NHS England

Clinical Commissioning Policy: Obesity surgery for children with severe complex obesity

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Clinical Commissioning Policy: Obesity surgery for children with severe complex obesity

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Prepared by NHS England Specialised Services Clinical Reference Group for Severe and Complex Obesity

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Contents

Policy Statement

NHS England will commission obesity surgery for children with severe complex obesity in accordance with the criteria outlined in this document. In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources. This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Plain Language Summary

About childhood and adolescent obesity

Obesity in children and adolescents is a major and growing health problem. Having a lot of body fat and being very overweight (called 'obesity') can lead to a number of serious problems such as:

- high blood pressure (called 'hypertension')
- a condition where the body produces insulin but does not use it effectively (called 'insulin resistance')
- a group of problems that can lead to heart disease, stroke and type 2 diabetes (called 'metabolic syndrome')
- lower life expectancy.

About current treatments

For most people, eating a healthy, reduced-calorie diet and exercising regularly is the most effective treatment for obesity. Some patients may benefit from psychological support from a trained healthcare professional, to help change the way they think about food and eating.

Specialist weight management programmes are also available, although they are often designed for adults. If lifestyle changes alone are not successful, treatment with medicines may be considered.

All of the above treatments are ‘non-invasive’ - they do not require an operation.

About the new treatment

If patients do not respond to the above ‘non-invasive’ therapies, obesity surgery may be considered. This refers to any surgical treatment or operation for obesity - this may include a gastric bypass, for example.

What we have decided

NHS England has carefully reviewed the evidence to treat childhood and adolescent obesity with obesity surgery. We have concluded that there is enough evidence to consider making the treatment available for a small number of highly selected children, 18 years and under with severe and complex obesity.

1 Introduction

This document describes the evidence that has been considered by NHS England in formulating clinical policy to routinely commission obesity surgery for children with severe and complex obesity for a small number of highly selected patients.

Obese children and adolescents are at an increased risk of developing various health problems, and are also more likely to become obese adults. Childhood obesity is associated with co-morbid conditions, commonly hypertension, obstructive sleep apnoea, insulin resistance, metabolic syndrome, non-alcoholic fatty liver disease and dyslipidaemia. The cost of obesity to society was estimated in 2007 to be £16 billion, and if rates continue to rise could reach up to £50 billion in 2050 (NICE CG189, 2014).

Obesity in children is currently managed predominately with lifestyle interventions, focusing on behavioural and dietary modifications, with evidence of short term success (Cochrane Review, 2009). Pharmacotherapy is less commonly used in adolescent patients: Cochrane review (2009) showed both orlistat and sibutramine in children greater than 12 years to be beneficial in reducing weight at 6 months. Some severely obese adolescents with significant and severe obesity-related comorbidities such as hypertension, fatty liver disease or uncontrolled diabetes, who have failed specialist multi-component, intensive, non-invasive weight management programmes, may benefit from a surgical approach.

Currently there is no evidence based care pathway in utilising obesity surgery in the paediatric/adolescent population. 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).

2 Definitions

Obesity: In adults, obesity is commonly defined as a body mass index of 30 or more. For children, in the UK, the British 1990 growth reference charts are used to define weight status.

Body mass index (BMI): a measure (kg/m²) of whether someone is a healthy weight for their height.

BMI SD: standard deviation score indicates how many units (of the standard deviation) a child's BMI is above or below the average BMI value for their age group and sex. Also referred to as a z score.

Co-morbidity: the presence of one or more additional diseases co-occurring with a primary disease (synergistic or coincidental); or the effect of such additional disease (clinically dominant).

Dyslipidaemia or high cholesterol: means that there is an imbalance of fats (lipids), circulating in the blood stream. Cholesterol is a fatty substance the body uses to make hormones and metabolise food.

Obesity surgery: also known as bariatric surgery, any surgical treatment for obesity.

Laparoscopic adjustable gastric band (LAGB, or gastric banding): helps reduce the amount of food eaten. It acts like a belt around the top portion of the stomach, creating a small pouch. Patients feel full after eating only a small quantity of food. It is adjustable and reversible.

Roux–en–Y gastric bypass (RYGB): the most popular variation of gastric bypass operation conducted in the UK. During surgery, the top section of the stomach is divided off by a line of staples, creating a small 'pouch' stomach. A new exit from this pouch is made into a 'Y' loop from the small intestine so that food bypasses the old stomach and part (about 100-150cm) of the small intestine. The size of stomach

pouch and the length of small intestine that is bypassed are carefully calculated to ensure that patients will be able to eat enough for their body's needs at normal weight.

Laparoscopic sleeve gastrectomy (LSG): the sleeve gastrectomy reduces the size of the stomach by about 75%. It is divided vertically from top to bottom leaving a banana shaped stomach along the inside curve, and the pyloric valve at the bottom of the stomach, which regulates the emptying of the stomach into the small intestine, remains intact. This means that although smaller, the stomach function remains unaltered.

Gastric balloon: an intra-gastric balloon is a soft silicone balloon that is surgically implanted into the stomach. The balloon is filled with air or saline solution (sterile salt water), and so takes up some of the space in the stomach. This procedure is only temporary, and the balloon is usually removed after six months.

Models of care: a typical model for managing obesity is outlined as follows:

- Tier 4 - Specialised Complex Obesity Services (including both medical management, obesity surgery and other elements of specialised multi-disciplinary team [MDT] care)
- Tier 3 - An MDT to provide an intensive level of input to patients
- Tier 2 - Primary Care with Community Interventions. The Tier 2 programme will typically be of 10-12 weeks duration. It can be provided by the NHS or commercially. Identification of co-morbidities can take place in either primary or secondary care. If necessary patients may be referred to Tier 3 for identification of co-morbidities. Patients with non-engagement or child protection issues can be transferred directly to Tier 4
- Tier 1 - Primary Care and Community Advice

3 Aims and Objectives

This clinical policy aims to define NHS England's commissioning position on obesity surgery as part of the treatment pathway for children 18 years and under with severe and complex obesity.

The objective is to ensure evidence based commissioning with the aim of improving outcomes for children with severe and complex obesity.

4 Epidemiology and Needs Assessment

Childhood and adolescent obesity is a major and growing health problem and associated with comorbid conditions, commonly hypertension, obstructive sleep apnoea, insulin resistance, metabolic syndrome, non-alcoholic fatty liver disease and dyslipidaemia.

The prevalence of childhood obesity has been increasing, and in 2011, 3 in 10 children aged 2-15 years were found to be overweight or obese in the UK (NICE CG189). Rates of obesity surgery are also increasing: there was 1 operation in 2000 and 31 in 2009 (Jones Nielson et al., 2013). It is estimated that around 6-8 patients receive obesity surgery each year, based on an average across the 30-40 undertaken over the last 5 years and data from the National Bariatric Surgery Registry (2014) that shows that 23 primary operations for patients aged 12-17 were undertaken between 2011 – 2013.

5 Evidence base

NHS England has concluded that there is sufficient evidence to support a clinical policy for the routine commissioning of obesity surgery for children with severe and complex obesity for a small number of highly selected patients.

What is the clinical effectiveness of obesity surgery in children and adolescents?
Is there any evidence for long term efficacy (more than 1 year? more than 5 years?)?

Overall, in the current literature there is evidence of clinical effectiveness for obesity surgery in adolescents (following skeletal maturity - Tanner Stage 4 and above),

predominately from non-Randomised Control Trial (RCT) studies (level 2 and 3 studies), with limited evidence about long term efficacy. There are limited studies on performing obesity surgery in younger children (level 3). There is insufficient evidence on selection criteria, indications, postoperative complications and long-term adverse effects of surgery. Although included in the literature search strategy, no evidence relating to duodenal switch procedures in adolescents could be found. The search strategy did not specifically include rare syndromes predisposing to adolescent obesity, but some pertinent information was found in the wider literature.

One RCT (level 1) by O'Brien et al. (2010) has been identified in the current literature, which evaluated LAGB with intensive lifestyle intervention (dietary and behavioural modification) in 50 obese adolescents aged 14-18. They found that LAGB resulted in substantial weight loss at two years, with a mean reduction of 34.6kg versus 3kg in the lifestyle group. They also observed improvements in health related quality of life. Twenty-eight percent of adolescents required revision surgery, removal or replacement of the band or replacement of the access port, a rate consistent with adult studies.

A recent meta-analysis (level -1) by Paulus et al. (2015) examined change in BMI one year post operatively, and reported on health related indices. The analysis included 23 studies (level 2 and 3), and found the mean BMI loss was -13.5kg/m², the greatest loss in the RYGB group (-17.2kg/m²) and smallest in the LAGB group (-10.5kg/m²). These findings were consistent with another meta-analysis that evaluated 37 studies (Black et al., 2013) (level -1), and found the mean BMI loss was greatest in the RYGB group (-16.6kg/m²), followed by LSG with 14.1kg/m² and LAGB with -11kg/m². Pedroso et al. (2015) (level -2) assessed LSG and LAGB in adolescent patients and at two year follow-up observed significantly greater percentage excess weight loss in the LSG group compared to the LAGB group (70.9% vs 35.5% respectively p=0.004). The Teen Longitudinal Assessment of Bariatric Surgery (Teen-LABS) study (Inge et al., 2015) showed that patients who underwent obesity surgery (RYGB and LSG) reported an overall decrease in mean weight of 27% and mean BMI decrease of 28% (BMI decreased from baseline from 53kg/m² to 38kg/m²) at 3 years post operatively. The mean weight loss of those patients who underwent RYGB was 28% compared to 26% in the LSG group at three

years. The study observed that at three years 26% of patients were no longer obese. At 3 years 2% of patients who underwent gastric bypass and 4% of those who underwent sleeve gastrectomy exceeded baseline weight.

Paulus et al. (2015) noted the overall poor quality of documentation of complications, with the majority of complications in the RYGB group involving nutrient deficiencies, hernia and wound infection. In LAGB the key complications were pouch dilatation, band slippage and port complications. Complications were rarely reported in LSG. Pedroso et al. (2015) observed that at 5 years the complication rate in the LAGB group was 23.4%, which included bowel obstruction, port leakage and band displacement. Follow-up at two years in the LSG group reported minimal overall complications. However, there was one death 12 days post LSG, as a result of mesenteric venous thrombosis. The Teen-LABS study (n=242) (level 3), which is an ongoing prospective study, evaluated outcomes within 30 days postoperatively (Inge et al., 2014). No mortality was recorded, 7.9% experienced major complications, 5% perioperative complications including one splenic injury, early reoperation for intestinal obstruction, bleeding or suspected gastrointestinal leak. 14.9% had minor complications including urinary tract infections, abdominal and gastrointestinal complaints including dehydration. The Teen-LABS study at 3 years post operatively (Inge et al. 2015) found 13% of patients had undergone one or more intra-abdominal procedure. Inge et al. also evaluated micronutrients, and found low ferritin levels were evident in 57% of patients ($p<0.001$), 16% of patients who undergone RYGB ($p=0.008$) and 8% of all patient being VitB12 deficient, at three years post-surgery. Case series of 345 patients Lennez et al. (2014) reported intraoperative complications rate of 0%-2.6%, and postoperative complications (18 months follow-up) rate of 9.1% to 2.5%. In this case series they found no difference in rates of complications at 18 months amongst the three surgical procedures (LSG, LAGB and RYGB). Long-term high quality studies are required to evaluate the risk of different obesity surgical procedures in children and adolescents.

In studies reporting co-morbidities variability in both the assessment and methodology is evident. There is level 2/3 evidence of improvement and resolution of co-morbidities. Paulus et al. (2015) found that over 50% of the RYGB and LGB reported resolution in associated co-morbidities, including hypertension, sleep

apnoea, insulin resistance and dyslipidaemia. Black et al. (2013) reported, 11/18 LAGB studies observed complete resolution of hypertension in 22-100% of studies, dyslipidaemia in 50% and 100% of diabetic cases after surgery. In RYGB 8/13 reported an improvement, and in LSG 4/5 studies reported resolution of co-morbidities in 75-100% of studies evaluating hypertension, 56-100% of dyslipidaemia and 50-93% of those with diabetes. Inge et al. (2015) observed (level 3) an improvement in insulin sensitivity and β cell function, and metabolic improvements even with obesity persisting at one year follow-up.

Psychosocial and mental health is increasingly becoming an important parameter requiring evaluation pre and post obesity surgery. A systematic review consisting of 12 adolescent studies (Herget al., 2014) (level 2+) reported depressive symptoms ranging from 15 to 70%, anxiety symptoms 15-33% and eating disorders in 48-70%, prior to surgery. A large case series by Sysko et al. (2012) reported a significant improvement in depressive symptoms ($p<0.001$) at 15 months. A systematic review evaluating 10 studies (Hilstrom et al., 2015 (level 2+)) observed an overall improvement in psychosocial outcomes post operatively. Herget et al. (2014) found studies varied in evaluation in time points and no clear documentation of pharmacotherapy pre and post-surgery. Studies have observed short term improvements in psychosocial parameters, however studies have also reported a persistence of symptoms post operatively.

Zeller et al. (2011) observed an increased tendency of depressive symptoms at 18-24 months postoperatively, and Orsorio et al. (2011) observed 21.4% of patients were still suffering from clinical depressive symptoms. Overall studies (level 2, level 3) have reported improvement in quality of life parameters, physical, self-esteem domains from baseline following obesity surgery, further high level evidence is required to further evaluate the psychosocial impact upon adolescents/children pre and post-surgery.

Cost effectiveness

There is a lack of studies evaluating cost effectiveness of obesity surgery in children and adolescents. Aikenhead at al. (2011) in a systematic review identified three studies on LAGB in adolescents, that showed net cost saving per disability adjusted life year was $AU4,400 (£2,092) (level 2+). Bairdain et al. (2015) (level 3) evaluated cost-effectiveness (n=11) and estimated that obesity surgery was not cost effective in the first 3 years, but cost effective after. It cost $80,065 (£52,925) per QALY in year 4 and $36,570 (£23,515) per QALY in year 7 (threshold of $100,000/QALY). This small study failed to include obesity specific comorbidities, and additionally the US findings may not be entirely applicable to the UK population cohort.

What is the evidence for selection criteria and previous weight management strategies?

There is no empirical evidence of a standardised care pathway, including selection criteria. The majority of the western world follows consensus guidance, including that obesity surgery should be performed on adolescents following a multidisciplinary evaluation. Obese adolescents (≥40kg/m² or ≥35kg/m² with at least one obesity associated co-morbidity) that have achieved skeletal maturation (linear growth), following failure of lifestyle interventions are considered. There is a variation and documentation in the studies in type, intensity and duration of lifestyle intervention prior to obesity surgery. The majority of obesity surgery appeared to be performed in a multidisciplinary environment. The majority of studies have excluded syndromic patients, those with severe medical or psychiatric problems and those who have disease related aetiology for obesity.

Patient participation prior to surgery provides an opportunity to evaluate behaviour and motivation. Fenning et al. (2015) pilot study (n=15) (level 3) involved two phases, firstly a 3 month preoperative program, consisting of medical examination, psychological measures, self-monitoring, physical activity, cognitive behaviour orientated therapy and psychosocial educational training, and phase two surgical phase. Phase I assessed adherence to program, parental involvement and weight loss preoperatively. They found both weight and BMI decreased over the three

months, mean loss -3.14kg/m² and the majority of patients followed the program. Interestingly, they observed poor parental participation. Compliance post operatively requires further evaluation.

Although the majority of surgery has been undertaken in non-syndromic adolescent, a recent study by Mohaidly et al. (2013) (Level 3) performed LSG on an obese 2.5 year old, and at 2 years the patient had a 27% weight loss with normalisation of BMI from 41kg/m² to 24kg/m². The authors did raise concern on parental compliance with instructions and poor attendance at follow-up. Growth, developmental and nutritional details were not included in the study. Alqahtani et al. (2015) (level -2) performed LSG on 24 patients with Prader Willi Syndrome (PWS) with a mean age of 10.7 years, observed at 5 years significant weight reduction, with rate of growth not significant between the PWS group and matched non-PWS group.

In summary, the available evidence indicates that any of these three procedures in adolescents lead to greater short-term (1-3 years) weight loss and improvements in HRQOL, psychological outcomes and comorbidities than non-invasive management alone, although there is little longer term follow-up evidence available at present. There was little evidence to indicate that one type of procedure was superior or inferior to another, and the adverse effects of obesity surgery in general are not well documented. The collection of longitudinal evidence on the short and long-term effects of obesity surgery in children, including endocrinological and metabolic effects, raises the importance of robust mechanisms to assess longer term outcomes and to ensure patients are in a position to give informed consent for the procedure.

6 Criteria for Commissioning

Surgical intervention is not generally recommended in children or young people (NICE CG189, 2014). However, obesity surgery may be considered in eligible individuals to achieve significant and sustainable weight reduction, if all the following criteria are fulfilled:

- The adolescent has been evaluated by the appropriate specialised MDT (see service specification for details) and deemed suitable appropriate for surgery.

- The adolescent has a post pubertal BMI ≥40kg/m² (BMI SD ≥3.0) or ≥35kg/m² (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 completed clinical assessment and management treatment within a commissioned Tier 3 service.

- The decision of the MDT regarding surgery will depend on the individual's engagement and response to weight management services, their co-morbidities and 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 adolescent and their family commits to the need for long-term follow-up.

- 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.

7 Patient Pathway

Before being considered for surgery, the adolescent must have completed assessment and treatment within a commissioned Tier 3 service. 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, intensity and duration of intervention/s will be determined by the specialist MDT: adolescents should remain in Tier 3 until all non-surgical avenues have been adequately explored and found to be unsuccessful; these approaches should be documented in the MDT discussions.

Adolescents indicated for obesity surgery should have a comprehensive clinical, psychological, educational, family and social assessment by an appropriate specialised multi-disciplinary team before undergoing surgery. This includes a full medical evaluation, and genetic screening or assessment to exclude rare, treatable causes of obesity.

Surgical care and follow-up should be coordinated around the patient and his/her family's needs, complying with the approaches outlined in the Department of Heath's ‘A call to action on obesity in England’ to increase attendance and compliance. Lifelong specialist follow up is advocated, with a minimum 5 year follow up care plan recommended, including transfer into the adult pathway at 18 years old where appropriate (in line with the principles outlined in the NICE guidance 'Transition from children's to adults' services' currently in development), or follow up beyond 18 years old in tertiary paediatric services or Tier 4 paediatric obesity services where adolescents are within a few years of surgery, or where local adult provision is weak.

Adolescents who have had obesity surgery should have a follow-up care plan for a minimum of 5 years within the Tier 4 obesity service, or through shared care follow up arrangements with the latter and more local specialist paediatric centres. 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
- information about professionally-led or peer-support groups.

See the NHS service specification for more details.

8 Governance Arrangements

Providers, surgeons, premises, on site services and obesity surgery throughput should at least meet the IFSO Guidelines for Safety, Quality, and Excellence in Bariatric Surgery.

There must be appropriate specialised MDT composition, co-option and support, specialist professional inputs and process design for all stages of the pathway (elective and emergency). In addition, organisational arrangements for patient safety (elective and emergency) should be risk assessed, regularly tested and improved. Protocols should be audited especially the use of questionnaires for clinical assessment, generic interdisciplinary roles and substitution and/or expansion of professional roles.

The surgical service should be seamless both pre- and post-operatively with the medical specialist Tier 3/4 service, and determined by local arrangements.

The obesity surgical and medical provider will be responsible for the organisation of structured, systematic and team based follow up for a minimum of 5 years. The latter 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 years of age in paediatric services or Tier 4 paediatric led services, where adolescents are within a few years of surgery, whilst transition to adult service provision is facilitated.

Follow up rates and nutritional and/or metabolic complications should be published.

9 Mechanism for Funding

Specialised complex obesity services, including obesity surgery pre-assessment, perioperative management, postoperative and longer term follow up where it occurs within the specialised service will be funded by NHS England.

10 Audit Requirements

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.

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. See specification for suggested outcome measures.

11 Documents which have informed this Policy

NHS England Clinical Commissioning Policy: Complex and Specialised Obesity Surgery NHSCB/A05/P/a.

National Institute for Health and Care Excellence Clinical Guideline 189 Obesity: identification, assessment and management of overweight and obesity in children, young people and adults..

National Institute for Health and Care Excellence Clinical Guideline 43 Transition from children's to adults' services.

12 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

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