in safe environment and protecting them from avoidable harm | |
| | Post-operative complication rates and types In-hospital mortality rates: for example, <0.3% gastric banding and 1% laparoscopic or open bypass (higher for BMI>60 kg/m ² and revisional operations). Surgical complication requiring HDU: 1% for gastric band and 5% for gastric bypass (higher for BMI>60 kg/m ² and revisional operations). | Due to current small numbers, providers should submit case data to mandatory NSBR monitoring. |

3 Scope

3.1 Aims and objectives of service

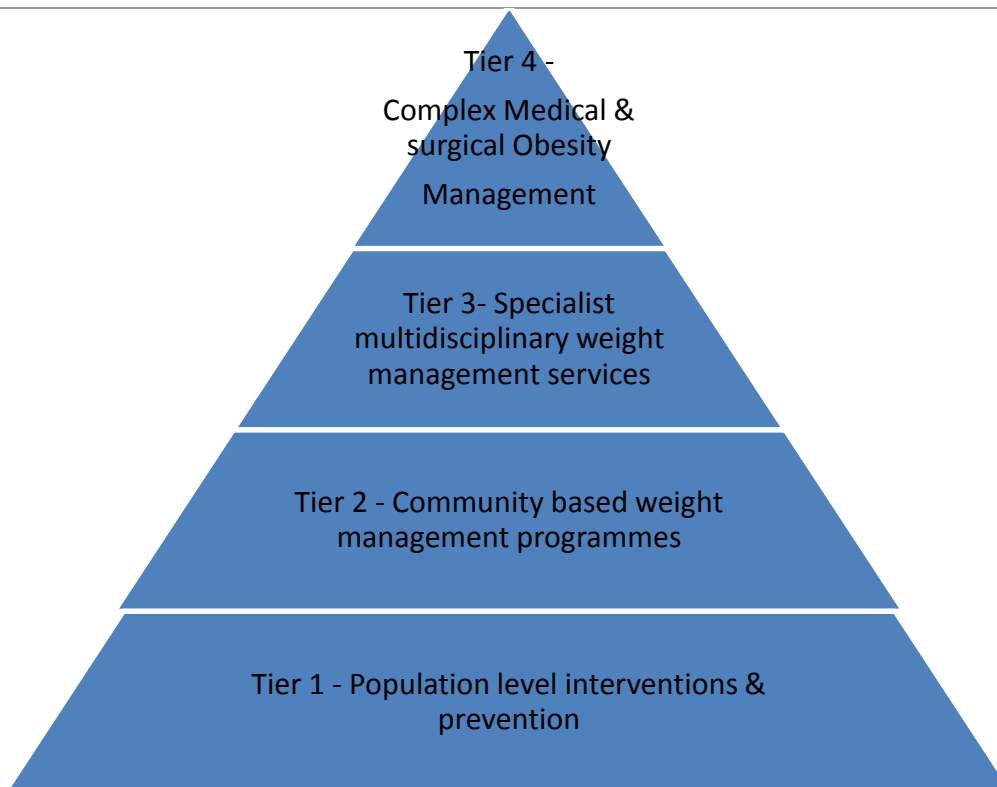
Children who have severe childhood obesity regrettably become severely obese adults (Freedman et al. 2007). The tendency is for increased weight gain over time. Without intervention they are likely both to develop significant co-morbidities and potentially require obesity surgery as young adults. Intervention in childhood is likely to be cost saving (NICE 2006).

As part of their review, CG43 in 2006, NICE provided a detailed economic evaluation of the cost of implementing aspects of the guidance it prioritised (they prioritised 2 areas, treatment of childhood obesity and obesity surgery for individuals (adults) with a BMI >50 kg/m²). NICE suggested that if addressed, these interventions would be cost saving at 10 years (treatment costs £35 million and estimated cost savings £55 million – a net saving to the NHS of £20 million – NICE CG43 Costing report) (NICE 2006).

The aim of the service specification is to direct delivery of evidence based, accessible Tier 4 weight management services, for children with severe obesity (equivalent to adult obesity II – BMI >35 kg/m²). Including where appropriate in exceptional circumstances criteria for consideration of obesity surgery in line with NICE guidance (CG43). The recent report of the working group into “Joined up pathways for obesity” suggested that Tier 3 services be commissioned by CCG’s and Tier 4 services be commissioned by NHS England [¹].

NHS England will maintain the responsibility for commissioning Tier 4 services for medical and surgical obesity management for children. It is proposed that the NHS England Women’s and Children’s National Programme of Care through its Clinical Reference Groups, will also provide advice for Clinical Commissioning Groups if requested in the design of commissioning specifications for Tier 3 services to support Tier 4 provision. This document provides a framework for commissioning Tier 4 services for children.

¹ <https://www.england.nhs.uk/wp-content/uploads/2014/03/owg-join-clinc-path.pdf>



3.2 Service description/care pathway

This specification concerns the use of surgery, known to achieve significant and sustainable weight reduction for patients who have attained or nearly attained physiological maturity (Tanner Stage 3+). Surgery should be reserved for paediatric and adolescent patients who have undergone an extensive behavioural change programme. It is not indicated for paediatric and adolescent patients with transient increases in weight and usually obesity should have been present for several years. It is envisaged that it would be an exceptional procedure. This is in line with NICE guidance which recommends weight loss surgery in those under <18 years only in exceptional circumstances.

Adolescents approaching or having reached the end of puberty can usefully be defined as having morbid obesity if they have a body mass index (BMI) either equal to or greater than 40kg/m^2 and if their BMI is $35 > 40\text{kg/m}^2$ in the presence of significant co-morbid conditions that could be improved by weight loss. Given the propensity for early puberty in obese adolescents, pubertal stage is a more appropriate than chronological age in decision making.

In very exceptional instances, surgery might be considered on a case by case basis in younger (prepubertal/peripubertal) children with life or sight threatening obesity. The definition of morbid obesity in their cases would need to be individualised for age and sex but would certainly be at least >3.00 standard deviations (1990 standards) and likely substantially higher. To date, to our knowledge, such cases have not been undertaken in the UK.

Other considerations are:

- If the co-morbid conditions can be predictably corrected with surgical weight loss
- The short and long term risks of not operating are thought to be greater than those associated with surgery
- Impact on psychological well being
- Impact on schooling/education (many children have poor attendance)
- Likelihood of the patient adhering to a follow-up programme.

The evaluation process is more complicated in morbidly obese adolescents than adults because:

- Any remaining growth might be adversely affected by the nutritional consequences of an obesity surgery procedure
- They may not be psychologically prepared for obesity surgery
- Overt co-morbidities are not as pronounced as in adults
- Compliance with health recommendations in general in this age group is poor e.g. 40 – 50% for adolescents with cystic fibrosis, diabetes, asthma
- After obesity surgery the welfare of the adolescent patient depends on complex interactions between the adolescent and family. Dysfunction in the family unit can manifest as poor compliance with post-operative dietary and nutritional supplement recommendations.

4 Service Model

There will be a specific multi-disciplinary team MDT including a surgeon to consider whether the patient should be transferred to the Tier 4 programme before patient is assessed.

- Patients may be only referred to Tier 4 services by Tier 3 teams. Direct GP referrals would not be accepted except where individuals have established type 2 Diabetes, where there were significant safeguarding concerns or where syndromic forms of obesity were felt likely. Patients will have typically been involved with Tier 3 services for a minimum of 6 months before referral.
- Co-morbidities must have been investigated and addressed by Tier 3 services. It is expected that the referrer would complete all necessary clinical and other investigations outlined above prior to referral for surgical assessment, to provide a baseline. Including reviewing possibility of syndromic or monogenic obesity (e.g. MC4R mutations and Prader-Willi Syndrome).

- Any decision regarding surgery will depend on the individual patient's response to Tier 3 treatment, their co-morbidities and their individual's risk-benefit analysis as assessed by the MDT.

4.1 The specialised multidisciplinary team should provide:

- Paediatric expertise in pre-operative assessment, including a risk-benefit analysis that includes preventing and managing complications of obesity, pre and post-operative dietary assessment and advice and specialist assessment for eating disorder(s)
- Intensive medical assessment and medical management that will be shared with the Tier 3 service. The Tier 3 service will refer patients for consideration of surgery. Patients with extreme obesity, genetic predisposition, severe life threatening co-morbidities, safe-guarding issues will need to be fast tracked
- Information on the different procedures, including potential weight loss and associated risks
- Regular post-operative assessment by specialised team, including specialist dietetic, medical and surgical follow up. Other MDT members may be co-opted when necessary.

Follow up should include the following:

- Gastric band cases: a range of around 6-8 times per year
- Sleeve gastrectomy or bypass monthly for 3 months and then 6 monthly and ultimately at least annual follow up for lifetime but at least 5 years in the Paediatric service.

4.2 Care Pathways

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.

Tier 4 specialist services also need to have capability to manage severely obese adolescents for whom surgical intervention is not appropriate, but who have significant comorbidities. This would for example include adolescents with genetic conditions such as Prader-Willi Syndrome, children with learning difficulties, and individuals where there are concerns about adherence to required follow-up protocols. Such services would encompass further more specific specialised lifestyle interventions, social services support, and access to both established pharmacological interventions e.g. Orlistat and pharmacological interventions in line with policy. Approximately 70% of all prescribed medication in Paediatric practice is unlicensed and where appropriate and supported by clinical evidence

such interventions should be made available by specialised Tier 4 services. Referral to a residential weight management facilities or camps (typically during the school summer holidays) should also be available under the auspices of Tier 4 services as a nonsurgical option in those individuals who would otherwise meet criteria for consideration of obesity surgery.

Tier 4 services would be expected to develop hub and spoke models and shared care arrangements with local Tier 3 services to ensure adequate follow-up of patients. In Adult services long term follow-up remains challenging. Given the likely centralised location of Tier 4 services some distance from patient's homes, protocolled hub and spoke follow-up arrangements with local Tier 3 services should be considered.

4.3 Types of Surgery

The type of procedure selected will depend upon a range of clinical factors, including pre-operative BMI, target weight loss, eating patterns, and co-morbidities. The choice of surgical intervention should be made jointly by the individual, their family/supporter and the clinician after considering the best available evidence, the facilities and the equipment available, and the experience of the surgeon who will perform the operation. This should ensure that any procedures are undertaken with the informed consent of the individual.

For complex patients, with a BMI greater than 50 the obesity surgery provider may take measures to lower the patient's surgical risk prior to proceeding with e.g. intra-gastric balloon. The surgeon and anaesthetist (Paediatric for those less than 16 years) will determine when a patient is fit for surgery. For high-risk patients and those not adhering to pre-operative diet care may be offered as an in-patient stay.

Laparoscopic adjustable gastric banding (LAGB)

LAGB surgery restricts intake of food / portion size by placing an adjustable band around the stomach. The operation for banding would usually be done laparoscopically but could be by open surgery.

Roux-en-Y gastric bypass (RYGB)

This is more extensive surgery. The result of the surgery mainly restricts food portions but also reduces absorption. This can be done laparoscopically or by open surgery.

Duodenal switch and biliopancreatic diversion (DS-BPD)

This type of surgery markedly reduces calorie absorption with limited restriction. Few surgeons regularly perform this procedure which is carried out in two separate surgical procedures. This procedure is not advocated in the paediatric or adolescent group.

Sleeve Gastrectomy (SG)

Sleeve Gastrectomy is a laparoscopic procedure which divides the stomach by stapling, reducing capacity by 75%. It can be converted to RYGB as a second stage operation at a later date. The timing of the second stage operation ranges from 12–18 months after the first, depending on the degree of weight loss.

This procedure may become a main stream procedure over the next few years. If a patient is superobese or has severe obesity-related conditions, their health state can make the complexity of a bypass operation too risky to proceed with. Some surgeons and centres are performing this procedure.

Intragastric Balloon (BIB)

For complex patients, with a BMI greater than 50 the obesity surgery provider may take measures to lower the patient's surgical risk prior to proceeding with e.g. intragastric balloon. The surgeon and anaesthetist (Paediatric for those less than 16 years) will determine when a patient is fit for surgery.

Such procedures may also be appropriate in patients for example with learning difficulties in whom more permanent procedures may not be appropriate

The intragastric balloon is designed to provide short-term weight loss therapy. The silicone balloon is placed endoscopically and filled with liquid so it partially fills the stomach and creates a feeling of fullness. The maximum time a balloon can be left in place is 6 months, after which it must be removed. The intragastric balloon may be used for weight loss in morbidly obese patients prior to obesity surgery, in order to reduce surgical risk. It may be appropriate in certain exceptional circumstances in younger children and those with learning difficulties.

4.4 Scope of Surgery

The specification and scope for surgery will evolve as the service, expertise and experience develops.

A provider of surgery to aid weight reduction for paediatric and adolescents with morbid obesity will be expected to provide:

Pre-operative preparation to include;

- Consideration of pharmacotherapy
- Extensive medical work up and investigation of possible genetic or syndromic obesity (consider sending samples to Genetics of Simple Obesity Study [GOOS] in Cambridge or referral to local genetics team)
- Access to social worker and child protection assessment where considered necessary
- For high risk patients and those not adhering to pre-operative diet, care may be

offered as an in-patient stay.

Post-operative care, surveillance and follow up to include;

- Post-operative care should be available to manage complications as they occur, including revision procedures.
- The obesity surgical provider will be responsible for the organisation of structured, systematic and team based follow up for a minimum of 5 years. The surgical provider will make arrangements to hand over care to the adult Tier 3 service when the adolescent reaches 18 years if appropriate, with the option of continued follow up beyond 18 in Paediatric services or Tier 4 Paediatric led services, where adolescents are within a few years of surgery or where local Adult provision is weak. Follow up rates and nutritional and/or metabolic complications should be published.
- All patients will be reviewed by the surgical team in the initial post-operative period. In the longer term, the surgical and Paediatric medical teams will be responsible for determining the most appropriate arrangements/model of care and locations for long term follow up of patients. Life-long follow up is ideally required for all patients. It is expected that long term follow up will be with the specialist medical Paediatric weight management team/s and following transition, with adult specialist weight management teams. Follow-up should include psychology & dietetics.
- Follow-up in a specialised unit for a minimum 5 years postoperatively for patients who have been fitted with a gastric band and at least initially follow up should be conducted at least every two months. Thereafter follow-up to be decided and agreed between the patient and clinicians. Gastric band patients will receive initial band adjustments by the Tier 4 specialist obesity surgery team. This will include up to four follow-up visits to the MDT. The specialist surgical and medical team will work with commissioners and Tier 3 specialist obesity clinics to develop services including gastric band adjustment and dietetic expertise to ensure that services may be delivered locally to patients.
- For patients who have received a sleeve gastrectomy or gastric bypass, lifelong follow-up is required by a team familiar with the specific health issues attendant on this form of treatment. This may be delegated to local Paediatric or Adult Tier 3 Units with appropriate expertise on a shared annual surveillance basis.
- The patient must receive regular haematological and metabolic follow-up and these data must be reported back to the Tier 4 team and recorded in the National Bariatric Surgery Registry database.
- Adolescents will transition to an appropriate adult service when they reach adulthood and/or are willing to make the transition to adult services. They will continue to be

followed up in accordance with the service specification.

4.5 Risks of surgery

As with any surgical procedure there are associated risks with obesity surgery.

In addition to the anaesthetic risks, there are documented complication risks in the range of 8 – 10% with LAGB. They are;

- Dysphagia (swallowing difficulties)
- Daily episodes of vomiting
- Severe reflux-like symptoms
- Band slippage
- Band deflation
- Band erosion
- Pouch dilatation/enlargement of the stomach above the band
- Needle injury to the tubing
- Protein malnutrition
- Anaemia
- Vitamin and micronutrient depletion
- Pouch necrosis
- Distal oesophageal cancer

The documented risks and complications of RYGB range from 13% for major Complications, to between 14 and 30% for minor complications. They are;

- Anastomotic leak – bowel contents leaking out through the join
- Anastomotic stricture – narrowing at the point that the bowel is joined together causing obstruction
- Internal hernias – bowel twisting into an abnormal pocket and getting blocked
- Vitamin and micronutrient depletion
- Dumping syndrome: an often transient condition with abdominal pain, cramping, nausea, flushing, tachycardia and sweating after meals.

The short term documented risks of all obesity surgery procedures grouped together are;

- Pulmonary embolism
- Gallstones
- Gastrointestinal bleeding
- Wound problems.

In adults the long term metabolic risks are highest with patients who have received a bypass. Little is known about the long term risks in children.

4.6 Environment

Providers of Paediatric/Adolescent obesity surgery must be able to demonstrate that they have the appropriate environment to provide pre-operative, operative and post-operative care for children and adolescents who require obesity surgery. To include;

- Appropriate specialised HDU/ITU facilities
- Under 16s to be treated in a full Paediatric service with a Paediatric ICU
- Paediatric out-patients for assessment and follow-up
- Patients aged 16 to 18 years can be treated in an Adult service providing it is integrated with a Paediatric or preferably a Teenage and Young Adult service

4.7 Equipment

Providers of obesity surgery must be able to demonstrate that they have suitably equipped facilities to provide pre-operative, operative and post-operative care for Paediatric and Adolescents who require obesity surgery.

The provider must have the specialist equipment and facilities required for the service to run including items such as:

- Weighing scales up to 300kg
- Chairs and examination couches suitable for morbidly obese patients
- Appropriate sized monitoring equipment such as BP cuffs
- Suitable bed frames (electric contouring beds), and pressure relieving mattresses
- Mobility and hygiene facilities such as floor mounted toilets, commodes, walking frames and grab rails
- Clinics and wards to be accessible to patients with limited mobility
- Patient lifting and transfer equipment such as hoists, transfer systems (e.g. Hovermatt and Hoverjack), wheelchairs
- Large bed space areas to accommodate equipment with curtaining and inpatient

clothing (including operation gowns) that enables patients to retain their modesty and dignity

- Suitable outpatient facilities and environment for paediatric and adolescent obesity patients, with patient measurement facilities provided in a discreet environment
- Operating theatre table up to 300kg and other suitable operating equipment such as extra-long laparoscopic instruments etc.
- Any other equipment specific to the requirements of this particular group of patients.

4.8 Staffing

Providers of Paediatric and Adolescent obesity surgery must be able to demonstrate that they have suitably trained staff to provide pre-operative, operative and postoperative care for paediatric and adolescent patients who require obesity surgery and appropriate assessment and follow-up.

This should include the ability and skills to undertake the proposed obesity surgery procedure and any other associated procedures that may be performed simultaneously (e.g. hernia repair or cholecystectomy).

The provider will ensure that it employs suitably trained and qualified staff in order to discharge its responsibilities. The provider must have the following staff assigned to or accessible to the service:

- At least one Paediatric medical consultant who will develop a specialist interest, experience and knowledge in management of obese paediatrics and adolescents
- At least two consultant general / upper gastro-intestinal surgeons (Paediatric or Adult), with specialist knowledge and experience of obesity surgery. They should have undertaken supervised training in the provision of both restrictive and/or malabsorptive operations
- A designated Paediatric surgeon with experience in laparoscopic surgery and a responsibility for patients operated on, under 16 years in the children's unit.
- The surgeons must be willing to submit data to The National Bariatric Surgery Registry
- At least two consultant anaesthetists with specialist interest, experience and knowledge of obesity surgery and obesity management. For those under 16 years, these should be Paediatric anaesthetists
- A consultant radiologist with specialist interest, experience and knowledge in Obesity surgery and obesity management.
- A clinical nurse specialist in the care and management of pre, peri and post-operative obesity patients.
- A clinical Paediatric psychologist/psychiatrist with a specialist interest, experience in

Obesity surgery and obesity management.

- High dependency/ intensive care staff with specialist knowledge and experience in the management of post-operative paediatric and adolescent obesity patients. Ward and outpatient staff who are experienced in the management of paediatric and adolescent obesity surgery patients
- Dietician with specialist knowledge and experience in managing obese paediatric and adolescent patients pre- and post-operatively.

The provider should be able to offer support to the patient and their families and/or supporters through a designated contact person and in the form of clear and comprehensive information in appropriate formats.

4.9 Additional surgical procedures

Patients and providers should be aware that additional surgical interventions, such as plastic surgery (e.g. apronectomy), might also be required at a later stage, usually around to 2-3 years after weight reduction surgery, to remove excess skin from the torso. These procedures do not form part of this specification and are not commissioned by NHS England Specialised Commissioning.

5 Population covered

The service outlined in this specification is for patients ordinarily resident in England*, or otherwise the commissioning responsibility of the NHS in England (as defined in “*Who Pays?: Establishing the responsible commissioner*” and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

6 Any acceptance and exclusion criteria and thresholds

6.1 Criteria for surgery

Surgical intervention is not generally recommended in children or young people (NICE CG189, 2014). When it is required obesity surgery will be undertaken by formally commissioned centres only. In very specific cases the patient’s eligibility for surgery will be assessed and determined by a specialist multidisciplinary team (MDT) (Tier 4). Obesity surgery may be considered as able to achieve significant and sustainable weight reduction, if all the following criteria are fulfilled:

- The adolescent has a post pubertal BMI $\geq 40\text{kg/m}^2$ (BMI SD ≥ 3.0) or $\geq 35\text{kg/m}^2$ (BMI SD ≥ 3.5) with significant associated comorbidities that are both predicted to have the potential to progress and are amenable to improvement/ resolution by weight loss. Obesity should have been present for several years. The adolescent has achieved physiological maturity (Tanner Stage 4 or above).

- The adolescent has been receiving or will receive intensive management in an appropriate MDT-led specialist Tier 3 service for an appropriate period of a minimum of 6 months and maximum of 2 years (adequacy of intensity and duration determined by MDT). 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 decision regarding surgery will depend on the individual's response to the above, their co-morbidities and their risk–benefit analysis. This analysis should assess the short and long term risks of not operating versus the risks associated with surgery. In addition psychological factors, motivation/compliance, learning difficulty issues and impact on education will also be taken into account.
- The adolescent is generally fit for anaesthesia and surgery.
- The hospital specialist and/or obesity surgeon should discuss the following with adolescents who are severely obese if they are considering surgery to aid weight reduction: the anatomical and physiological changes, the potential benefits, surgical risks and complications, choice of intervention and requirement for life long follow up. The discussion should also involve the adolescent's family, as appropriate.
- Informed consent should also include information on the evidence, the environment/facilities and surgeon experience. The operative, ward, clinic environment should be appropriate for paediatric/adolescent patients and be suitably staffed and equipped. HDU/ITU facilities should be available on site including PICU for patients < 16 years.
- The adolescent and their family commits to the need for long-term follow-up. Specialist Tier 4 services will be responsible for follow up for a 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.
- Adolescents with syndromic or monogenic obesity will also be discussed by the MDT on a case by case basis and arrangements made by the MDT to seek further national expert advice/opinion on the ethical issues and supporting research.

6.2 Interdependencies with other services/providers

Co-located services

- Paediatric Endocrinologist / Diabetologist / Obesity specialist
- Paediatric Psychologist
- Paediatric Dietician
- Access to Psychiatry
- Access to Paediatric specialised medical team
- Critical Care facilities: HDU/ITU

Interdependent services

- Adult obesity surgical team
- Paediatric anaesthesia

Related services

- Social work
- Safeguarding

Links should also be maintained with local providers of non-emergency patient transport services to ensure that transport providers meet the needs of those patients who are eligible for such transport.

Hub and spoke models of shared care, with Tier 3 services, must be maintained to ensure appropriate referral and the availability of appropriate, high quality, local follow-up for patients, in order to ensure continued follow-up and to provide high quality, local care.

7 Applicable Service Standards

7.1 Applicable national standards e.g. NICE

- NICE Clinical Guideline 43

7.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

- Pediatric Best Practice Guidelines – American Society for Bariatric and Metabolic Surgery – January 2012
- Indications and Limitations of Bariatric Intervention in Severely Obese Children and Adolescents with and without Non-alcoholic Steatohepatitis: ESPGHAN Hepatology Committee Position Statement - Journal of Paediatric Gastroenterology & Nutrition: April 2015

Annexe 1 - NHS England provision of services for children

8 Applicable quality requirements and CQUIN goals

Target Outcomes

- Percentage of total preoperative weight loss at 1 year post surgery - Total weight loss of 20% of preoperative weight for gastric banding, 25% for sleeve gastrectomy and 30% for RYGB or Excess Weight Loss (EWL): at 2 years post-operatively, 50%

for a gastric band and 65% for a bypass, sleeve gastrectomy or duodenal switch.

- Reduction in BMI at 1 year post procedure - Percentage achieving a reduction in BMI of 10kg/m² for gastric banding, 14kg/m² for sleeve gastrectomy and 17kg/m² for RYGB
- Type 2 diabetes frequently resolves following surgery, and it is estimated that there would be resolution of type 2 diabetes in 80% of subjects. Similarly it is expected that in 80% of patients with obstructive sleep apnoea it would improve.
- Further targets include:
 - Resolution of hypertension in 50% of individuals and resolution of dyslipidaemia in 60% of patients
 - Reduction in objective measures of identified co-morbidities e.g. no change, improvement (i.e. clinically significant change, a reduction in medication/dose or support) and in remission (i.e. no longer on any treatment for this problem).
 - Improved health quality of life: Peds QL
- Post-operative complication rates and types: for example, <0.5% gastric banding and <15% for laparoscopic and open bypass (comprising leak rate 3%, early obstruction 3%, deep vein thrombosis (DVT)/pulmonary embolism (PE) 2%, bleeding 1%, chest complications 3%, others 2%).
- In-hospital mortality rates: for example, <0.3% gastric banding and 1% laparoscopic or open bypass (higher for BMI>60 kg/m² and revisional operations).
- Surgical complication requiring HDU: 1% for gastric band and 5% for gastric bypass (higher for BMI>60 kg/m² and revisional operations).

9 Applicable quality requirements (See Schedule 4 Parts A-D)

- Surgical centres and Weight Management clinics are required to input into the National Bariatric Surgery Registry database (or equivalent) for audit and evaluation purposes.
- Providers will audit their outcomes on an ongoing basis and take part in multi-centre audits against other NHS contracted services both regionally and nationally.
- The information collected by the provider for auditing and monitoring will be made available to commissioners on an agreed basis.

9.1 Applicable CQUIN goals (See Schedule 4 Part E)

10 Location of Provider Premises

The Provider's Premises are located at:

It is considered that specialised Paediatric obesity services will be provided in a very limited number of providers. A formal procurement process will support selection of centres.

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ANNEX 1 TO SERVICE SPECIFICATION:

PROVISION OF SERVICES TO CHILDREN

Aims and objectives of service

This specification annex applies to all children's services and outlines generic standards and outcomes that would be fundamental to all services.

The generic aspects of care:

The Care of Children in Hospital (Health Service Circular 1998/238) requires that:

- Children are admitted to hospital only if the care they require cannot be as well provided at home, in a day clinic or on a day basis in hospital.
- Children requiring admission to hospital are provided with a high standard of medical, nursing and therapeutic care to facilitate speedy recovery and minimize complications and mortality.
- Families with children have easy access to hospital facilities for children without needing to travel significantly further than to other similar amenities.
- Children are discharged from hospital as soon as socially and clinically appropriate and full support provided for subsequent home or day care.
- Good child health care is shared with parents/carers and they are closely involved in the care of their children at all times unless, exceptionally, this is not in the best interest of the child. Accommodation is provided for them to remain with their children overnight if they so wish.

Service description/care pathway

All paediatric specialised services have a component of primary, secondary, tertiary and even quaternary elements.

The efficient and effective delivery of services requires children to receive their care as close to home as possible dependent on the phase of their disease.

Services should therefore be organised and delivered through "integrated pathways of care" (National Service Framework for children, young people and maternity services (Department of Health & Department for Education and Skills, London 2004)

Interdependencies with other services

All services will comply with *Commissioning Safe and Sustainable Specialised Paediatric Services: A Framework of Critical Inter-Dependencies* – Department of Health (DH)

Imaging

All services will be supported by a 3 tier imaging network ('Delivering quality imaging services for children' DH 13732 March 2010). Within the network:

- It will be clearly defined which imaging test or interventional procedure can be performed and reported at each site
- Robust procedures will be in place for image transfer for review by a specialist radiologist, these will be supported by appropriate contractual and information governance arrangements
- Robust arrangements will be in place for patient transfer if more complex imaging or intervention is required
- Common standards, protocols and governance procedures will exist throughout the network.
- All radiologists, and radiographers will have appropriate training, supervision and access to continuing professional development
- All equipment will be optimised for paediatric use and use specific paediatric software.

Specialist Paediatric Anaesthesia

Wherever and whenever children undergo anaesthesia and surgery, their particular needs must be recognised and they should be managed in separate facilities, and looked after by staff with appropriate experience and training.¹ All UK anaesthetists undergo training which provides them with the competencies to care for older babies and children with relatively straightforward surgical conditions and without major co-morbidity. However those working in specialist centres must have undergone additional (specialist) training² and should maintain the competencies so acquired³ *. These competencies include the care of very young/premature babies, the care of babies and children undergoing complex surgery and/or those with major/complex co-morbidity (including those already requiring intensive care support).

As well as providing essential co-dependent service for surgery specialist anaesthesia and sedation services may be required to facilitate radiological procedures and interventions (for example MRI scans and percutaneous nephrostomy) and medical interventions (for example joint injection and intrathecal chemotherapy), and for assistance with vascular access in babies and children with complex needs such as intravenous feeding.

Specialist acute pain services for babies and children are organised within existing departments of paediatric anaesthesia and include the provision of agreed (hospital wide) guidance for acute pain, the safe administration of complex analgesia regimes including epidural analgesia, and the daily input of specialist anaesthetists and acute pain nurses with expertise in paediatrics.

*The Safe and Sustainable reviews of paediatric cardiac and neuro- sciences in England have noted the need for additional training and maintenance of competencies by specialist anaesthetists in both fields of practice.

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1. Guidelines for the Provision of Anaesthetic Services (GPAS) Paediatric anaesthetic services. RCoA 2010 www.rcoa.ac.uk
2. Certificates of Completion of Training (CCT) in Anaesthesia 2010
3. Continuing Professional Development (CPD) matrix level 3

Specialised Child and Adolescent Mental Health Services (CAMHS)

The age profile of children and young people admitted to specialised CAMHS day/in-patient settings is different to the age profile for paediatric units in that it is predominantly adolescents who are admitted to specialised CAMHS in-patient settings, including over-16s. The average length of stay is longer for admissions to mental health units. Children and young people in specialised CAMHS day/in-patient settings generally participate in a structured programme of education and therapeutic activities during their admission.

Taking account of the differences in patient profiles the principles and standards set out in this specification apply with modifications to the recommendations regarding the following:

- Facilities and environment – essential Quality Network for In-patient CAMHS (QNIC) standards should apply (<http://www.rcpsych.ac.uk/quality/quality accreditation/audit/qnic1.aspx>)
- Staffing profiles and training - essential QNIC standards should apply.
- The child/ young person's family are allowed to visit at any time of day taking account of the child / young persons need to participate in therapeutic activities and education as well as any safeguarding concerns.
- Children and young people are offered appropriate education from the point of admission.
- Parents/carers are involved in the child/young persons care except where this is not in the best interests of the child / young person and in the case of young people who have the capacity to make their own decisions is subject to their consent.
- Parents/carers who wish to stay overnight are provided with accessible accommodation unless there are safeguarding concerns or this is not in the best interests of the child/ young person.

Applicable national standards e.g. NICE, Royal College

Children and young people must receive care, treatment and support by staff registered by the Nursing and Midwifery Council on the parts of their register that permit a nurse to work with children (Outcome 14h Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

- There must be at least two Registered Children's Nurses (RCNs) on duty 24 hours a day in all hospital children's departments and wards.
- There must be an Registered Children's Nurse available 24 hours a day to advise on the nursing of children in other departments (this post is included in the staff establishment of 2RCNs in total).

Accommodation, facilities and staffing must be appropriate to the needs of children and separate from those provided for adults. All facilities for children and young people must comply with the Hospital Build Notes HBN 23 Hospital Accommodation for Children and Young People NHS Estates, The Stationary Office 2004.

All staff who work with children and young people must be appropriately trained to provide care, treatment and support for children, including Children's Workforce Development Council Induction standards (Outcome 14b Essential Standards of Quality and Safety, Care Quality Commission, London 2010).

Each hospital who admits inpatients must have appropriate medical cover at all times taking account of guidance from relevant expert or professional bodies (National Minimum Standards for Providers of Independent Healthcare, Department of Health, London 2002). "Facing the Future" Standards, Royal College of Paediatrics and Child Health.

Staff must carry out sufficient levels of activity to maintain their competence in caring for children and young people, including in relation to specific anaesthetic and surgical procedures for children, taking account of guidance from relevant expert or professional bodies (Outcome 14g Essential Standards of Quality and Safety, Care Quality Commission, London 2010).

Providers must have systems in place to gain and review consent from people who use services, and act on them (Outcome 2a Essential Standards of Quality and Safety, Care Quality Commission, London 2010). These must include specific arrangements for seeking valid consent from children while respecting their human rights and confidentiality and ensure that where the person using the service lacks capacity, best interest meetings are held with people who know and understand the person using the service. Staff should be able to show that they know how to take appropriate consent from children, young people and those with learning disabilities (Outcome 2b) (Seeking Consent: working with children Department of Health, London 2001).

Children and young people must only receive a service from a provider who takes steps to prevent abuse and does not tolerate any abusive practice should it occur (Outcome 7 Essential Standards of Quality and Safety, Care Quality Commission, London 2010 defines the standards and evidence required from providers in this regard). Providers minimise the risk and likelihood of abuse occurring by:

- Ensuring that staff and people who use services understand the aspects of the safeguarding processes that are relevant to them
- Ensuring that staff understand the signs of abuse and raise this with the right person when those signs are noticed.
- Ensuring that people who use services are aware of how to raise concerns of abuse.
- Having effective means to monitor and review incidents, concerns and complaints that have the potential to become an abuse or safeguarding concern.
- Having effective means of receiving and acting upon feedback from people who use services and any other person.
- Taking action immediately to ensure that any abuse identified is stopped
- and suspected abuse is addressed by:
 - having clear procedures followed in practice, monitored and reviewed that take account of relevant legislation and guidance for the management of alleged abuse

- separating the alleged abuser from the person who uses services and others who may be at risk or managing the risk by removing the opportunity for abuse to occur, where this is within the control of the provider
- reporting the alleged abuse to the appropriate authority
- reviewing the person's plan of care to ensure that they are properly supported following the alleged abuse incident.
- Using information from safeguarding concerns to identify non-compliance, or any risk of non-compliance, with the regulations and to decide what will be done to return to compliance.
- Working collaboratively with other services, teams, individuals and agencies in relation to all safeguarding matters and has safeguarding policies that link with local authority policies.
- Participates in local safeguarding children boards where required and understand their responsibilities and the responsibilities of others in line with the Children Act 2004.
- Having clear procedures followed in practice, monitored and reviewed in place about the use of restraint and safeguarding.
- Taking into account relevant guidance set out in the Care Quality Commission's Schedule of Applicable Publications
- Ensuring that those working with children must wait for a full CRB disclosure before starting work.
- Training and supervising staff in safeguarding to ensure they can demonstrate the competences listed in Outcome 7E of the Essential Standards of Quality and Safety, Care Quality Commission, London 2010

All children and young people who use services must be:

- Fully informed of their care, treatment and support.
- Able to take part in decision making to the fullest extent that is possible.
- Asked if they agree for their parents or guardians to be involved in decisions they need to make.

(Outcome 4I *Essential Standards of Quality and Safety*, Care Quality Commission, London 2010)

Key Service Outcomes

Evidence is increasing that implementation of the national Quality Criteria for Young People Friendly Services (Department of Health, London 2011) have the potential to greatly improve patient experience, leading to better health outcomes for young people and increasing socially responsible life-long use of the NHS.

Implementation is also expected to contribute to improvements in health inequalities and public health outcomes e.g. reduced teenage pregnancy and STIs, and increased smoking cessation. All providers delivering services to young people should be implementing the good practice guidance which delivers compliance with the quality criteria.

Poorly planned transition from young people's to adult-oriented health services can be associated with increased risk of non adherence to treatment and loss to follow-up, which can have serious consequences. There are measurable adverse consequences in terms

of morbidity and mortality as well as in social and educational outcomes. When children and young people who use paediatric services are moving to access adult services (for example, during transition for those with long term conditions), these should be organised so that:

- All those involved in the care, treatment and support cooperate with the planning and provision to ensure that the services provided continue to be appropriate to the age and needs of the person who uses services.

The National Minimum Standards for Providers of Independent Healthcare, (Department of Health, London 2002) require the following standards:

- **A16.1** Children are seen in a separate out-patient area, or where the hospital does not have a separate outpatient area for children, they are seen promptly.
- **A16.3** Toys and/or books suitable to the child's age are provided.
- **A16.8** There are segregated areas for the reception of children and adolescents into theatre and for recovery, to screen the children and adolescents from adult patients; the segregated areas contain all necessary equipment for the care of children.
- **A16.9** A parent is to be actively encouraged to stay at all times, with accommodation made available for the adult in the child's room or close by.
- **A16.10** The child's family is allowed to visit him/her at any time of the day, except where safeguarding procedures do not allow this
- **A16.13** When a child is in hospital for more than five days, play is managed and supervised by a qualified Hospital Play Specialist.
- **A16.14** Children are required to receive education when in hospital for more than five days; the Local Education Authority has an obligation to meet this need and are contacted if necessary.
- **A18.10** There are written procedures for the assessment of pain in children and the provision of appropriate control.

All hospital settings should meet the Standards for the Care of Critically Ill Children (Paediatric Intensive Care Society, London 2010).

There should be age specific arrangements for meeting Regulation 14 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. These require:

- A choice of suitable and nutritious food and hydration, in sufficient quantities to meet service users' needs
- Food and hydration that meet any reasonable requirements arising from a service user's religious or cultural background
- Support, where necessary, for the purposes of enabling service users to eat and drink sufficient amounts for their needs
- For the purposes of this regulation, "food and hydration" includes, where applicable, parenteral nutrition and the administration of dietary supplements where prescribed
- Providers must have access to facilities for infant feeding, including facilities to support breastfeeding (Outcome 5E, of the Essential Standards of Quality and Safety, Care Quality Commission, London 2010)

All paediatric patients should have access to appropriately trained paediatric trained dieticians, physiotherapists, occupational therapists, speech and language therapy, psychology, social work and CAMHS services within nationally defined access standards.

All children and young people should have access to a professional who can undertake an assessment using the Common Assessment Framework and access support from social care, housing, education and other agencies as appropriate.

All registered providers must ensure safe use and management of medicines, by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines (Outcome 9 Essential Standards of Quality and Safety, Care Quality Commission, London 2010). For children, these should include specific arrangements that:

- They are supported to have a health action plan
- Facilities meet the appropriate requirements of the Disability Discrimination Act 1995

They meet the standards set out in Transition: getting it right for young people. Improving the transition of young people with long-term conditions from children's to adult health services. Department of Health, 2006, London.

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