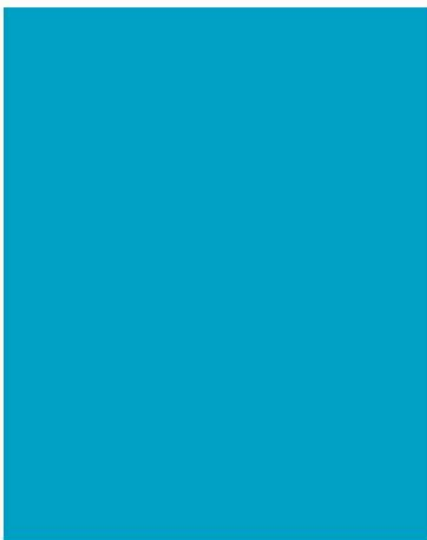


Clinical Commissioning Policy: Complex And Specialised Obesity Surgery

December 2012

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NHS Commissioning Board

Clinical Commissioning Policy: Complex And Specialised Obesity Surgery

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**Prepared by the NHS Commissioning Board Clinical Reference Group for
Morbid Obesity**

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Policy Statement

The NHS Commissioning Board (NHS CB) will commission Bariatric surgery as a treatment for selected patients with severe and complex obesity that has not responded to all other non-invasive therapies, in accordance with the criteria outlined in this document.

In creating this policy the NHS CB 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

The NHS Commissioning Board (NHS CB) is committed to ensuring equality of access and non-discrimination, irrespective of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

In carrying out its functions, the NHS CB will have due regard to the different needs of different protected equality groups. This applies to all the activities for which they are responsible, including policy development, review and implementation.

Plain Language Summary

People whose weight to height ratio (or Body Mass Index, BMI) is significantly high are more likely to suffer from a range of illnesses (e.g. type-2 diabetes) and have a lower life expectancy.

Programmes designed to support people in losing weight include lifestyle changes such as diet, exercise and behavioural change. Low and very low calorie diets, drug treatments, psychological support and specialist weight management programmes are also available. Bariatric (or weight-loss) surgery (e.g. gastric bypass) is a highly specialised intervention used in appropriate, selected patients with severe and complex obesity that have not responded to all other non-invasive therapies.

Within these patient groups bariatric surgery has been shown to be highly cost effective in reducing BMI and the associated illnesses, promoting longer term health.

Patients need to be motivated and adequately prepared for surgery and for the post surgical treatment and monitoring which is necessary for success.

1. Introduction

Obesity and being overweight is a global epidemic. The World Health Organisation (WHO) predicts that by 2015 approximately 2.3 billion adults worldwide will be overweight and more than 700 million will be obese.¹

The prevalence of obesity in England is one of the highest in the European Union. In England just over a quarter of adults (26% of both men and women aged 16 or over) were classified as obese in 2010 (Body Mass Index (BMI) 30kg/m² or over).²

Using both BMI and waist circumference to assess risk of health problems, 22% of men were estimated to be at increased risk; 12% at high risk and 23% at very high risk in 2010. Equivalent figures for women were: 14%, 19% and 25%. There has been a marked increase in the proportion (doubling) that are obese, a proportion that has gradually increased over the period from 13.2% in 1993 to 26.2% in 2010 for men and from 16.4% to 26.1% for women.²

Obesity is directly associated with many different illnesses, chief among them insulin resistance, type 2 diabetes, metabolic syndrome, dyslipidaemia, hypertension, left atrial enlargement, left ventricular hypertrophy, gallstones, several types of cancer, gastro-oesophageal reflux disease, non alcoholic fatty liver disease (NAFLD), degenerative joint disease, obstructive sleep apnoea syndrome, psychological and psychiatric morbidities. It lowers life expectancy by 5 to 20 years. Direct costs of obesity are estimated to be £4.2 billion.³

As BMI increases the number of obesity-related comorbidities increases. The number of patients with ≥ 3 comorbidities increases from 40% for a BMI of < 40 to more than 50% for BMI 40-49.9 to almost 70% for BMI 50-59.9 and ultimately to 89% for BMI > 59.9 .

The treatment of obesity should be multi-component. All weight management programmes should include non-surgical assessment of patients, treatments and lifestyle changes such as improved diet, increased physical activity and behavioural interventions. There should be access to more intensive treatments such as low and very low calorie diets, pharmacological treatments, psychological support and specialist weight management programmes.

Surgery to aid weight reduction for adults with morbid/severe obesity should be considered when there is recent and comprehensive evidence that an individual patient has fully engaged in a structured weight loss programme; and 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 patients clinical needs (NICE CG43 recommendations).⁴ The patient should in addition have been adequately counselled and prepared for bariatric surgery.

This surgery, which is known to achieve significant and sustainable weight reduction within 1-2 years, as well as reductions in co-morbidities and mortality, is commonly known as bariatric surgery. The current standard bariatric operations are gastric banding, gastric bypass, sleeve gastrectomy and duodenal switch. These are usually undertaken laparoscopically.

Bariatric surgery is the most effective weight-loss therapy and has marked therapeutic effects on patients with Type 2 diabetes. The economic effect of the

clinical benefits of bariatric surgery for diabetes patients with BMI 35 kg/m has been estimated in patients aged 18-65 years. Surgery costs were fully recovered after 26 months for laparoscopic surgery. The data suggest that surgical therapy is clinically more effective and ultimately less expensive than standard therapy for diabetes patients with BMI 35 kg/m. Other groups have been less well studied but bariatric surgery is reported to be cost effective against a wider range of co-morbidities.

2. Definitions

Table 1: Body Mass Index (BMI) categories

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
Overweight including obese	25 and over
Obese including morbidly obese	30 and over

Gastric banding

The gastric band (or sometimes referred to more fully as laparoscopic adjustable gastric band – LAGB) 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.

Gastric bypass

There are a number of variations of gastric bypass operation but the most popular one conducted in the UK is called a Roux-en-Y gastric bypass (RNY). At 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 your 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.

Sleeve gastrectomy

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.

Duodenal switch

The duodenal switch (DS) works primarily by malabsorption. The operation can be performed as an open operation through a midline incision from the base of the breastbone, or laparoscopically. Technically it is a complex operation which can take 5–7 hours to complete, and will usually require a post-op hospital stay of 4–6 days.

Following a sleeve gastrectomy a short segment of the duodenum at the base of the stomach is left but the remainder cut and the second half of the small intestine brought up and joined to the duodenum (this part of the operation is very similar to a RNY gastric bypass but is slightly lower down in the digestive tract). The bypassed section of small intestine is then rejoined to carry bile and pancreatic juices to the latter part of the small intestine near where it joins the large intestine (colon).

Digestion and absorption of fat depends on it mixing with bile (from the liver and normally entering the duodenum). As this mixing does not occur until much further on in the intestine after a DS, the body's ability to digest and absorb calories from fat is severely reduced. As a result weight drops, even when eating quite normally.

Definitions adapted from BOSPA⁵

Models of care

A typical model for managing obesity is outlined as follows:

- Tier 4 - Specialised Complex Obesity Services (including bariatric surgery)
- Tier 3 - A primary/community care based multi-disciplinary team (MDT) to provide an intensive level of input to patients.
- Tier 2 - Primary Care with Community Interventions
- Tier 1 - Primary Care and Community Advice.

From: South East Coast Specialised Commissioning Group, 2010

3. Aim and Objectives

To define eligibility criteria for NHS commissioned bariatric surgery.

4. Criteria for commissioning

Bariatric surgery is a treatment for appropriate, selected patients with severe and complex obesity that has not responded to all other non-invasive therapies. Within these patient groups bariatric surgery has been shown to be highly cost effective.

Bariatric surgery is recommended by NICE as a first-line option for adults with a BMI of more than 50kg/m², in whom surgical intervention is considered appropriate. However, it will be required that these patients also fulfil the criteria below.

Selection criteria of patients for bariatric surgery should prevent perverse incentives for example patients should not become more eligible for surgery by increasing their body weight. Similarly the selection criteria should not forbid bariatric surgery for patients who have lost weight with non-surgical methods

Eligibility for bariatric surgery

Surgery will only be considered as a treatment option for people with morbid obesity providing all of the following criteria are fulfilled:

- The individual is considered morbidly obese. For the purpose of this policy bariatric surgery will be offered to adults with a BMI of 40kg/m² or more, or between 35 kg/m² and 40kg/m² or greater in the presence of other significant diseases.
- There must be formalised MDT led processes for the screening of co-morbidities and the detection of other significant diseases. These should include identification, diagnosis, severity/complexity assessment, risk stratification/scoring and appropriate specialist referral for medical management. Such medical evaluation is mandatory prior to entering a surgical pathway.
- Morbid/severe obesity has been present for at least five years.
- The individual has recently received and complied with a local specialist obesity service weight loss programme (non surgical Tier 3 / 4), described as follows: This will have been for duration of 12-24 months. For patients with BMI > 50 attending a specialist bariatric service, this period may include the stabilisation and assessment period prior to bariatric surgery. The minimum acceptable period is six months. The specialist obesity weight loss programme and MDT should be decided locally. This will be led by a professional with a specialist interest in obesity and include a physician, specialist dietician, nurse, psychologist and physical exercise therapist, all of whom must also have a specialist interest in obesity. There are different models of local MDT structure. Important features are the multidisciplinary, structured and organised approach, lead professional, assessment of evidence that all suitable non invasive options have been explored and trialled and individualised patient focus and targets. In addition to offering a programme of care the service will select and refer appropriate patients for consideration for bariatric surgery.

The non-surgical Tier 3 / 4 service may be community or hospital-based but will have as their role

- Education
- Dietary advice/support (which may be delivered through specialist obesity dietitians, or slimming clubs – Weight Watchers, Slimming World etc.)
- Enabling access to appropriate level of physical activity where not limited due to obesity related problems such as osteoarthritis, cardio respiratory disease
- Exclusion of underlying contributory disease e.g. hypothyroidism, Cushing's
- Evaluation of co-morbidities (diabetes, sleep disorder breathing, etc) and instigation of appropriate management plans
- Evaluation of patient's engagement with non-surgical measures
- Evaluation of psychological factors relevant to obesity, eating behaviour, physical activity and patient engagement.
- There is evidence of attendance, engagement and full participation in the above non surgical Tier 3 / 4 service Engagement can be judged by attendance records and achievement of pre-set individualised targets (for example steady and sustained weight loss of 5-10%, or maintaining constant weight whilst stopping smoking).
- The patient has been assessed and referred by the lead physician/ clinician for the specialist obesity weight loss MDT.
- The patient has been unable to lose clinically significant weight (i.e. enough to modify co-morbidities) during the period of intervention. Patients who lose sufficient weight to fall beneath the NICE guidance should not be considered appropriate for surgery.

The final decision on whether an operation is indicated should be made by the specialist hospital bariatric MDT. For all bariatric surgery candidates, an individual risk benefit evaluation will be done by the Bariatric Surgery MDT, this will be informed by their own clinical assessment and information provided by primary care and by non-surgical Tier 3 / 4. In some locations there may be close liaison (and perhaps even overlap of personnel) between non-surgical Tier 3/4 and Bariatric Surgery MDT. For example, a specialist bariatric physician would be on both MDTs.

The risk:benefit evaluation will consider:

- Existing co-morbidities and their reversibility
- Risk of future co-morbidities and their reversibility
- Patients age and general level of health
- Anticipated weight reduction
- Alternatives if bariatric surgery is not undertaken
- Peri-operative mortality
- Post-operative complications of bariatric surgery

The Bariatric Surgery Team will satisfy itself that:

- Bariatric surgery is in accordance with relevant guidelines
- There are no specific clinical or psychological contraindications to this type of surgery
- The individual is aged 18 years or above.
- The patient has engaged with non-surgical Tier 3 / 4 Services.

- The anaesthetic and other peri-operative risks have been appropriately minimised
- the patient has engaged in appropriate support or education groups/schemes to understand the benefits and risks of the intended surgical procedure
- the patient is likely to engage in the follow up programme that is required after any bariatric surgical procedure to ensure
- Safety of the patient,
- Best clinical outcome is obtained and then maintained.
- Change eating behaviour
- Change physical behaviour as advised
- The overall risk:benefit evaluation favours bariatric surgery

Revisional procedures will only be considered electively for clinical reasons due to complications and will require prior approval unless they are required on an acute emergency basis. (A separate policy will need to be developed for revisional procedures).

Any new/novel bariatric surgery procedures outside of this policy will not be routinely commissioned. Where a clinician wishes to make a request for a new device/procedure, an application for exceptional funding through the NHS CB Individual Funding Request (IFR) process should be made in the first instance. The latter should be free to seek advice from the CRG leads. This request will then serve as an indicator for the CRG to undertake an evidence based review prior to developing a policy agreed by the CRG for the device/procedure requested.

5. Patient pathway

Non surgical and intensive management

The non surgical and intensive management of morbidly obese patients in Tier 3/4 settings to optimise risk and subsequent referral process of eligible patients is an integral part of this pathway. This has already been described in section 4.

Pre-operative preparation

As it is an elective procedure it is critical that individuals being considered for bariatric surgery are carefully selected, appropriately referred, fully evaluated and their medical condition optimised in order to achieve the best operative, post operative and long term outcomes. This is best done by MDTs at Tier 3 / 4 services and also after referral to the Bariatric Surgical Centre.

This patient population has unique and challenging issues including an extensive range of medical and psychological and potentially psychiatric comorbidities. Often patients have unrealistic expectations of the surgery. Therefore a multidisciplinary, comprehensive and timely assessment pre-operatively is of great importance.

The diagnostic work up, pre operative evaluation, risk stratification and provision of counselling, education and information is best undertaken by a dedicated hospital

multidisciplinary team specialising in the management of morbidly obese patients including:

- Surgeons
- Anaesthetists
- Physicians
- Psychologists – will provide assessments and targeted interventions e.g. Cognitive Behavioural Therapy and also post operative support
- Dieticians
- Nurses
- Radiologist
- Dedicated administrative support
- Access to Psychiatry*
- Access to Pharmacists*
- Access to Physiotherapists or sports and exercise medicine specialists*

* with special interest in bariatric surgery

This team should also have links to independent patient support groups and also provides in-house patient support groups.

The surgical provider will have robust arrangements for surgical follow up and for receiving, assessing patients with post-operative complications and their emergency management by bariatric surgeons. This includes access to a fully staffed emergency theatre on a 24 hour basis. There will also be a contact point for advice on queries.

Structured, systematic and team-based follow up should be organised by the surgical provider for 2 years after surgery. Life long specialist follow up is also advocated although will usually be provided by the Tier 3 / 4 services. Such an approach will monitor weight loss outcomes, complications, adherence to iron, vitamin D/Calcium and Vitamin B12 supplementation, facilitate clinical suspicion of specific or combined micronutrient deficiencies leading to appropriate laboratory tests for confirmation. Psychological input, management of comorbidities, dietary and lifestyle advice and liaison with general practice will also be other functions of the follow up process. (A separate policy including consideration of automated annual recall systems will need to be developed for this).

6. Governance arrangements

- Providers, surgeons, premises, on site services and bariatric surgery throughput should at least meet the IFSO Guidelines⁶ for Safety, Quality, and Excellence in Bariatric Surgery.

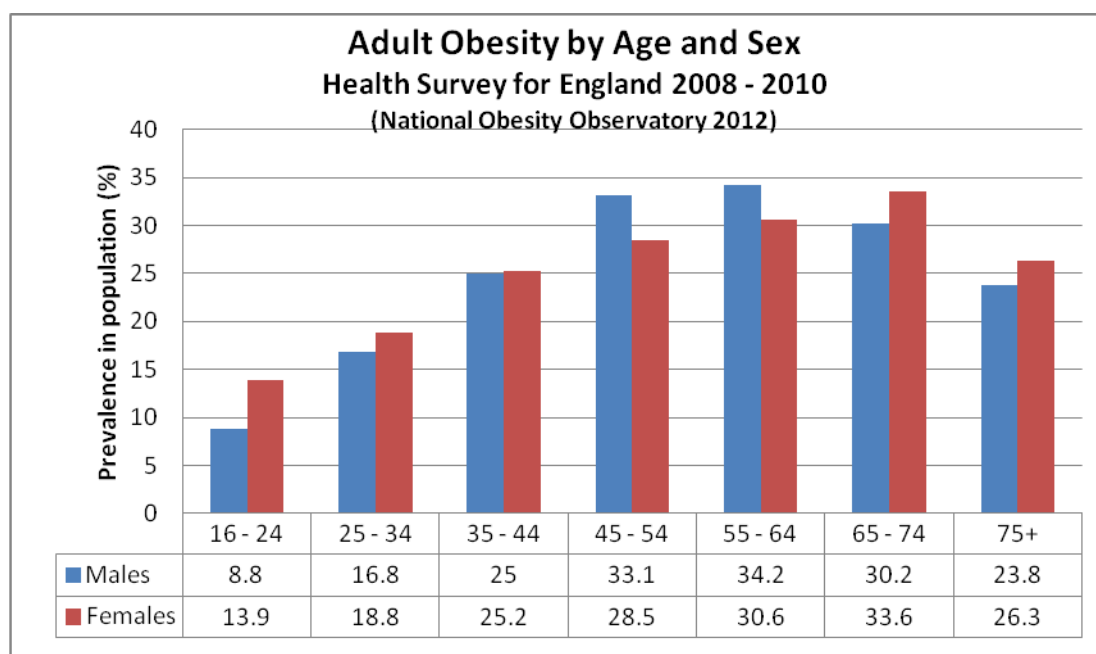
- However, it is recognised that the IFSO hospital and surgeon volume standards were meant to imply minimum volumes only (125 per hospital and 50 per surgeon). There is clear data show that mortality and complication rates, both for bypass and banding are better with greater volumes, and the data are a continuum, so the more cases that are done the better the outcomes are likely to be, just as for all other examples of elective surgery. In addition there are two benefits of commissioning only high volume providers: higher volumes bring in more funding to support the infrastructure (nurses, dieticians, psychologists), and they allow several surgeons to take part in an on call rota e.g. 1 in 4 is practical whereas 1 in 2 is not.⁷ Thus major centres should be built up and other centres started only when capacity is reached. There are no hospital or surgeon volume data for sleeve gastrectomy or duodenal switch but there is no reason to doubt that the same relationship exists and therefore the same governance rules should apply.
- Appropriate MDT composition, professional inputs and process design for all stages of the pathway. 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 / expansion of professional roles i.e. use of GPs or other therapists for band-fills as an alternative to consultant radiologists; use of Skype, telephone etc. for consultations.
- The surgical service should be seamless both pre- and post operatively with the medical Tier 3 / 4 service and decided by local arrangements,
- The mandatory collection and submission of data to the National Bariatric Surgical Register. Audit timeliness and completeness of data submitted.
- The bariatric surgical provider will be responsible for the organisation of structured, systematic and team based follow up for 2 years. Just before this period is finished the surgical provider will make arrangements to hand over care to the tier 3 service.

7. Epidemiology and needs assessment

The Health Survey for England⁸ shows that the proportion of adults (aged 16+) who are morbidly obese with a BMI 40kg/m² or more has risen from 0.9% in 1993-95 to 1.9% in 2006-08. Over this period, the prevalence of morbid obesity was consistently higher in women (increasing from 1.5% in 1993-95 to 2.6% in 2006-08) than in men (increasing from 0.3% in 1993-95 to 1.3% in 2006-08), although the rate of increase in recent years has been higher in men. Based on these figures, the number of adults with morbid obesity in England would be around 800,000; in a CCG covering a population of 500,000, one would expect around 8,000 adults with morbid obesity.

Predicting future trends in morbid obesity has proven difficult. Two different models

have estimated markedly different prevalence figures. The first predicts a prevalence of almost 3% in men and 6% in women by 2030; the second predicts a prevalence of 1% for men and 4% for women by 2050. Straight-line extrapolation of the prevalence of adult men with BMI greater than 40 kg/m² predicts a level of around 3% by 2050.



NHS Commissioning Board Region	Estimated Population Obese ('000)	Estimated Population Morbidly Obese ('000)
London	1,286	122
Midlands & East of England	2,689	202
North of England	2,528	231
South England	2,331	165
Grand Total	8,836	722

Notes:

% Obese and Morbidly obese taken from Table 2.10; HSE 2007 (NHS IC 2009)

Population Statistics taken from PCO Population Estimates 2010 (Release September 2011)

In 2006 the National Institute for Health and Clinical Excellence (NICE) estimated a total prevalence of patients, meeting NICE BMI threshold criteria, of approximately 2.22% of the population, or approximately 1.1 million people. NICE further adjusted this figure to allow for those patients who may not be considered clinically eligible for surgery and again to allow for patient choice of treatment and those who would not accept surgery even if offered.

Applying the NICE algorithm indicates that there is a potential cohort of patients who may be eligible for, and who wish to take up, bariatric surgery of approximately 0.53% of the adult population in England or 257,000 people.

2010/2011 SUS data indicates that less than 9,000 patients were admitted in that year.

Analysis of the Health Survey for England data suggest that, of those recorded as having Morbid Obesity, 7% have a BMI of 50 kg/m². Therefore there is a population, estimated at 51,000 people, in England who are eligible for bariatric surgery as first-line treatment for their obesity. For the remainder surgery is only considered after all other forms of medical management have been attempted, but adequate, clinically beneficial weight loss has not been achieved or maintained.

8. Evidence Base

In the short term, providing bariatric surgery as a solution to weight loss is significantly more expensive than conservative management and this cost has often been used as a reason for not commissioning surgical services, or limiting access. However the remission of co-morbidities as a result of surgery or the associated weight-loss means that the overall cost of managing a patient on a care pathway that includes surgery is more cost effective in the long term than one without.

The Canadian and New Zealand Health Technology Assessment (HTA) agencies^{9, 10} both reported the cost per quality-adjusted life year (QALY) for bariatric surgery compared to non-surgical interventions for obesity to be within acceptable cost-effectiveness thresholds and concluded that bariatric surgery is cost effective. However, they also reported the relative paucity of data on cost effectiveness, the poor quality of the economic evaluations undertaken to date and inability to make recommendations for bariatric surgery techniques.

In 2009 a UK National Institute for Health Research (NIHR) HTA¹¹ updated the economic review on bariatric surgery for obesity, broadening its scope to include obese as well as morbidly obese people. The HTA reviewed five original economic evaluations (including four economic models) and undertook a primary economic evaluation adopting an NHS and personal social services perspective to develop a state-transition model comparing surgical to non-surgical interventions with a time horizon of 20 years. The UK HTA authors concluded that bariatric surgery appears to be a cost-effective treatment for obesity compared with non-surgical interventions. However, their findings suggested that bariatric surgery is likely to be

less cost effective in less obese subjects and there was limited evidence to enable conclusions to be drawn on the relative cost effectiveness of different bariatric procedures.

Quality Improvement Scotland (2010)¹² noted that economic analyses to date have typically assumed observed weight loss lowers both the severity and incidence of obesity-related comorbidities and associated treatment costs which, while reasonable assumptions, remain to be verified.

In 2011 the NHS South East Coast Health Policy Support Unit released a policy recommendation incorporating an economic analysis with a time-horizon of 10 years.¹³ This showed bariatric surgery is cost-effective in the medium term, reaching a break-even point within 3-years of surgery. This analysis supported the UK HTA conclusions that surgery is less cost effective in less obese patients.

A study of cost-utility of bariatric surgery for morbid Obesity in Finland¹⁴ was published in 2011, showing similar results

9. Rationale behind the policy statement

Bariatric surgery for the morbidly obese is an increasingly available intervention.

However, surgical intervention is not the whole solution and appropriate clinical selection of fully informed patients is important.

It is also important to ensure that surgery is not offered prematurely in a patient's weight loss pathway. Bariatric surgery is only one component of the multimodal lifetime treatment pathway: multidisciplinary medical assessment, pre operative management of comorbidities, conservative treatments and life-long follow-up care.

Patients need to be informed of the benefits and risks as well as the life-long implications of bariatric surgery.

With informed choice patients are better able to cope with the eating restrictions of a post surgically altered gastrointestinal anatomy and mandatory follow up for nutritional supplementation and monitoring to prevent nutritional deficiencies; the management of comorbidities; and adjustment of medications and dosage post operatively.

Preparation will improve patient awareness of their role in following a healthy lifestyle to consolidate surgically achieved weight loss and resolution of comorbidities.

Patients also need information about when and where and from whom to seek help, advice and to attend for regular follow up and the actions to take in the event of the onset of surgical complications as well as gastrointestinal symptoms/ side effects arising from an altered anatomy.

Morbid obesity is a complex syndrome for which bariatric surgery is a highly specialised intervention reserved for patients with a high clinical case of need and in whom all prior efforts of intensive weight reduction have failed. Patients should also

be motivated and adequately prepared for surgery to ensure their post surgical compliance which is necessary for success. Patient selection processes should ensure that only those patients who stand to benefit the most from surgery are offered it. As a highly specialised intervention, bariatric surgery should only be undertaken by appropriately specialist trained and experienced surgeons with appropriately high caseloads working within multidisciplinary specialist teams in hospitals where these operations are commonly performed and who have the requisite institutional experience.

10. Mechanism for funding

Specialised Complex Obesity services, including bariatric surgery pre-assessment, perioperative management, postoperative and longer term follow up where it occurs within the specialised service will be funded by the NHS Commissioning Board.

Tier 1, 2, 3 services will be commissioned and funded by Clinical Commissioning Groups (CCGs). Population prevention / health promotion measures and strategies will be funded from local authority budgets.

11. Audit Requirements

Mandatory compliance by Bariatric Surgery providers with National Bariatric Surgery Registry¹⁵ requirements, including 100% provision of required data.

12. Documents which have informed this policy

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13. Links to other policies

- Primary care commissioning policies on cosmetic plastic surgery procedures
- Policies on referral to private sector providers
- The mechanism operated by the NHS CB for funding requests outside of the clinical criteria in this policy is yet to be finalised

14. Date of Review

To be confirmed

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