

COMMISSIONING POLICY

Morbid Obesity in Adults: Secondary Care Referral Pathway

Specialty: General Surgery

Diabetic Medicine Respiratory Medicine

January 2013

This commissioning policy applies to patients for:

South Worcestershire Clinical Commissioning Group (CCG) Redditch & Bromsgrove Clinical Commissioning Group (CCG) Wyre Forest Clinical Commissioning Group (CCG)

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	and guidelines from local, national and		
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Target audience:	NHS Trusts, GP's		
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	patients, Worcestershire MP's, Public & Patient		
	Involvement Forum		
Equality & Diversity Impact Assessment	May 2012		



CONTRIBUTION LIST

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Section 1: What Is Morbid Obesity?

- 1.0 Obesity is defined as abnormal or excessive fat accumulation that may impair health. The most commonly used measure for classifying obesity is the body mass index (BMI), calculated as body weight in kilograms divided by height in metres squared (kg/m2). In adults a desirable BMI is between 18.5 to 25 kg/m2 and overweight is between 25 to 30 kg/m2.
- 1.1 People are defined as being morbidly obese if they have a body mass index (BMI) either equal to or greater than 40kg/m². The National Institute for Clinical Excellence (NICE) guidance also defines people as being morbidly obese if their BMI is between 35kg/m² and 40kg/m² with the presence of significant co-morbid conditions that could be improved by weight loss.
- 1.2 Obesity is associated with increased morbidity and mortality. It is a risk factor for cardiovascular disease, hypertension, type 2 diabetes, cancer, musculo-skeletal disease, reproductive disorders and respiratory disorders. People with a BMI greater than 35 kg/m² have a rate of mortality at any given age double that of someone with a healthy BMI (range 20-25 kg/m²).
- 1.3 People who are defined as having morbid obesity will often experience a decreased quality of life. There is a social stigma attached to obesity and those affected often face prejudice and discrimination. Morbid obesity has a negative impact on mobility, productiveness, employment and psychosocial functioning. Many people who are defined as having morbid obesity are left feeling depressed, defensive and unable to live life to the full.
- 1.4 Weight loss improves obesity-related comorbidities and may have a mortality benefit. The intensity of intervention depends on the degree of obesity and presence of comorbidities. Management usually begins in primary care and moves to a specialist setting when initial measures, including lifestyle changes and drugs, have failed and surgery is being considered.

Section 2: What Guidance Is Available Regarding The Management Of Obesity?

- 2.0 Three pieces of guidance with relevance to the UK are:
 - Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. NICE Clinical Guideline 43. Issue date: December 2006. This guideline replaces three earlier pieces of NICE guidance (Technology Appraisal (TA)22 Obesity orlistat, TA31 Obesity sibutramine and TA46 Obesity (morbid) surgery) and largely supersedes the 2003 Royal College of Physicians report Anti-obesity drugs. Guidance on appropriate prescribing and management.
 - Rimonabant for the treatment of overweight and obese patients. NICE Technology appraisal. Issue date June 2008. NICE has temporarily withdrawn its guidance on the use of rimonabant for the treatment of overweight and obese patients. The withdrawal of this guidance follows the decision of the European Medicines Agency (EMEA) in October 2008 to recommend suspension of the marketing authorisation for rimonabant. The EMEA concluded that the benefits of rimonabant no longer outweigh its risks. NICE will continue to review the status of its guidance in light of any further changes to rimonabant's marketing authorisation.
 - Scottish Intercollegiate Guidelines Network *Management of obesity: A national clinical guideline* (February 2010).

Section 3: What Is Bariatric Surgery?

- 3.0 Bariatric surgery aims to reduce weight and maintain any loss through restriction of intake or malabsorption of food, or a combination of these. It is usually only considered when all other treatments have failed.
- 3.1 The key aims of bariatric surgery are to achieve weight reduction and maintain any loss through restriction of intake and/or malabsorption of food. However, bariatric surgery should only be considered as a final treatment option for patients with significant morbid obesity who may become seriously ill, if surgery is not undertaken.
- 3.2 There are two main types of surgical intervention mal-absorptive and restrictive.
- 3.3 With mal-absorptive surgery, parts of the gastrointestinal tract are bypassed so that absorption of food is limited. With restrictive surgery, the size of the stomach is restricted so the person experiences the feeling of fullness with less food. Mal-absorptive procedures include jejunoilenal bypass, gastric bypass and biliopancreatic diversion. Restrictive procedures include gastroplasty and gastric banding. Please note that the "What Surgical Interventions Are Available on the NHS" section provides a description of each procedure. Traditionally, gastric surgery has been carried out as an open procedure, but increasingly laparoscopic techniques are being used. Laparoscopic surgery is as effective as open surgery, with fewer complications and a reduced length of hospital stay.

Section 4: What Is The Potential Demand For Bariatric Surgery?

- 4.0 There is little reliable and valid data that can be used to estimate the potential demand for bariatric surgery. It is therefore somewhat problematic to precisely identify the demand for bariatric surgery with any degree of certainty.
- 4.1 However, in order to estimate the demand, the calculations used by NICE guidance have been used to provide a proxy of the potential demand for bariatric surgery in Worcestershire. In 1998, NICE estimated that 0.6% of men and 1.9% of women in England and Wales had a BMI of 40kg/m² or more. Nationally, this is equivalent to 124,000 men and 412,700 women or 2,500 people for a typical primary care trust (PCT) population of 200,000. In addition to this, NICE concluded that there was a further 600,000 people with a BMI of between 35 and 39.99kg/m², with a serious co-morbidity, giving an estimated target group of 1.2 million people.
- 4.2 The rate of growth of this target group is unknown, although recent estimates suggest a 1.05% growth in the overall prevalence of obesity per year.
- 4.3 The proportion of the target group actually presenting for access to bariatric surgery is again unknown. However, it can be assumed that approximately 60% of the cohort identified by NICE would be eligible for surgery. Of this 60%, around two-thirds (i.e. 40% of the total) would actually choose to undergo surgery. The impact of this in terms of surgical activity is modelled below for 2012/13.

Table 1: Potential demand for bariatric surgery in Worcestershire, 2012.

2012	Est responsible population	No. <u>eligible</u> in accordance with NICE CG43 (BMI 35- 39.9 with comorbidities and BMI ≥40)	No. appropriate (in accordance with NICE CG43)	No. <u>willing</u> to undergo surgery
WFCCG	99,300	2,693	1,616	646
R&BCCG	174,200	4,724	2,834	1,134
SWCCG	289,000	7,837	4,702	1,881
TOTAL	562,500	15,253	9,152	3,661

Sources:

NICE (2007) Bariatric surgical service for the treatment of people with severe obesity: Commissioning guide. www.nice.org.uk.

West Midlands NHS Specialised Services (2011) Commissioning Bariatric Surgery for Morbid Obese Patients.

- 4.4 As Table 1 shows, selecting patients for surgery based on NICE criteria solely would entail performing an estimated 3,661 operations in 2012/13. Based on existing prices for bariatric procedures, this would cost between £19.4 and £27.8m.
- 4.5 Whilst NHS Worcestershire recognises the recommendations made by the National Institute for Health and Clinical Excellence in Clinical Guideline No. 43, full implementation of these recommendations require investment at a level which is unattainable at present. Therefore, the commissioner has reviewed the clinical evidence regarding the most equitable way to prioritise patients, and sought local specialist and generalist opinion to establish the clinical eligibility criteria stipulated in this document. This has been done with a view to maximising the health gain for Worcestershire patients within the financial constraints of the service. NHS Worcestershire would expect any patient who meets the clinical eligibility criteria to receive appropriate treatment, without discrimination.

Section 5: Referral Pathway for Secondary Care Management

- 5.0 Patients being considered for specialist management (inc surgery) should be referred by their GP to the secondary care weight management service. To be considered eligible against this policy, patients must have a BMI of at least 35kg/m². No direct referrals specifically for bariatric surgery should be accepted by surgical providers unless they are received via the secondary care weight management service. If such a referral is received, the onus is on the surgery provider to return the referral to the originating clinician, with a copy of that referral forwarded to the patient's GP for information.
- 5.1 NHS Worcestershire expects that clinicians will manage patient expectations appropriately and refer patients on to the appropriate level of management to ensure that the patient pathway is maintained and all interventions are provided in a fair and equitable manner to all.
- 5.2 The referral criteria that NHS Worcestershire has adopted to prioritise referrals is shown on the next page.

Referral criteria:

- 5.3 Patients can be referred into the secondary care weight management programme when the following criteria are met:
- BMI of at least 35kg/m²;
- An obesity and comorbidity score of >=14;*
- 18yrs and over (as per NICE guidelines);
- Evidence/testimony of a proper, persistent attempt at personal weight management control for a minimum period of 2 years;
- Evidence of failure of all other non-surgical weight management measures to maintain weight loss in the patient including dietary restrictions and pharmacological treatment (duration of more than 12 months if clinically appropriate);
- Confirmation that all underlying metabolic causes of obesity have been excluded through standard screening in primary care.
- * The obesity and comorbidity scoring tool is included as a separate Appendix.
- 5.4 If, as part of secondary care weight management, a patient is accepted for bariatric surgery, the specialist must ensure that the patient has been fully assessed in terms of their clinical and psychological suitability for surgical intervention. This will include evidence of compliance to previous efforts at non-surgical weight management measures as well as the following:
 - Demonstrated an awareness of the potential benefits and longer-term implications of the surgery, as well as the associated risks, including complications and post-operative mortality;
 - Demonstrated a clear commitment to long term behavioural change to lose weight. This
 will include confirmation of the patient's preparedness to participate in the follow-up
 regimes and long term management arrangements associated with post-operative
 weight management services;
 - Demonstrated realistic expectations of the outcomes of surgery together with an understanding that cosmetic procedures to remove excess skin folds will not be funded by the NHS.
- 5.5 Patients eligible for bariatric surgery will be referred to one of the specialised services designated providers following discussion with secondary care weight management specialists.
- 5.6 Appendix 1 provides a summary of the treatment pathway for weight management services for Worcestershire patients.

Contra-Indications for Bariatric Surgery:

- 5.7 It is important to remember that bariatric surgery for obesity is a major surgical intervention with a risk of significant early and late morbidity and of perioperative mortality.
- 5.8 Therefore, due to these significant risks, bariatric surgery cannot be considered for patients who have for example:
 - poor myocardial reserve,
 - significant chronic obstructive airways disease or respiratory dysfunction,
 - psychological disorders of a significant degree.

- 5.9 Additionally, if a patient has demonstrated non-compliance of recommended non-surgical treatment then surgery will not be indicated as the post surgical follow up regimen is extensive.
- 5.10 The final decision for fitness for surgery will be made by the surgical consultant.

Section 6: Surgical Interventions Available on the NHS

- 6.0 The two methods of bariatric surgery funded by NHS Worcestershire are:
 - Laparoscopic gastric banding (or gastroplasty) or
 - Jejuno-ilial bypass, gastric bypass and bilipancreatic diversion.
- 6.1 The final decision on the surgical technique will be at the surgeon's discretion.
- 6.2 The laparoscopic gastric banding or gastroplasty, procedures normally undertaken are:

Roux-en-Y gastric bypass (GBP)

Which incorporates both restrictive and malabsorptive components. A small pouch is created from the original stomach which remains attached to the oesophagus at one end, and at the other end is connected to a section of the small intestine, thus bypassing the remaining stomach and the initial loop of small intestine. Patients are at risk of nutritional deficiencies, and must take life-long supplements of vitamin B12, iron and calcium.

Laparoscopic adjustable gastric banding (AGB)

An adjustable silicone band is placed around the upper stomach to create a small pouch and a restricted outlet. The diameter of the outlet can be changed by injecting or removing saline through a portal under the skin, and if the procedure is not effective or complications develop the band can be removed.

6.3 The Jejuno-ilial bypass, gastric bypass and biliopancreatic diversion procedures undertaken in exceptional clinical circumstances, with prior approval, are:

• Biliopancreatic diversion (BPD)

This is a malabsorptive procedure where portions of the stomach are removed. The small pouch which remains is connected to the final section of the small intestine, and so can result in severe long-term vitamin deficiency and biochemical disruption.

Sleeve Gastrectomy (SG)

The sleeve gastrectomy divides the stomach vertically to reduce its size to about 25%. It leaves the pyloric valve at the bottom of the stomach intact, which means that the stomach function remains unaltered and digestion is therefore unaltered. It is not reversible. This procedure is becoming increasingly popular and, although it probably only accounts for less than 5% of bariatric procedures worldwide at present, it is likely that it will become one of the commoner operations together with GBP and AGB.

Vertical banded gastroplasty (VBG)

This procedure is now used infrequently the laparoscopic adjustable gastric band has effectively replaced VBG as the purely restrictive procedure because of its better side-effect profile.

Many types of bariatric surgery require long-term supplementation with vitamins and iron, and patients often have a very restricted liquid diet in the immediate weeks after surgery. Hospital stay is generally between 2 to 7 days for most procedures, however patients may be able to go home the day following laparoscopic adjustable gastric band (AGB) surgery and some units routinely perform AGB as day case procedures. Most patients go home on day 2 or 3 following laparoscopic Roux-en-Y gastric bypass (GBP) surgery.

- 6.5 The Designated Provider of the surgery will be responsible for following up patients put forward for surgery. The patient will be reviewed every three months for a period of 12 months after surgery, and thereafter will be monitored on an annual basis to assess the impact of surgery on the patient's weight, diet and lifestyle. Patients must have agreed to be engaged in this follow-up programme prior to being put forward for surgical intervention. In addition, Primary Care will continue to regularly monitor patient's progress.
- The Designated Provider and GP must ensure that patients are fully informed of the fact that NHSW will not routinely fund cosmetic procedures (e.g. abdominoplasty) to remove any excess skin folds that may result from rapid weight loss. This is in accordance with the PCTs Aesthetic Surgery Policy.(the documentation is available on the internet website at the following address: http://www.worcspct.nhs.uk/default.aspx?pid=131.
- 6.7 Patients should also be informed that maximum weight loss following surgery may not occur for one to two years after the procedure has been undertaken.

Section 7: Management of Patients Outside of the Eligibility Criteria

- 7.0 Patients who do not meet the eligibility criteria noted in the **Tier 4: Secondary Care Managed Surgical Interventions** section above, or who are contra-indicated for surgery, should continue to receive primary care based weight management services to help them to manage their weight problem.
- 7.1 This policy relates to adults in accordance with NICE guidelines. Surgical intervention is not generally recommended in children or young people (i.e. <18yrs). Bariatric surgery <u>may</u> be considered for young people only in exceptional circumstances, and if they have achieved or nearly achieved physiological maturity. Under these circumstances, application should be made via an individual funding request (IFR).
- 7.2 Patients with other, secondary, co-morbidities, who do not meet the eligibility criteria noted in the **Tier 4: Secondary Care Managed Surgical Interventions** section above, or who are contra-indicated for surgery should be referred on to the appropriate secondary care services, e.g. diabetic medicine, respiratory medicine, to ensure that they are effectively managed.
- 7.3 NHS Worcestershire expects clinicians to manage patient expectations at all times in an appropriate manner by ensuring the patient pathway is maintained and that all interventions are provided in a fair and equitable manner.

Section 8: Previously Treated Patients

- 8.0 Surgery is only part of the process of treating morbid obesity in secondary care. Patients will require a significant amount of post-operative advice and management if they are to get the most out of surgery. This includes ongoing dietetic advice and motivational support, as well as a number of gastric band adjustments. Where patients have chosen to access bariatric surgery in the independent sector (also known as "private treatment"), ongoing advice and management is expected to be accessed in that setting and patients must be aware of this when meeting their clinicians to discuss surgical options. Privately treated patients will not be automatically eligible to enter the NHS secondary care post-operative management pathway at any point. Under such circumstances, patients should either be advised to recontact their private provider, or if there are exceptional clinical reasons why secondary care support is required, an application should be made via the individual funding review (IFR) procedures.
- 8.1 This position does <u>not</u> apply in instances where there are any concerns about a patient's clinical safety, e.g. when a gastric band has become dislodged. Urgent gastric band removal will be provided whenever there are any patient safety concerns, regardless of whether the

original intervention was provided by the NHS or by a non-NHS provider. However, patients previously treated privately should be made aware that band reinsertion will not automatically be funded, and if this intervention is needed, their clinical presentation will need to be reconsidered against this policy. In instances of safety concern, patients should be referred to secondary care as normal, i.e. not via IFR procedures.

8.2 In accordance with the principle of continuity of care, patients who have previously received bariatric surgery via the NHS will be eligible to access whatever secondary care weight management support is available. If NHS treated patients present post-surgery seeking either surgical or general management advice, they should be referred to the Worcestershire Weight Management Service based at Worcestershire Royal Hospital or the Kidderminster Treatment Centre as normal.

Section 9: Commissioning of Bariatric Surgery

- 9.0 NICE recommends that bariatric surgery should only be provided by a designated NHS service provider who has demonstrated their access to suitably equipped facility with appropriately trained staff.
- 9.1 All providers of such surgery are expected to undertake a comprehensive assessment of the patient prior to being put on the waiting list. Any patient assessed as not suitable for surgical intervention should be referred back to the referring clinician, their GP, for local, non-surgical management of their morbid obesity.
- 9.2 Bariatric surgery is included under Payment by Results national tariff, however, it is currently subject to a local tariff. Such surgery will be funded on a cost per case arrangement through contractual agreements.
- 9.3 Patients will be assessed by the secondary care clinician for surgical intervention based on their eligibility, suitability and compliance.

Section 10: Monitoring Requirements

10.0 The Surgical Service Provider will be responsible for monitoring the number of patients being put forward for surgery and notify NHS Worcestershire. This will include an annual audit of those patients receiving surgery to ensure that they meet with the eligibility criteria noted in the **Tier 4: Secondary Care Managed - Surgical Interventions** section noted above.

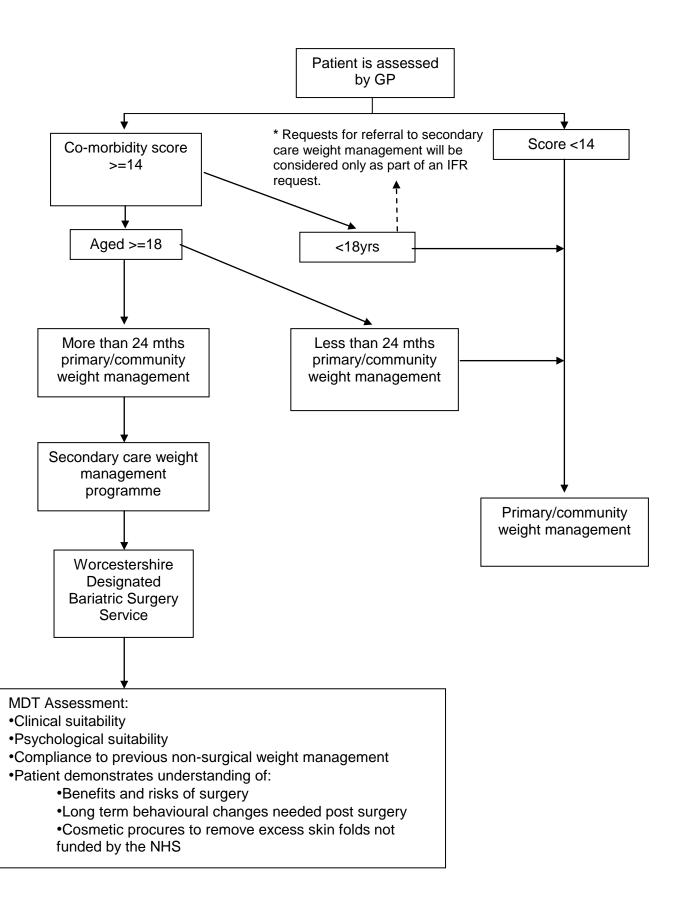
The Surgical Service Provider will ensure that appropriate monitoring information is provided for this service within the standard performance management report, which is provided on a monthly, cumulative, basis.

Section 11: Documents Referenced To This Policy

- West Midlands Specialised Commissioning Group Designating Adult Morbid Obesity Surgical Services Local Designation Standards
- West Midlands Specialised Commissioning Group Specialised Adult Morbid Obesity Surgical Services Service Specification
- West Midlands Specialised Commissioning Group Commissioning Bariatric Surgery for Morbid Obese Patients
- NHS Worcestershire Bariatric Surgery for treatment of morbid Obesity Draft Commissioning Policy

- NHS Worcestershire Individual Funding Requests Operating Procedures
- NHS Worcestershire Prioritisation Framework
- NICE Clinical Guideline 43. Issue date: December 2006.
- NICE Technology Appraisal Guidance 22 Obesity Orlistat,
- NICE Technology Appraisal Guidance 31 Obesity Sibutramine
- NICE Technology Appraisal Guidance 46 Obesity (morbid) surgery)
- 2003 Royal College of Physicians report Anti-obesity drugs. Guidance on appropriate prescribing and management'.
- The Scottish Intercollegiate Guidelines Network (SIGN) is in the process of updating it guidance on obesity.

Secondary Care Weight Management Referral Pathway



Equality Analysis Report Template

Your Equality Analysis Report should demonstrate what you do (or will do) to make sure that your function/policy is accessible to different people and communities, not just that it can, in theory, be used by anyone.

1. Name of policy or function:

Morbid Obesity in Adults, Primary and Secondary Care Treatment Pathway Commissioning Policy

Responsible Manager:

Dr Stuart Bourne - Deputy Director of Public Health/Consultant in Public Health - 01905 760066

3. Date Equality Analysis completed:

15th March 2012

4. Description of aims of function/policy:

This policy is intended to communicate the treatment pathways available for obese (and morbidly obese) adult patients in both primary and secondary care.

The policy also provides clarification about the different clinical eligibility criteria that patients must meet before they can access various treatments as NHS funded patients (including bariatric surgery).

- 5. Brief summary of research and relevant data:
 - West Midlands Specialised Commissioning Group Designating Adult Morbid Obesity Surgical Services Local Designation Standards
 - West Midlands Specialised Commissioning Group Specialised Adult Morbid Obesity Surgical Services Service Specification
 - West Midlands Specialised Commissioning Group Commissioning Bariatric Surgery for Morbid Obese Patients
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 - 2003 Royal College of Physicians report Anti-obesity drugs. Guidance on appropriate prescribing and management'.
 - The Scottish Intercollegiate Guidelines Network (SIGN) is in the process of updating it guidance on obesity.
- 6. Methods and outcomes of consultation:

Face to face discussions, policy presentations with forum discussions and various clinical and Policy Working Group meetings

7. Results of Equality Analysis

Equality Analysis	
Protected Characteristics	Assessment of Impact
Age:	Medium risk – age range evidence based NICE CG43
Disability:	Low risk
Gender reassignment:	Low risk
Marriage and Pregnancy:	Low risk
Marriage and Civil Partnership:	Low risk
Race:	Low risk
Religion or Belief:	Low risk
Sex:	Low risk
Sexual Orientation:	Low risk
Any other groups:	Not Applicable

8. Decisions and or recommendations (including supporting rationale)

Policy criteria justified, mitigation actions identified – continue to publish policy