Wolverhampton City NHS
Primary Care Trust

Commissioning Policy/Referral Guidelines for Bariatric Surgery for morbid obesity

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1. Aim of Policy

1.1 This document outlines the policy of Wolverhampton City PCT (WCPCT) with reference to bariatric surgery, considering both banding and bypass procedures, via open and laparoscopic approaches. We have reviewed and assessed the evidence, and find that the most clinically and cost effective procedures are open bypass (usually Roux-en-Y), and laparoscopic banding procedures.

1.2 NICE recommends that planning for morbid obesity should be underpinned by a care pathway for obesity, and in line with specific referral criteria. NICE replaced the 2002 TAG with the Clinical Guideline on Obesity in 2006, including guidance and additional criteria for access to morbid obesity surgery. There is therefore no mandatory directive for the PCT to fund bariatric surgery, therefore the referral criteria below have been developed to benefit those at the greatest need recognising the finite resources available.

1.3 WCPCT will fund bariatric surgery according to the referral criteria set out below:

Patients who have a BMI of equal to or greater than 50kg/m2 with or without co morbidities and patients with a BMI of equal to or greater than 45kg/m2 with diabetes **and**

- where all appropriate non-surgical measures have been tried, but failed to attain or maintain adequate clinically beneficial weight loss for at least 6 month
- patient to receive intensive management in a specialist obesity service.
- patient generally fit for anaesthesia and surgery
- patient commits to long-term follow up
- psychological assessment should be available pre- and post-operatively
- provision of pre- and post-operative dietetic support
- access to suitable equipment for ongoing weight management

- **Or** patients who do not meet these criteria, but for whom the PCT has agreed funding as an exceptional case.

1.4 Bariatric surgery will not be routinely commissioned for patients who fall outside these criteria except in exceptional circumstances. In such cases WCPCT will consider requests through the Individual Funding Panel, in line with the PCT Individual Funding Policy.

1.5 Comorbidities recognised under this policy are

- Type II diabetes, especially severe, uncontrolled diabetes;

- Other co-morbid conditions which have been agreed by the PCT as exceptional, for example Pickwickian syndrome, on an individual patient basis; and/or

- a condition which requires surgery at the same time as bariatric surgery, based upon clinical need and urgency for such surgery (e.g. hernia repair, cholecystectomy for severe gall bladder disease);

- a condition which needs surgery or complex technological intervention as soon as possible after bariatric surgery (e.g. hip or knee replacements)

1.6 Patients must be informed that the PCT will not fund cosmetic procedures to remove any excess skin folds that may result from rapid weight loss. (Aesthetic guidelines)

1.7 WCPCT will only commission bariatric surgery from designated providers. The current list, effective from 9th November 2010, is as follows

Walsall Hospitals NHS Trust
Heart of England NHS Foundation Trust
Shrewsbury and Telford Hospitals NHS Trust
University of Coventry and Warwickshire NHS Trust
University Hospital of North Staffordshire NHS Trust

This list will be updated as and when necessary.

2. Background

2.1 Obesity, particularly severe obesity, substantially increases the risk of coronary heart disease and various cancers. There is also substantial co-morbidity, with increased incidence of type 2 diabetes, hypertension, osteoarthritis, sleep apnoea, and obesity hypoventilation syndrome. Obesity can be a psychosocial burden, often resulting in social stigma, low self esteem, reduced mobility and a generally poor quality of life.

2.2 People with a BMI above 35kg/m^2 have a mortality rate at any given age twice that of someone with a healthy BMI. Even a modest weight loss is associated with substantial health benefits, particularly in terms of co-morbidities.

2.3 Morbid obesity is defined by a body mass index (BMI) either equal to or greater than 40 kg/m^2, or between 35 kg/m^2 and 40 kg/m^2 in the presence of significant co-morbid conditions that could be improved by weight loss.[1] It represents a serious health problem that is occurring much more frequently and at a younger age.

The classification of obesity

Classification	BMI (kg/m^2)
Healthy weight	18.5–24.9
Overweight	25–29.9
Obesity I	30–34.9
Obesity II	35–39.9
Obesity III	40 or more

2.4 There is a wide spectrum of risk factors relating to obesity which have a significant impact on individual health, as well representing a burden on the health service. Tackling the obesity epidemic is currently a major public health initiative, with national targets for improving diet, increasing activity levels, and providing appropriate treatment for those whose health is already compromised.[1]

2.5 Bariatric surgery is defined as surgery designed to either reduce or bypass the stomach or small intestine, so that severely overweight people can achieve significant and permanent weight loss. It is an option for those patients where lifestyle interventions and medication have not been effective. The surgical approach can be combined with other treatments, and referrals are usually made via a specialist obesity management service. Bariatric surgery is generally recommended as a first-line option for adults with a BMI of more than 50 kg/m^2, in whom surgical intervention is considered appropriate. Or for BMI >40, or 35+ with severe co-morbidities that could be improved by weight loss, where other measures have failed. The risk/benefit ratio is less certain for the young, the elderly and those with a BMI >70. It is not generally recommended for children or young people. Evidence from published studies shows that bariatric surgery is effective in improving diabetes, hypertension (in the short term), hypertriglyceridemia, and obstructive sleep apnoea.

2.6 People with morbid obesity should have surgery to aid weight loss only after they have had a full assessment by the specialist and other healthcare professionals involved in their care. In addition, counseling and support should be arranged for people before and after the surgery.[2]

2.7 Bariatric surgery can cause side effects both at the time of the operation and in the long-term. These include nausea, vomiting, diarrhoea, heartburn and vitamin deficiency. Surgical complications include wound infection, the band or staples breaking, or ulcers forming around them.

2.8 Whilst there is reasonable evidence for some forms of bariatric surgery for patients selected according to NICE criteria, other studies have produced very mixed, even contradictory, results. It is important to differentiate between the different procedures, and to clarify commissioning criteria for WCPCT.

3. Prevalence

3.1 Data on the prevalence of overweight and obesity at national and regional Levels, with subgroup analysis by age, gender and social status, are published annually by the 'Health Survey for England' and the 'Welsh Health Survey'. Figures from the UK indicate that around 1 in 4 adults are obese and 2% are morbidly obese.[3]

3.2 Existing estimates suggest more than 1.1 billion people worldwide are already classified within the pre-obese or obese categories, using WHO classic definitions based on a BMI of 25 and above for overweight, and BMI 30 and above for obesity. Obesity now affects more people world-wide than malnutrition.

3.3 In England the prevalence of obesity has now reached 21% for males and 23.5% for females, and has almost trebled since 1980, tending to be higher in lower socio-economic groups. This pertains particularly for women, where the prevalence in social class V is double that found in class I. Estimates suggest that more than 12 million adults and 1 million children in England will be obese by 2010 if no action is taken.

Prevalence of obesity among adults, by age and sex, England 2004

Gender/Age	16-24	25-34	35-44	45-54	55-64	65-74	75+	16-75
Men								
Overweight	23.1%	41.0%	50.3%	48.2%	47.5%	48.4%	54.4%	44.7%
Obese	9.3%	17.9%	25.6%	31.2%	32.1%	28.5%	19.0%	23.4%
Women								
Overweight	24.1%	31.2%	30.4%	35.9%	37.0%	39.9%	45.9%	34.9%
Obese	13.9%	19.1%	27.0%	29.9%	34.5%	32.5%	20.9%	25.4%

Source: NHS Health and Social Care Information Centre (2005). Health Survey for England 2004: Updating tables to include 2004 data. London: NHS Health and Social Care Information

3.3 In WCPCT people are estimated to have a BMI of more than 40, and therefore eligible for bariatric surgery according to NICE criteria.

3.5 The 2001 National Audit Office report highlighted that 6% of all deaths can be attributed to obesity, and deaths linked to obesity shorten life by 9 years on average.

3.6 NICE estimates that around 0.01% of the population per year meet the criteria for bariatric surgery. This is over three times the current estimated rate of bariatric surgery commissioned by the NHS. The proportion of the target group who may be eligible for, and may choose, surgery is not known. In the absence of reliable data, an indicative range of between 2% and 4% has been assumed.[4] However, not all individuals who meet the NICE criteria will wish to undergo surgery. Therefore strict selection criteria should be applied, with the MDT in each hospital act as 'gatekeepers'.

4. The Intervention

We have considered the two principal surgical approaches to reducing food intake, namely **gastric banding** and **gastric bypass**. In addition, both **open** and **laparoscopic procedures** for these types of surgery have been reviewed.

4.1 **Current Treatment**

- Current treatments for obesity include advice on diet, exercise and life style, referral to specialist weight-loss clinics, low calorie diets, and therapy designed to modify eating behaviour. Surgery to aid weight reduction may be considered when all other measures have failed.
- Pharmacotherapy, such as Orlistat or Sibutramine, provided the patient meets the prescribing criteria.
- NICE advises consideration of surgery as a first-line option for adults with a BMI of more than 50kg/m2 in whom surgical intervention is considered appropriate; and to consider orlistat or sibutramine before surgery if the waiting time is long.

4.2 **Bariatric Surgery**

- Surgery should be performed by a multi-disciplinary team (MDT). The surgeon in the MDT should have undertaken a supervised training programme, have specialist experience in bariatric surgery and be willing to submit data for a national clinic audit scheme. The team should have expertise in pre-operative assessment, including risk benefit analysis and specialist assessment for eating disorders, as recommended in the NICE guidance. The assessment will include surgical, anaesthetic, radiological, specialist nursing, psychological and dietetics input, as clinically appropriate.

- The two main types of bariatric surgery may be described as 'Malabsorptive' and 'restrictive', or a combination of the two:

    - **Malabsorptive surgery** works by shortening the length of the digestive tract so that the amount of food absorbed by the body is reduced. This type of surgery involves creating a bypass by joining one part of the intestine to another, limiting calorie uptake from the intestine. An example of this is **biliopancreatic diversion** with/without duodenal switch.
    - **Restrictive surgery** limits the size of the stomach so it feels full after eating only a small amount of food. Restrictive procedures do not interfere with normal digestion and absorption of nutrients. This type of surgery can involve stapling parts of the stomach together or fitting a tight band to make a small pouch for food to enter, known as **gastric stapling or banding**.
    - **Combination surgery** combines restriction with a small Malabsorptive component. Examples are **Roux-en-Y** and **mini-gastric bypass** procedures

- The most common surgical procedures undertaken are **gastric banding** and **Roux-en-Y bypass** operations, and these are compared below.

Gastric banding	**Gastric bypass**
100% restrictive procedure	70% restrictive, 30% Malabsorptive
Takes around 45 minutes	Takes around 1.5 - 2 hours
Hospital stay 1 night	Hospital stay 3 nights
Unlikely to require HDU	May require HDU facilities
Recovery time 10-14 days	Recovery time up to 6 weeks
Fully reversible procedure	Not easily reversible
50-60% excess weight loss	60 – 70% excess weight loss
<5% early complication rate	5-10% early complication rate
Mortality 1: 1000 (0.1%)	Mortality 1:200 (0.5%)
No risk of metabolic complications	Risk of metabolic complications
Vitamin and mineral supplementation recommended but not essential.	Lifelong vitamin and mineral supplementation essential.
Regular band adjustments required to achieve desired weight loss.	Regular blood tests required to prevent anaemia, protein deficiency.

- **Gastric Banding**

  Banding is a restrictive technique that has now generally replaced gastric stapling; it reduces intake and leads to early satiety. The tightness can be adjusted by filling the inflatable band via a subcutaneous port injection, so producing a greater or lesser restrictive effect on eating. Hospital stay is 0-1days, and on average 3 adjustments are required during the first 2 years, with a mean of 50% excess weight loss expected at 18 months.

- **Roux-en-Y bypass**

  The Roux-en-Y Gastric bypass (RYGBP) creates a small gastric pouch (restrictive element) joined to the jejunum, bypassing the duodenum and proximal jejunum (Malabsorptive). The limited evidence available suggests that weight loss following gastric bypass is greater than vertical banded gastroplasty or adjustable gastric banding. Bowel obstruction is increasingly recognized as an important complication after gastric bypass. Capella et al found an unanticipated high incidence of bowel obstruction after laparoscopic gastric bypass surgery.[5]

- **Surgical approaches** may be either **open** or **laparoscopic** procedures.

Laparoscopic procedure	Open procedure
Small incision	Large incision
Hospital stay is 1-3 days	Hospital stay of about 5 days
Return to work 5-10 days	Return to work in about 4 weeks
Technically more difficult	Greater risk of infection
Less pain	More painful
Less chance of hernias	Herniation more likely

- **Open procedures**

  Open surgery was the original intervention, but the advent of laparoscopic procedures has caused a minor surgical revolution. A group of open surgeons compared more than 25,000 open cases of RYGBP with reported series of laparoscopic RYGBP.[6] They concluded that the open procedure was safer, cheaper, shorter operating time, led to fewer re-operations, and caused less complications (particularly small bowel obstruction), while producing similar long-term weight loss.

- **Laparoscopic procedures**

  Both procedures can be done laparoscopically and patients tend to favour it, but technically the Roux.en-Y is more difficult by this method and therefore requires a particular degree of skill. Reduced postoperative pain, shorter hospital stay and shorter time off work are obvious benefits of laparoscopy, but conversions and/or reoperations in 25% of the patients indicate that laparoscopic Roux-en-Y (LRYGBP) at present must be considered an investigational procedure. The procedure has been increasing in popularity, but outcomes are compromised by small numbers of patients, longer operative times and seemingly higher initial complication rates compared to the traditional open procedure. The minimally invasive LRYGBP continues to be a challenge even to the most experienced laparoscopic surgeons. Laparoscopic banding, however, is an easier operation, especially in the hands of surgeons doing good numbers of operations.

5. Evidence of Clinical Effectiveness

5.1 A 2004 Cochrane review of 18 trials involving 1891 subjects concluded that, on average, morbidly obese patients who underwent bariatric surgery lost 23-28kg more weight at 2 years than patients who were managed non-surgically. Impact on co-morbidities is significant. Buchwald et al recently conducted a systematic review of 22,094 patients. 86% resolved or improved diabetes, 79% resolved or improved hypertension, 84% resolved or improved obstructive sleep apnoea and there was improvement in hyperlipidaemia. Malabsorptive and mixed Malabsorptive/restrictive procedures have been shown to be more effective in terms of weight loss and controlling diabetes than restrictive procedures.[7]

5.2 A further Cochrane systematic review in 2005 found no significant difference between open and laparoscopic gastric bypass in weight loss at 1 year. One RCT found no significant difference in BMI between groups at 1 year, and another found no significant difference in weight loss at a mean 23 months between open and laparoscopic techniques.[8]

5.3 The review by Clegg suggests that surgery is more effective than conventional treatment in achieving long-term weight loss and improving QoL and co-morbidities. Gastric bypass surgery was more beneficial than gastroplasty or jejunoileal bypass, with laparoscopic placement producing fewer complications than open procedures.[9]

5.4 A large prospective cohort study, the Swedish Obese Subjects Intervention Study, considered a variety of surgical interventions, done either as open or laparoscopic procedures.[10] 2010 subjects underwent either gastric banding, vertical banded gastroplasty, or gastric bypass were matched to 2037 subjects who received conventional treatment. At two year follow up, the weight of the control group had increased by 0.1% whereas the weight of the surgical group had decreased by 23.4%. This advantage was maintained at 10 years, with a weight gain of 1.6% in the control group, but loss of 16.1% in the surgical group.

6. Evidence of Cost Effectiveness

- Comparative costs:
  Open gastric bypass: £5,298
  Laparoscopic gastric bypass: £9,200
  Open gastric banding: £7880/£5118 (depending upon level of comorbidity)
  Laparoscopic banding: £7,650

The cost of surgical options in the HTA report (NICE)6

Surgery option	Laparoscopic	Open
Vertical gastric banding	£3223	
Gastric bypass	£3992	£3 333
Adjustable silicone gastric band	£4450	£4 753
Non-surgical care	£336	

- NICE evidence suggests that surgery in general is a cost-effective intervention, relative to a limited non-surgical management option, in a typical severely obese group.[2]
- Over time, the costs of surgery are likely to be offset by savings brought about by a reduction in the prevalence of co-morbidities such as diabetes and hypertension.
- Surgery appears cost effective compared with conventional treatment.[9] The economic evaluation of surgery compared with nonsurgical management suggested that surgery was cost effective at £11,000 per QALY. Comparisons of the different types of surgery were equivocal. The outcomes assessed included weight change, quality of life, peri- and postoperative morbidity and mortality, revision rates and obesity comorbodities.
- NICE considers cost-effectiveness to be comparable for open bypass and open banding.
- Given the uncertainty surrounding the evidence for the relative safety and effectiveness of different surgical interventions, it is not possible to distinguish between them on grounds of cost effectiveness. The choice of surgical intervention should therefore be made jointly by the individual and the clinician after considering the best available evidence, the facilities and equipment available, and the experience of the surgeon who would perform the operation.
- LRYGBP has markedly increased overall cost, reducing surgical access. Many surgeons believe that the traditional open approach is a cheaper, safer, equally effective alternative.[6]

- NICE recently did a full evaluation of the cost-effectiveness of bariatric surgery based on Clegg's study[9], showing that each option is cost effective relative to usual care.

Cost-effectiveness of each surgical options (NICE)

Surgical option	Cost per QALY (£)
Vertical gastric banding	10,237
Adjustable silicone gastric band	8,527
Gastric bypass	6,289

- In addition to the above costs, counseling will be required to help patients cope with the consequences of long-term weight management as outlined in NICE Guidance, and plastic surgery may also be required at a later stage to remove excess skin. Neither of these factors has been costed in here. Over time the costs of surgery are likely to be offset by savings brought about by a reduction in the prevalence of long-term co-morbidities such as diabetes and hypertension.

7. Conclusions

The Cochrane review[8] found that surgery results in greater weight loss than conventional treatment in people with BMI greater than 30, as well as those with more severe obesity. Weight loss following open and laparoscopic surgery was similar. Recovery was often quicker following laparoscopic surgery, with fewer wound problems, although some studies found more re-operations were needed. Surgery also leads to improvements in quality of life and obesity related diseases, such as hypertension and diabetes. Complications may occur with any bariatric procedure, but information from the included trials did not lead to any conclusions about the safety of these procedures compared with each other.

The most popular procedures are gastric banding and gastric bypass, although some surgeons advocate isolated sleeve gastrectomy or banded gastric bypass in some situations. However, WCPCT will not routinely commission these techniques.

Whilst there is reasonable evidence for some forms of bariatric surgery for patients selected according to NICE criteria, particularly for the Roux-en-Y procedure, there is currently little to recommend LRYGBP. Studies have produced very mixed, even contradictory, results. The increased complications and costs for this intervention outweigh the generally less invasive advantages of laparoscopy, and indicate a recommendation to select the open procedure when referral criteria are met.[6]

Surgery for morbid obesity appears to be clinically and cost effective. Because of the nature of the evidence, particularly the uncertainty in the clinical and economic evaluations, it is difficult to distinguish between the different surgical procedures. Due to the poor quality and small number of trials comparing each pair of procedures the information should be viewed with caution.[9]

The Ontario Ministry of Health Health Technology Assessment Database found bariatric surgery to be effective for sustained weight loss of about 16% of people with BMIs of at least 40 kg/m^2, or at least 35 kg/m^2 with co-morbid conditions. It also is effective at resolving the associated co-morbid conditions. This conclusion is largely based on level 3a evidence from the prospectively designed Swedish Obese Subjects study, which recently published 10-year outcomes for patients who had bariatric surgery compared with patients who received nonsurgical treatment.[11]

The demand for bariatric surgery is likely to increase in addition the PCT has to proritise resources for those at the greatest end of the spectrum in terms of health gain hence the revision of the referral criteria.

8. References

1. NICE Clinical Guideline 43, December 2006: Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. National Institute of Clinical Excellence 2006. London.

2. NICE Technology Appraisal No 46. Guidance on the use of surgery to aid weight reduction for people with morbid obesity. NICE London 2002. (Now obsolete)

3. The Information Centre. Health Survey for England 2006: latest trends.

4. NICE: Determining local service levels for a bariatric surgical service for the treatment of people with severe obesity.

5. Capella RF et al. J Am Coll Surg vol. 203, 328 - 335, 2006

6. Jones K. et al. Open v Laparoscopic Roux-en-Y Gastric Bypass: A comparative study of over 25,000 open Cases and the major laparoscopic bariatric reported series. Obesity Surgery Vol. 16, No. 6, June 2006,721-727(7). Publisher: Springer.

7. Buchwald H. et al. Bariatric surgery: a systematic review and meta-analysis. JAMA. 2004 Oct 13;292(14):1724-37

8. Colquitt J et al. Surgery for morbid obesity. Cochrane Database Syst Rev. 2005 Oct 19;(4) (abstract)

9. Clegg A. et al. Clinical and cost effectiveness of surgery for morbid obesity: a systematic review and economic evaluation. Int J Obesity (2003) 27, 1167–1177

10. NHS QIS, Surgery for Obesity, September 2007.

11. Ontario Ministry of Health and Long-Term Care Health Technology Assessment Database: Bariatric surgery