

Bariatric Surgery Commissioning Policy

Policy name	Adult Bariatric Surgery Commissioning Statement
For the treatment of	Obesity and associated co-morbidities
Background	<p>Health problems and illnesses which are associated with obesity are an ever increasing problem in the UK. The primary concerns are rates of type 2 diabetes mellitus (T2DM), as well as several types of cancer, non-alcoholic fatty liver disease (NAFLD), and degenerative joint disease. The presence of obesity correlates with a lower life expectancy of 5 to 20 years, and as BMI increases the number of lifestyle-related comorbidities increases.</p> <p>Because the causes of obesity and lifestyle related co-morbidities are multi-factorial, so too should be the care and support offered. NHS England uses this (2013) model:</p> <p>Tier 1 - Primary Care and Community Advice, health promotion activities.</p> <p>Tier 2 - Primary Care with Community Interventions (lifestyle)</p> <p>Tier 3 - A primary/community care based multi-disciplinary team (MDT) to provide an intensive level of input to patients (specialist weight management services).</p> <p>Tier 4 - Specialised Complex Obesity Services (including bariatric surgery)</p> <p>At present the CCG commissions a pilot Tier 3 Obesity Management Service from York Teaching Hospitals Trust, which offers 100 places to adult patients who have a BMI >35, AND who have maximised primary care and community conservative management. Due to the limited number of places on the programme, patients with a BMI <50 are prioritised using a scoring system (patients with a BMI ≥50 are automatically eligible). The scoring system prioritises patients based on their BMI, as well as their co-morbidities and how recently these were diagnosed. The project is being evaluated by colleagues at the Centre for Health Economics (CHE).</p> <p>More information regarding making a referral to the Tier 3 service can be found on the CCG's Referral Support Service pages.</p>

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	<p>Bariatric surgery</p> <p>The current standard bariatric operations are gastric banding, gastric bypass, sleeve gastrectomy and duodenal switch. These are usually undertaken laparoscopically. This surgery is an effective weight-loss therapy and can achieve significant and sustainable weight reduction within 1-2 years, as well as reductions in co-morbidities and mortality, with particularly marked therapeutic effects on patients with Type 2 diabetes. Although there is good evidence for the longer-term cost-effectiveness of bariatric surgery, it is not expected to result in cost savings at any time point.</p>
<p>Exclusions</p>	<p>Smoking</p> <p>Patients to be listed for bariatric surgery who are smokers must stop smoking prior to being put on the waiting list. The patient can be placed on the waiting list once they have successfully stopped smoking for 8 weeks.</p>
<p>Red Flags</p>	
<p>Commissioning position</p>	<p>Referral to tier 4 bariatric surgery</p> <p>Bariatric <i>surgery</i> is not routinely commissioned but <i>referral</i> to Tier 4 will be considered by the Tier 3 weight management programme (WMP) multi-disciplinary team (MDT) panel following completion of the Tier 3 WMP, for the most cost-effective subgroups⁷ where the patient has a</p> <ul style="list-style-type: none"> • BMI ≥50, OR • BMI ≥45 with significant poorly controlled type 2 diabetes (based on medication and IFCC). <p>The Tier 3 MDT Panel will consider bariatric surgery as a treatment for selected patients with severe and complex obesity, where all of the following criteria have been met:</p> <ul style="list-style-type: none"> • the person has not responded to ALL other non-invasive therapies and is willing to have the surgery • there is no specific clinical or psychological contraindications to this type of surgery • the person is generally fit for anaesthesia and surgery, with assessment of peri-operative mortality and post-operative complications of bariatric surgery • the person commits to long-term follow-up and dietary compliance and is considered likely to engage in the follow up programme that is required after any bariatric surgical procedure

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	<p>Funding in all other circumstances will only be considered where there are exceptional clinical circumstances. The clinician needs to submit an application to the CCG's Individual Funding Request Panel (IFR).</p> <p>NB Referrers and patients should be aware of the following:</p> <ul style="list-style-type: none"> • Revision/re-do bariatric surgery <p>Vale of York CCG does NOT routinely commission revision/re-do surgery.</p> <p>Revision or re-do surgery is commissioned for 'urgent' surgical reasons. Patients must be advised this as part of the informed consent process. Where there has been a surgical failure (e.g. slipped band) that is remediable relative easily.</p> <p>Revision/re-do surgery is NOT routinely commissioned where there is failure to lose weight despite successful surgery. Where there is clinical exceptionality an application can be made for prior approval from IFR panel.</p> <p>Any new/novel bariatric surgery procedures outside of this policy are not commissioned.</p> <ul style="list-style-type: none"> • Non-designated providers or private funding <p>Specialist post-operative and locality MDT weight management support will not be routinely funded for patients who have chosen to receive their bariatric surgery from a provider who is not a designated regional provider of morbid obesity surgical services or where surgery has been privately funded.</p> <ul style="list-style-type: none"> • Body contouring surgery <p>Body contouring surgery following substantial weight loss is not routinely commissioned.</p>
<p>Summary of evidence/rationale</p>	<p>Introduction and prevalence</p> <p>The prevalence of obesity in England is one of the highest in the European Union. In England just over 25% of adults aged 16 or over were classified as obese in 2010 (defined as BMI of 30 or over).</p> <p>Around 20% of the VoY CCG population are estimated to have a BMI > 30 (i.e. around 72,000 people). Based on a</p>

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sample of CCG GP practices, the estimated prevalence of higher BMI ranges suggests that over 30% of these (around 21,600 people) have a BMI >35, about 11% have a BMI >40 (i.e. around 8,000 people) and about 0.8% have a BMI >50 (i.e. around 580 people). The sample may underestimate overall numbers but these proportions are the best figures available.

Evidence base for bariatric surgery/tier 4 services

Bariatric surgery is recommended by NICE (although not as part of a mandatory TA) as a first-line option for adults with a BMI of more than 50, when other interventions have not been effective, and in whom surgical intervention is considered appropriate – but they are also required to fulfil the criteria given above^{1, 2}. It should always be performed in a specialist centre with MDT support, and long-term follow-up of patients is necessary.

NICE and NHS England^{1, 2, 3} have considered bariatric surgery an appropriate option to aid weight reduction for adults with morbid/severe obesity with the lower thresholds of BMI ≥40, or ≥35 with significant comorbidities, if also

- there is recent and comprehensive evidence that an individual patient has fully engaged in a structured weight loss programme;
- that all appropriate non-invasive measures have been tried continuously and for a sufficient period; but have failed to achieve and maintain a clinically significant weight loss for the patient's clinical needs.
- the patient has been adequately counselled and prepared for bariatric surgery as it does require engagement with long-term follow up and compliance with dietary restrictions.

Trade-off between clinical benefits and harms

Any intervention carries risk to the individual. Surgical intervention in overweight or obese people carries an increased risk of complications, for example, in relation to anaesthesia. However, this needs to be balanced against the potential benefits of surgical treatment, including potential 'remission' of diabetes in this population, thereby avoiding long-term harm from that condition, and the avoidance of future weight related illness.

Clinical effectiveness

The evidence for bariatric surgery being effective and cost-effective is considerable, particularly for people with type 2

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DM, compared to non-surgical interventions^{1, 2}. The 6 clinical effectiveness studies on which the NICE guidance is based comprise about 530 patients in total, although with follow-up mostly no more than 1-2 years, and none done in the UK. They comprise a mix of laparoscopic adjustable gastric band (LAGB), bypass and sleeve gastrectomy.

The Guideline Development Group (GDG) concluded that the body of evidence considered, based on these 6 studies, showed that bariatric surgery consistently improved weight and diabetic outcomes compared to non-surgery in people with recent onset T2DM (less than 10 years). Most of the evidence considered included people who had diabetes for less than 10 years, but some studies also included individuals who had diabetes for more than 10 years (who might respond less, but this would underestimate the impact on outcomes).

The GDG felt that the evidence supported and strengthened the existing recommendation from CG43 for people with T2DM and a BMI of 35 or above being offered surgery.

Cost effectiveness

The cost-effectiveness is largely driven by reduction in the cost of diabetes medication and care, and the health consequences of long term diabetes. The potential to prevent longer-term complications is considered better with “recent onset” T2DM, but any “remission” depends on maintaining weight loss. There is no firm evidence of cost savings, however, and with limited resources, it is not necessarily possible to fund all cost-effective procedures; choices need to be made.

For the latest NICE Guidance, four economic studies were identified which evaluated the cost effectiveness of bariatric surgery in individuals with recent-onset T2DM. Two (one based in UK) were funded by Allergan (manufacturer of the LAP-BAND LAGB product). Several did not account for weight regain/possible relapse of DM or look at mortality and loss of quality of life (QoL) associated with surgical complications.

Three studies looked at LAGBs compared to medical management of T2DM. Of these studies, 2 found that LAGB was cost effective compared to non-surgical management for treating obese patients with recent-onset T2DM (ICERs: £3602 per QALY gained and £1634 per QALY gained). Both of these studies used a UK NHS perspective and are therefore directly applicable to the UK NHS.

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The remaining study found that LAGB dominated (less costly and more effective) non-surgical management of T2DM; however this was conducted using an Australian healthcare perspective and is therefore only partially applicable to a UK setting. The GDG agreed that, despite the limitations of these studies, the evidence to suggest that LAGB is cost effective in this population was convincing and that bariatric surgery is highly likely to be cost effective for obese individuals with recent-onset T2DM. Robust sensitivity analyses conducted within the studies supported this conclusion.

While there is good evidence of expected cost-effectiveness of bariatric surgery, the evidence is largely based on short term follow up, so there is a degree of uncertainty in the expected health and cost implications. Careful follow up of patients who undergo bariatric surgery in York to ensure expected benefits will be beneficial. For this reason, and to focus (and match) available resources on the most cost-effective groups, the BMI threshold is held at 45 rather than the lower figure considered by NICE.

It is clear from this and other evidence that the greatest benefit of bariatric surgery is for people who also have T2DM which is what has led to the above commissioning position. A follow up study noted, however, that remission rates peaked at two years follow-up, with a degree of relapse seen at five years. Roux-en-Y Gastric Bypass (RYGB) saw a 75% remission rate at two years, falling to 37% at five years. No medical patients experienced remission and this difference between surgical and non-surgical arms was statistically significant ($P < 0.0001$)⁴.

More recent extensive evaluations from a UK perspective, funded by NIHR, support the idea that bariatric surgery is cost effective, arguably without any specific caveats around diabetes^{5,6}. One analysis⁵ covers several important categories, including different BMI groups and diabetes, all of which are cost-effective with a large degree of certainty, with ICERs ranging from £6,176 per QALY for patients with BMI ≥ 40 and T2DM to £7,675 per QALY for all patients with BMI ≥ 35 . The other model reports a higher ICER (£10,126 per QALY) but fails to conduct any subgroup analysis (only looking at all patients with a BMI > 35)⁶. Both indicate that bariatric surgery is likely to be associated with greater costs than alternative interventions at any point in patients' lifetimes.

Further limitations to the evidence base include:

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	<ul style="list-style-type: none"> • selection for surgery without adequate psychological assessment – probably a major cause of subsequent weight gain and dissatisfaction with body contour • limited follow-up (2 years is common), and likely weight gain thereafter – not only after gastric banding but also gastric sleeves and bypass. This was explored in some of the studies but is highly uncertain. • loss to follow up and the unknown reasons for this in surgical series • inconsistent definition of benefit – in particular on ‘regression’ of diabetes and clinical/cost effectiveness extrapolated beyond the power of available data to show • limited reporting of adverse events other than major surgical complications: one concern is significant and unrecognised (not mechanical obstruction) gastro-paresis after disruption of gastric nerve supply • lack of a good understanding of what contributes to a successful patient or how tier 3 and 4 services are best combined • the perspectives of the cost-effectiveness evaluations in concluding cost-effectiveness, in terms of weighing future health gains with short term expenditure, may not reflect the funding reality faced by the CCG <p><i>This summary has benefited from personal communications with a colleague at CHE⁷</i></p>
<p>OPCS codes</p>	<p>G27 Total excision of stomach G271 Total gastrectomy and excision of surrounding tissue G272 Total gastrectomy and anastomosis of oesophagus to duodenum G273 Total gastrectomy and interposition of jejunum G274 Total gastrectomy and anastomosis of oesophagus to transposed jejunum G275 Total gastrectomy and anastomosis of oesophagus to jejunum NEC G278 Other specified total excision of stomach G279 Unspecified total excision of stomach</p> <p>G28 Partial excision of stomach G281 Partial gastrectomy and anastomosis of stomach to duodenum G282 Partial gastrectomy and anastomosis of stomach to transposed jejunum G283 Partial gastrectomy and anastomosis of stomach to jejunum NEC G284 Sleeve gastrectomy and duodenal switch</p>

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	G285 Sleeve gastrectomy NEC G288 Other specified partial excision of stomach G289 Unspecified partial excision of stomach
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Effective from	20 September 2019
Review date	September 2021

References	<ol style="list-style-type: none"> 1. Obesity: identification, assessment and management NICE Guidelines CG 189 November 2014 https://www.nice.org.uk/guidance/cg189 2. Obesity: The Prevention, Identification, Assessment and Management of Overweight and Obesity in Adults and Children. London: NICE CG43; 2006; last updated March 2015 https://www.nice.org.uk/guidance/cg43 3. Clinical commissioning policy: complex and specialised obesity surgery April 2013 NHS Commissioning Board NHSE obesity 4. Bariatric-metabolic surgery vs conventional medical treatment in obese patients with type 2 DM: 5 years follow-up of an open-label, single-centre, randomised controlled trial. Mingrone et al <i>The Lancet</i> Vol 386, no 9997, p 964-73, Sept 2015 5. Costs and outcomes of increasing access to bariatric surgery: cohort study and cost-effectiveness analysis using electronic health records Gulliford et al <i>Health services and delivery research</i>, NIHR, Southampton UK 2016 6. Bariatric surgery, lifestyle interventions and orlistat for severe obesity: the REBALANCE mixed-methods systematic review and economic evaluation Avenell et al <i>Health Technology Assessment</i> Volume: 22, Issue: 68, December 2018 7. https://www.journalslibrary.nihr.ac.uk/hta/hta22680#/abstract Personal communications with Sebastian Hinde, University of York, NIHR CLAHRC Y&H, 14/6/2019
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Version	Created	Nature of Amendment	Approved by	Date
V1.0	05/03/2019	Review of statement		

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V2.0	18/06/2019	Updated policy		
V2.1	13/08/2019	Minor amendment following consultation	Members of the Executive Committee	14/08/2019