



NHS Birmingham and Solihull CCG

Policy for Bariatric Surgery in Adults

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The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

41. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
42. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
43. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
44. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
45. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
46. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
47. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
48. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Category: Restricted

Obesity is commonly defined as a Body Mass Index (BMI) of 30 kg/m² or greater (Table 1). Individuals living with obesity are at greater risk of a variety of different health conditions. These include:

- type 2 diabetes mellitus (T2DM),
- non-alcoholic fatty liver disease,
- hypertension, asthma,
- gastro-oesophageal reflux disease,
- depression and
- a variety of other conditions [1].

The risk of developing obesity-related co-morbidities increases as an individual's BMI increases [2].

Table 1.

Definition	BMI range (kg/m ²)
Underweight	Under 18.5
Normal	18.5 to less than 25
Overweight	25 to less than 30
Obese	30 to less than 40
Obese I	30 to less than 35
Obese II	35 to less than 40
Morbidly obese	40 and over

Source: NICE. *Obesity: identification, assessment and management* [1]

Epidemiology

Obesity is a global problem, estimated to have affected over six hundred million adults worldwide in 2014 [14]. In England, in both men and women, more than one in four adults are obese (28.2%) and 2.7% are classed as morbidly obese [15].

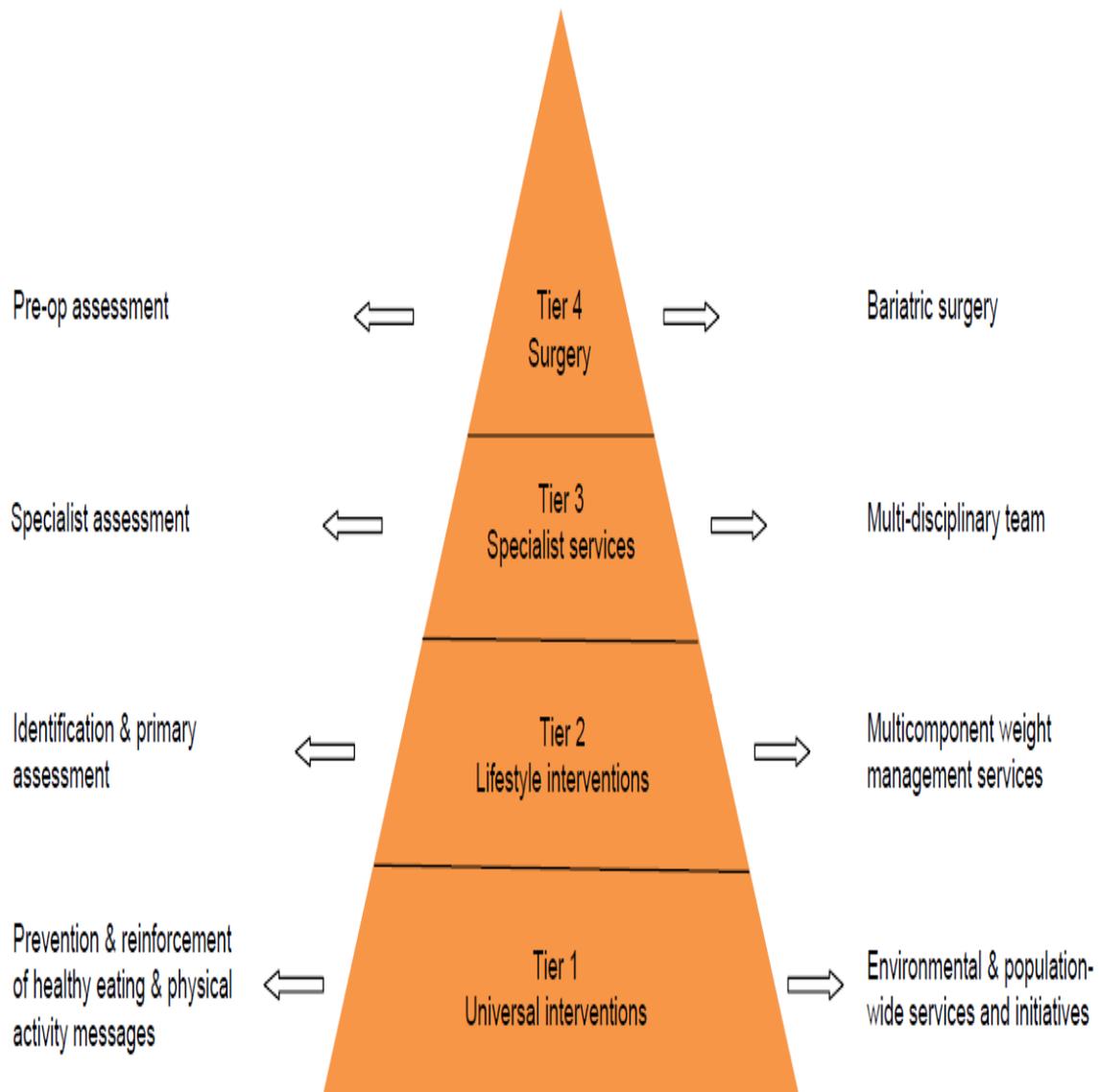
The prevalence of obesity in the UK rose between 1993 and 2014, the rate of increase began to slow in 2001 but the overall trend is still continuing to rise. According to the Health Survey for England, 61.7% of adults were overweight or obese in 2014, with more men being obese (65.3%) than women (58.1%) [16, 17]. Over the same time period, the prevalence of morbid obesity has also continued to climb, with a sharp rise in female prevalence between 2007 and 2011 (see Figure 4). Whilst the trend for males appears to have levelled off in recent years, the current level still represents a sizeable increase from that seen in the early 1990's. The number of people classed as obese in the UK is expected to increase by 11 million by 2030, with a likely corresponding increase in those with morbid obesity [18].

According to forecasts produced by the World Health Organisation, 31% of men and 30% of women will be obese by 2020, rising to 36% and 33% respectively by 2030 [19].

National Guidance

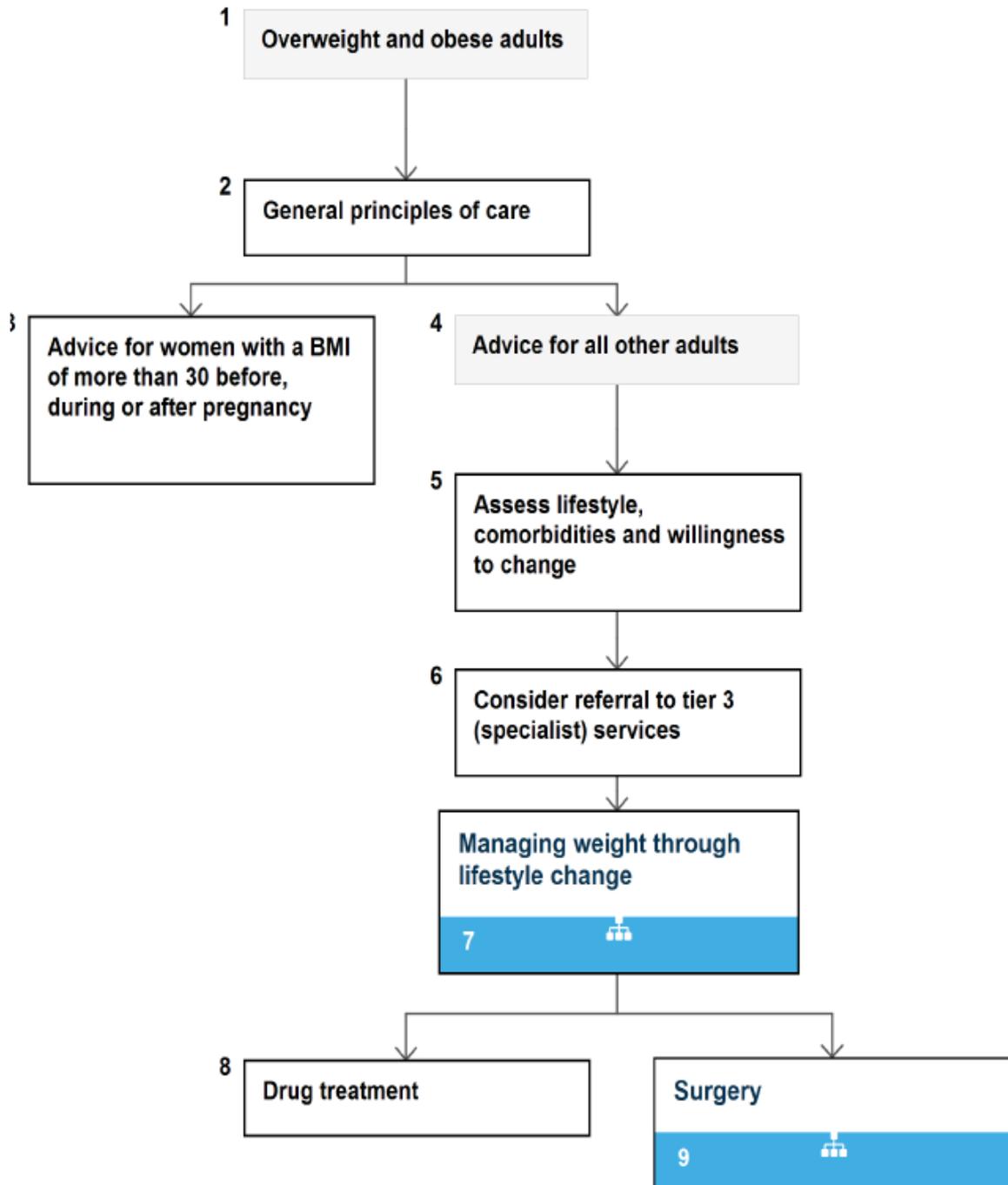
In England, obesity is managed through a tiered system (Figure 1), ranging from preventive population-based health promotion strategies (Tier 1) and lifestyle interventions (including diet, exercise, and behavioural) in primary care settings (Tier 2), through to more intensive specialist services provided by multi-disciplinary teams (tier 3) and bariatric surgery (tier 4) [3].

Figure 1: Tiered management of obesity



In November 2014, NICE published clinical guidance on the identification, assessment and management of obesity (NICE clinical guideline 189). [1]. The proposed NICE pathway is outlined below in Figure 2.

Figure 2: NICE pathway for overweight and obese adults



Co-Morbidities

The health issues associated with being overweight or obese include type 2 diabetes mellitus, cardiovascular disease and musculoskeletal disorders amongst others. People aged 35 to 59 with a BMI measurement of between 40 kg/m² and 50 kg/m² are five times more likely to die from ischaemic heart disease than those with a BMI of 22.5 kg/m² to 25 kg/m².

Between the same groups, the risk of dying from stroke was 6.5 times higher and the risk of dying from diabetes was 22.5 times higher. Vascular risk factors also exhibit a strong relationship with BMI; both systolic and diastolic blood pressure increases with BMI [20].

The prevalence of diabetes amongst those with normal weight was around 1.5%, compared to 15% in the severely obese [20].

On its own, BMI is a strong predictor of mortality and is strongly associated with diabetes for which sex-specific prevalence may rise more than five-fold from baseline across the BMI range. Table 3 shows a simplified version of the relationship between BMI and health risk.

Table 3: Co-Morbidity Risk by BMI Classification

Classification	BMI (kg/m ²)	Risk of Obesity Related Co-Morbidities
Underweight	<18.5	Low risk (but risk of other clinical problems increased)
Normal Range	18.50 – 24.99	Average risk
Overweight	≥25.0	Increased risk
Obese	≥30.0	Medium to high risk
Morbidly Obese	≥40.0	Very high risk

Non-Surgical Interventions

Non-surgical interventions for obesity consist of a wide variety of measures which may be used in varying combinations as part of a multi-component pathway. Generally this comprises dietary intake, physical activity levels and behaviour change and may also include pharmacological interventions [25]. These should be clinically led and involve multi-disciplinary assessment [13].

The Tier 3 service should be provided via a multidisciplinary team containing a bariatric physician, dietitian, specialist nurse, clinical psychologist and a liaison psychiatry professional. In addition to this there should also be access to a physical therapist.

The current Tier 3 offer differs across Birmingham and Solihull and is going through a process of harmonisation whereby Tier 3 service are being modelled to accommodate a range of patients in need of clinically-led weight management support. Once finalised, the patient will follow the Tier 3 commissioned pathway.

Non-surgical weight-management interventions (also known as 'Lifestyle Interventions') are commonly split into four categories:

1. Behavioural interventions
2. Physical activity
3. Behaviour change
4. Pharmacological interventions.

Interventions should be seen as multicomponent and incorporate combinations of the interventions described below.

Behavioural interventions

Behavioural interventions are provided with the support of an appropriately trained professional and include various strategies for adults which are incorporated as appropriate. These include (but are not limited to) self-monitoring of behaviour and progress, stimulus control, goal setting, ensuring social support is available, cognitive restructuring (modifying thoughts), reinforcement of changes and providing strategies for dealing with weight regain [1].

Physical Activity

Encouragement should be given to increase levels of physical activity, regardless of whether this will lead to weight-loss. This is due to the general fitness improvements it can bring and the associated reduced risk of cardiovascular disease and type 2 diabetes. This may comprise of 45-60 minutes of moderate-intensity exercise per day, increasing to 60-90 minutes for those who have already lost weight to prevent regaining of excess weight. Suitable activities include brisk walking, gardening, cycling, supervised exercise programmes, swimming, stair-climbing etc [1].

Dietary

Dietary interventions should not be unduly restrictive but should be tailored to individual food preferences and also be nutritionally balanced. As with physical activity, dietary improvements should be encouraged for reasons other than weight loss alone due to the associated health benefits which a balanced diet can bring. The primary requirement for a dietary intervention however is to reduce energy intake to a point below energy expenditure by approximately 600 kcal/day or by reducing fat content. This should be partnered with expert support and intensive follow-up. Low (800-1600 kcal/day) and very low (800 kcal/day or less) calorie diets should be used with some degree of caution due to issues around nutritional completeness [1].

Pharmacological Interventions

Pharmacological interventions should only be considered after behavioural, physical and dietary interventions have been started and evaluated. This applies especially to those service-users who have not achieved their target weight loss or have plateaued. It may also be utilised to maintain weight-loss as opposed to continuing weight loss [1]. Orlistat is the only pharmacological treatment for obesity currently recommended by NICE. This medication is a lipase inhibitor which works through preventing approximately a third of consumed fat from being absorbed, However, in addition to the well-documented side effects, there are potential issues related to the heightened risk of kidney problems [26].

Bariatric Surgery

Bariatric surgery includes a group of procedures that promote weight loss. They are usually performed laparoscopically, with decreased time in hospital and a shorter recovery time compared to open procedures. In the UK and Ireland, there were over 18,000 bariatric surgery operations in the three financial years ending 2011, 2012, and 2013; 95.4% of all primary operations were performed laparoscopically over this period [22]. More recently, minimally invasive surgical techniques also include robotic procedures, though their feasibility and safety are debated. Bariatric surgery may be categorised under three headings: restrictive; malabsorptive and combined procedures.

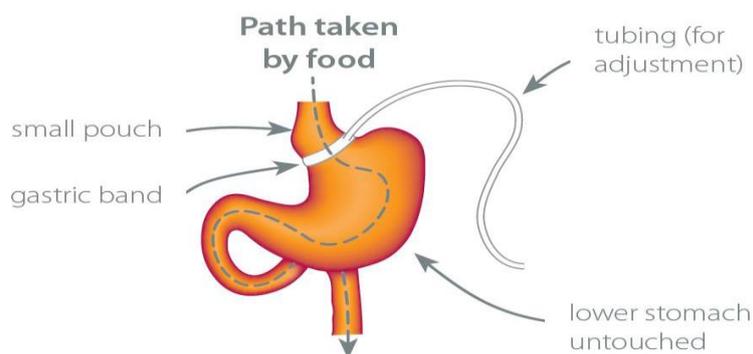
Restrictive procedures

Restrictive procedures, described below, lead to a fixed or adjustable reduction in the size of the upper gastrointestinal tract.

Adjustable gastric banding (AGB)

This procedure places an adjustable silicone band around the upper stomach, creating a small pouch above the band and a narrowing between the pouch and main part of the stomach below it (Figure 6). This restricts the amount of food that can be eaten and reduces hunger sensations by pressing on the surface of the stomach. The band may be tightened or loosened by injecting or removing saline through a portal under the skin that is connected to the band. The procedure is reversible and relatively non-invasive. AGB has replaced the older restrictive gastroplasty (horizontal, vertical, and banded) procedures that are no longer performed in the UK due to poorer performance. Gastric banding made up 22.3% of all bariatric surgery operations in the UK between 2011 and 2013 [22, 23, 24].

Figure 6: Diagrammatic representation of a gastric band in place

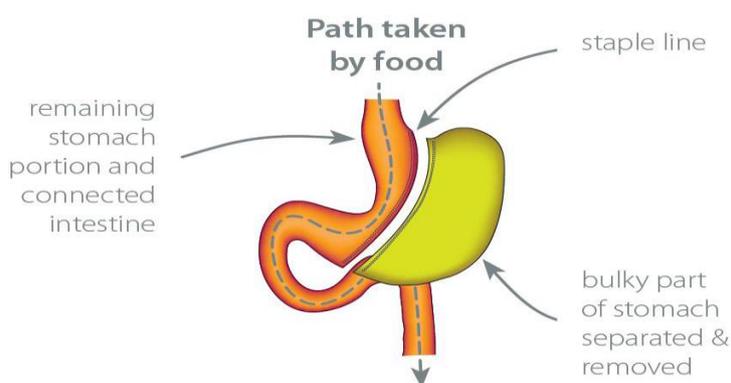


Source: *National Bariatric Surgery Register. NSBR Second Registry Report. 2014* [22]

Sleeve gastrectomy (SG)

This procedure divides the stomach vertically to reduce its size by seventy-five percent, whilst keeping the stomach function and digestion unaltered by leaving the pyloric valve intact (see Figure 7). The procedure is not reversible, but is relatively quick to perform and is one of the most commonly performed restrictive procedures. It was initially used as the first of a two-part procedure for patients at high risk from bariatric surgery, followed by a conversion to either a Roux-en-Y gastric bypass or a duodenal switch (see below). However, as some patients achieve significant weight loss with the sleeve gastrectomy alone, it is now also used as a stand-alone procedure. In some patients, the procedure may be followed by a duodenojejunal bypass, which involves bypassing the first part of the small intestine, resulting in food moving directly to the latter part of the small intestine, thereby reducing absorption of calories. SG made up 20.8% of all bariatric surgery operations in the UK between 2011 and 2013 [22]. A further 12 (0.07%) SG procedures were performed in combination with a biliopancreatic diversion with duodenal switch

Figure 7: The basics of a sleeve gastrectomy procedure



Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Intragastric balloon (IGB)

Intragastric balloon procedures involve placing a silicon balloon endoscopically to float freely inside the stomach, thereby reducing the volume of the stomach, leading to an earlier sensation of satiety. It is typically used either in patients who are at least 40% of their optimal weight, or in morbidly obese patients for whom surgery is high risk. IGB made up 2.1% of all bariatric surgery operations in the UK between 2011 and 2013 [22].

Gastric plication (or gastric imbrication)

A newer procedure that reduces the stomach volume by folding the stomach into itself and stitching it to create a narrow tube shape, similar to that of SG, but without removing any stomach tissue (Figure 6). The Registry report does not present the

exact number or proportion of all November 2017 bariatric surgery operations that involve gastric plication. However, it is less than the 2.1% procedures labelled as 'other' in the Registry report [22].

Malabsorptive procedures

Malabsorptive procedures bypass a section of the intestine, with less physical restriction of food intake.

Biliopancreatic diversion (without duodenal switch)

This procedure is typically no longer performed in the UK due to risk of post gastrectomy syndrome (including, for example, dumping syndrome, bile reflux, diarrhoea). It involved portions of the stomach being removed through a horizontal gastrectomy (a restrictive procedure), with the small remaining pouch being connected to the final section of the small intestine. This is now replaced with the biliopancreatic diversion with duodenal switch (BDDS) procedure, which may be classed as a combined procedure (see group 3 below).

Jejunioileal bypass (JIB)

This procedure is no longer performed in the UK, where a significant part of the small intestine was detached and set to the side.

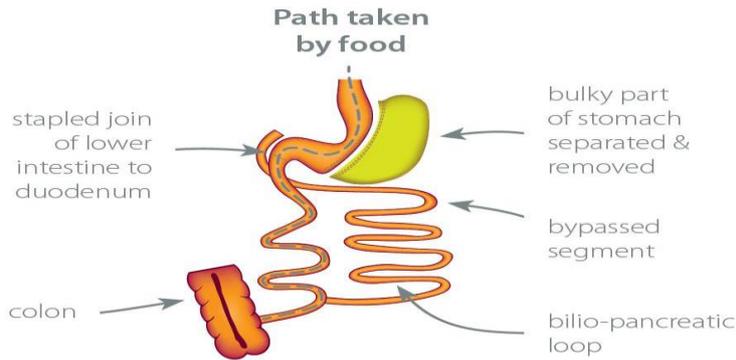
Combined procedures

Combined procedures include both restrictive and malabsorptive components.

Biliopancreatic diversion with duodenal switch (BDDS)

Biliopancreatic diversion with duodenal switch involves an initial restrictive vertical gastrectomy, followed by the malabsorptive component which re-routes a long portion of the small intestine, creating two separate pathways and one common channel (Figure 8). The shorter of the two pathways, the digestive loop, takes food from the stomach to the common channel. The longer pathway, the biliopancreatic loop, carries bile from the liver to the common channel. This procedure reduces the amount of time the body has to capture calories from food in the small intestine, and selectively limits the absorption of fat. The procedure is partially reversible, but there were only 19 BDDS procedures (0.1%), together with a further 12 procedures combined with SG in the UK between 2011 and 2013 [22].

Figure 8: Biliopancreatic diversion with duodenal switch

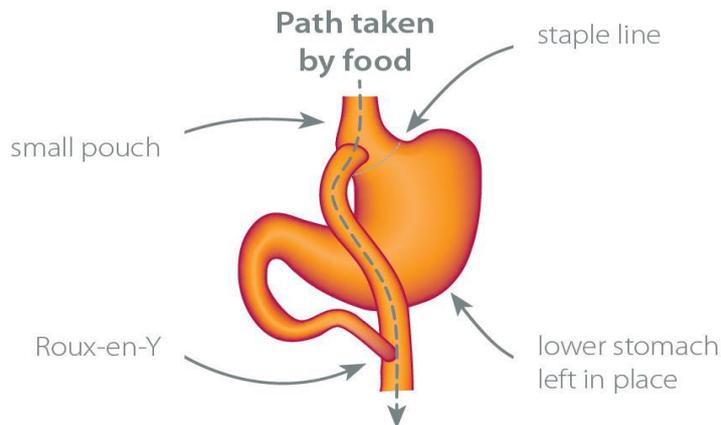


Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22]

Roux-en-Y gastric bypass (RYGB)

Roux-en-Y gastric bypass has replaced the older banded gastric bypass, and involves creating a small pouch from the stomach which remains attached to the oesophagus at one end, and connected to a section of the small intestine at the other end, thereby bypassing the remaining stomach and the initial loop of small intestine (Figure 9). This procedure reduces intestinal absorption. Adaptations of the procedure have been used to increase malabsorption and increase weight loss. The procedure is technically reversible. Roux en Y gastric bypass comprises 52.1% of bariatric surgery in the United Kingdom [22].

Figure 9: Diagrammatic representation of a Roux-en-Y gastric bypass procedure



Source: National Bariatric Surgery Register. NSBR Second Registry Report. 2014 [22].

Eligibility Criteria: Restricted

Patients eligible for surgery must have the following:

- BMI of $>35\text{kg/m}^2$
AND
Type 2 diabetes mellitus which has been diagnosed within the last 10 years.
- OR
- BMI of $>50\text{kg/m}^2$

The choice of surgery must be undertaken by a specialist bariatric surgeon following a shared decision making discussion with the patient:

- Listen to patients and respond to their concerns and preferences.
- Give patients the information they want or need in a way they can understand.
- Respect patients' right to reach decisions with the doctor about their treatment and care.
- Support patients in caring for themselves to improve and maintain their health.

If the patient is obese and does not meet the above criteria, the patient should be referred to Tier 3 services.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means **(for patients who DO NOT meet the above criteria)**, the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that request is supported by the CCG.

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