NHS England

CCG Pack

Appendix 9 Guidance for Clinical Commissioning Groups (CCGs): Service Specification Guidance for Obesity Surgery

Service Specification Guidance

Version number: Appendix 9v2

First published: 2016

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Classification: OFFICIAL

Contents

1 Introduction

This service specification has been developed to assist Clinical Commissioning Groups in commissioning obesity surgery services from April 2017 and includes reference to the NICE clinical guidelines published in 2015.

2 Population Needs

2.1 National / local context and evidence base

Obesity and being overweight are a global epidemic. The prevalence of obesity in England is one of the highest in the European Union. Furthermore, it has been predicted that the prevalence of obesity in the UK will be greater than 25% of all adult females and greater than 30% of all adult males (based on 5 centile predictions).
In England: 62% of adults were overweight or obese (Body Mass Index (BMI) 25kg/m2 or over) and 26% obese (BMI 30kg/m2 or over in 2014. There has been a marked increase in the proportion that are obese, a proportion that has gradually increased over the period from 13.2% in 1993 to 27% in 2014 for men and from 16.4% to 27% for women. Using both BMI and waist circumference to assess risk of health problems, 17% of men were estimated to be at increased risk; 13% at high risk and 21% at very high risk in 2014. Equivalent figures for women were: 13%, 18% and 25%.

BMI 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/obese III/severe	40 and over
Overweight including obese	25 and over
Obese including morbidly obese	30 and over

Obesity is directly associated with, and increases the risk for, many different metabolic derangements, illnesses and diseases (comorbidities. These include 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, asthma, obstructive sleep apnoea syndrome, psychological and psychiatric morbidities. It lowers life expectancy by 5 to 20 years.

Estimates of the direct costs to the NHS for treating overweight and obesity, and related morbidity in England, have ranged from £479.3 million in 1998 to £4.2 billion in 2007. Estimates of the indirect costs (those costs arising from the impact of obesity on the wider economy such as loss of productivity) over the same time period ranged between £2.6 billion and £15.8 billion [1,2].

As BMI increases, individuals suffer an increasing number of obesity-related comorbidities. The number of patients with ≥ 3 comorbidities increases from 40% for a BMI of < 40 kg/m^2 to more than 50% for BMI 40 - 49.9 kg/m2 to almost 70% for BMI 50 - 59.9 kg/m^2 and ultimately to 89% for BMI > 59.9 kg/m^2. Mortality is related to the number of co-morbidities.

The treatment of obesity should be multi-component. All weight management programmes for the obese should include medical assessment of patients, non-surgical treatments and advice and support for lifestyle changes such as improved diet, increased physical activity and behavioural interventions. There should be access to more intensive and personalised treatments including pharmacological treatments, psychological support and specialist weight management programmes, provided by a multi-professional team of specialists.

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 patient's clinical needs (National Institute for Health and Care Excellence (NICE) CG189 recommendations). The patient should in addition have been adequately educated, counselled and prepared for obesity surgery. Surgery should be considered during this phase for patients with recently diagnosed type 2 diabetes (less than 10 years).

Obesity surgery, which is known to achieve rapid, significant and sustainable weight reduction, as well as reductions in co-morbidities and premature mortality, is commonly known as bariatric surgery. However patients need to be appropriately selected according to guidelines (NICE CG189) and must be willing and able to adapt to post-surgical capacity restriction and comply with follow-up support and monitoring to optimise surgical outcomes.

The current standard obesity operations are gastric banding, gastric bypass, sleeve gastrectomy and duodenal switch. These are usually undertaken laparoscopically. Obesity surgery is the most effective weight-loss therapy and has marked beneficial therapeutic effects on patients with Type 2 diabetes. Following surgery, most people with diabetes (particularly if of recent diagnosis) are able to maintain normo-

[1] National Audit Office. Tackling Obesity in England. London: The Stationery Office, 2001.

[2] Butland B et al. Tackling obesities: future choices – project report. London: Foresight Programme of the Government Office for Science, 2007. (2nd Ed).

glycaemic without hypoglycaemic medication (so-called 'remission'). The economic effect of the clinical benefits of obesity surgery for diabetes patients with BMI 35 kg/m^2 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 of ≥35 kg/m^2. Other groups have been less well studied but obesity surgery is reported to be cost effective against a wide range of co-morbidities. Since this economic evaluation was made, it has become clear that diabetes does 'relapse' after a period of time in a proportion of patients and this may be related to the severity of the diabetes [3].

Obesity surgery is a treatment for appropriate, selected patients with severe and complex obesity that have not responded to all other non-invasive therapies. Within this patient group, obesity surgery has been shown to be a highly cost effective therapy that prevents the development of co-morbidities.

Obesity surgery is recommended by NICE as a treatment of choice for adults with a BMI of more than 50kg/m^2 when other interventions have not been effective (CG189) and in whom surgical intervention is considered appropriate. However, these patients with BMI > 50 will need to have attended or be attending a specialist obesity service for a period to undertake the assessment and preparation of such patients, including stabilisation of any co-morbidities, prior to obesity surgery. Selection criteria of patients should prevent perverse incentives for example patients should not attempt to become more eligible for surgery by increasing their body weight. Similarly the selection criteria should not automatically exclude obesity surgery for motivated patients who have lost weight with non-surgical methods and who desire surgical assistance with maintaining initial improvements in weight loss and securing further reductions.

Obesity surgery is also recommended by NICE (CG189) for adults with BMI greater than 40, or 35 with serious co-morbidities that would be improved by weight loss. NICE also recommend that patients with BMI 30-35 with recently diagnosed diabetes mellitus should be considered for obesity surgery and that Asian patients should be considered for obesity surgery at lower BMI (2.5 kg/m^2 lower values)

Not all patients with severe obesity (> BMI 40) will be suitable, or desire, obesity surgery. Specialist non-surgical weight management (Tier 3/4) should be available including access to expert obesity MDTs including obesity physicians and associated multi-disciplinary specialists with experience in severe and complex obesity.

[3] Arterburn DE et al. A multisite study of long-term remission and relapse of type 2 diabetes mellitus after gastric bypass. Obesity Surg 2013;23:93-103.

3 Outcomes

3.1 NHS Outcomes Framework Domains

Domain 1	**Preventing people from dying prematurely**	√
Domain 2	**Enhancing quality of life for people with long-term conditions**	√
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	√
Domain 4	**Ensuring people have a positive experience of care**	√
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	√

3.2 Commissioning Data and Minimum Datasets

Commissioners will require data on the services in order to benchmark the service against this specification and provide assurance on the expected service delivery and clinical outcomes, together with information required to monitor and manage the contractual agreement. This data will be provided through national and local information collection.

It is suggested providers shall comply with guidance relating to clinical coding as published by the NHS Classification Services and with the definitions of activity maintained under the NHS Data Model and Dictionary.

Providers should collect and provide national datasets within the timescales set out in the relevant Information Centre guidance and all applicable Information Standards Notice(s) and submit coded data to SUS.

Providers should ensure that all patients seen within the service are entered onto the National Bariatric Surgery Registry, and comply with the data requirements of the registry.

Providers should comply with all local information collection requirements as listed in this service specification and in the contractual agreement with the commissioner.

3.3 Outcome Measures

In addition to the measures in the paragraphs above, there should be documentation for all patients referred to the secondary care provider describing the person's weight management history describing their experience in non-surgical services; information about reasons for referral for obesity surgery, and notes of any exceptional aspects of care.

Providers should ensure that the patient has followed an appropriate weight management pathway and engaged with Tier 1, 2 & 3 services of an appropriate duration as deemed necessary by the lead obesity physician (Tier 3/4 service). Routine referral for surgery should be made by the obesity physician lead for the Tier 3 service.

3.4 Co-morbidity improvement (domain 1, 2 and 3): Reduction in objective measures of identified co-morbidities.

3.4.1 Weight Loss

Weight should be recorded at onset of engagement with Tier 3 weight management programme (whether it be in a community or secondary care centre). Weight and height should be recorded at the time of referral and at assessment at surgical MDT. Weight should be recorded at 6, 12, 18 and 24 months post-surgery by type of surgery. The weight loss parameters to be calculated include percentage weight loss, BMI reduction and absolute weight loss in kg.

Those patients judged clinically to be unsuitable for surgery who remain within a Tier 3 medical service should also have their weight recorded at similar intervals that is at 6 months, 12 months, and 24 months.

All surgical procedures carried out will be entered into the National Bariatric Surgery Registry as per Dendrite data entry criteria with 100% data submission rate.

% patients lost to follow-up: 6 months; 12 months; 24 months. It is the responsibility of the obesity surgery provider to ensure follow up to 2 years. There is an expectation of a minimum 75% follow-up at 2 years.

3.4.2 Evolution of co-morbidities

Co-morbidities should be monitored at 6, 12, 18 and 24 months' post-surgery. They should be described by co-morbidity, e.g. type 2 diabetes, hypertension. Parameters recorded could include change in disease severity and treatment/medication requirements. This should include HbA1c.

3.4.3 Morbidity and Mortality (domain 4, 5)

Post-operative complication rates shall be recorded by operation type: leaks, obstruction, infection, bleeding or other; when they occurred and investigation and treatment required.

In-hospital mortality rates: classified by operation type, BMI band and surgical risk score; (separate data to be recorded for revisional procedures).

Post-discharge mortality rate: All deaths that occur post-discharge, reporting at 30 days, 3 months, 6 months and 12 months following primary or revisional surgery.

There should be some attempts to ensure that all post-operative mortality over this period is captured, including;

- Surgical/Medical complications requiring critical care: Observed admissions post operatively into ITU/HDU.

- The numbers of patients who present for revision by primary obesity procedure type.

4 Scope

4.1 Aims and Objectives of the service

The main clinical aim of a Tier 4 specialist medical and surgical service for severe and complex obesity is to achieve a significant risk reduction in the burden of obesity-related co-morbidities, where all other services have been unable to achieve this. This will be achieved by facilitating a significant, and sustained, weight reduction in the patient and improvement in pre-treatment co-morbidities.

The provider of a severe and complex obesity service will, as part of the continuous pathway of care (as above) deliver a service providing specialist care, including both specialist non-surgical interventions and surgical interventions, for patients who have been unable to achieve and/or maintain significant weight-loss. This will be after all non-surgical avenues have been explored, although earlier consideration should be given to patients with early onset type 2 diabetes. The service will also provide/arrange follow-up on a hub and spoke model either with a specialist Tier 3 community-based service, or through a secondary care specialist obesity clinic. Agreed protocols should determine criteria for re-referral to the surgical provider.

Providers will have clinical protocols and programmes of care that deal with the patient journey through assessment, medical and surgical intervention, post-operative care, discharge and long term clinical surveillance, including the transition back to a specialist weight management service local to the patient's home, as part of a life-long shared care arrangement of follow-up and surveillance. It is recommended that commissioners should contract the whole pathway through specialist weight management, surgery and follow-up as a single care pathway and this should include referrals to appropriate specialists.

Providers will be required to demonstrate that they have specialist multi-disciplinary obesity (medical and surgical) teams that can provide such assessments and treatments and that clinically appropriate referrals to other specialties for further consultation and clinical management will be made, when clinically necessary.

Whilst obesity surgery is an intervention used after persistent failure of non-surgical weight management programmes, it is essential that comprehensive follow up procedures are in place. These should include: 1) a structured follow up by professionals for weight loss progress, medical and surgical complications, 2) nutritional monitoring and supplementation and 3) life-style weight maintenance

support for the patient. Moreover, this should be a lifetime commitment for the patient.

Patients referred for obesity surgery assessment should already have received appropriate specialist non-surgical weight management interventions. It should not be the responsibility of the obesity surgery service to arrange or provide such services if patients are inappropriately referred without having received appropriate support prior to the referral.

4.2 Service Description / Care Pathway

The services provided will cover secondary and tertiary clinical settings. Assessment and diagnosis of underlying causes of overweight and obesity where this cannot be identified or managed in primary care or community/secondary care based medical obesity services (Including but not limited to rare genetic syndromes, endocrine disturbances and abnormalities).

There should be assessment and treatment using specialist non-surgical methods, or onward referral to other tertiary specialties, of those with complex disease states and/or comorbidities that cannot be managed adequately in either primary or secondary care.

These will include:

- Treatment for those using non-surgical modalities where conventional weight management treatment has failed in primary or secondary care or in complex cases where surgical treatment is considered unsuitable
- Specialist interventions
- Obesity Multidisciplinary Team (MDT) evaluation and pre-operative assessment, surgical intervention and immediate post-operative follow-up
- Pre- and post-surgical patient support group either within the service or available locally (e.g. through British Obesity Surgery Patient Association)
- Protocols for post-operative procedures for removal of redundant tissue should be available with definitions of offered procedures.

4.3 Eligibility Criteria

Referrals should only be considered for patients who are adults (aged 18 and over) as a treatment option for people with severe and complex obesity providing the patient fulfils all of the NICE criteria. These include that patients will have attempted

"All appropriate non-surgical measures……but the person has not achieved or maintained adequate, clinically beneficial weight loss" (NICE CG189). NICE also states that the person has been receiving or will receive intensive management in a tier 3 service.

Obesity surgery should be considered for:

- adults with a BMI of 40kg/m2 or more (NICE CG189)
- adults with BMI between 35 and 40 kg/m^2 or greater in the presence of other significant diseases (NICE CG189)
- Obesity surgery should be considered as a primary form of weight loss for patients with a BMI greater than 50 kg/m^2 (NICE CG189)
- Adults with BMI between 30 and 35 kg/m^2 with newly diagnosed diabetes (< 10 years). These individuals should be expedited for consideration of obesity surgery (NICE CG189).
- Adults with newly diagnosed diabetes who have Asian ethnicity should be considered at 2.5 kg/m^2 lower BMI levels (NICE CG189).
- All groups must be treated in a Tier 3 specialist weight management services although this can be concurrent for newly diagnosed diabetes as above.

Obesity surgery is an important event in the long term management of severe and complex obesity. It is fundamental that this procedure is performed on the right patient at the right time for that patient. It is also important that it is performed by the right professional, in the right place of treatment. It is therefore essential that individual patients should have an appropriate period of self-management and weight management advice and support by specialist professionals before surgery.

Services for children and adolescents (aged up to 18 years with severe and complex obesity are considered to be specialised and within the commissioning remit of NHS England. A separate policy and service specification will be published in 2016.

This specification does not cover:

1. Patients with a BMI under 35 kg/m^2. There may be rare occasions (see 2 below) when special factors (e.g. prior to renal transplant or fertility treatment) necessitate referral to a specialist complex obesity service; it is recommended that these will be treated as exceptional cases and managed through the individual funding processes.
2. Ethnic groups are at increased risk of obesity related co-morbidities at lower BMI than Caucasians and may access obesity services at lower BMI cut-off values
3. Children and adolescents (to be commissioned by NHS England)
4. Revisional surgery (see specific document related to revisional surgery)
5. Follow-up after 2 years
6. Metabolic surgery for severe insulin resistant diabetes

4.4 The Multi-Disciplinary Team (MDT) - see Annex 4

It is recommended the provider will have two pathways of care available for each patient; medical / non-surgical and surgical. These pathways should be sequential, not parallel except for patients with newly diagnosed type 2 diabetes. In many units the Tier 3 service and Tier 4 service will be co-located but where the Tier 4 service is separate:

At referral a non-surgical team will assess the patient to determine:

- the cause of obesity,
- the presence and severity of co-morbidities,
- to stratify/score risk (Obesity Surgery Mortality Risk Score (OS-MRS, EOSS scores (see Annex 3),
- to evaluate the adequacy of modalities of weight loss and weight loss management experience, that the patient has previously engaged with,
- appropriate liaison with other clinicians managing the patient (e.g. renal physician for patients in renal failure, psychiatrist for those receiving treatment for mental health disorders, diabetes physician or respiratory physician for those with obstructive sleep apnoea)
- to detect other diseases and to optimise their medical condition.

The non-surgical MDT will include, as a minimum;

- Physician with specialist obesity training
- Dietician with specialist obesity training
- Obesity specialist nurse
- Physical activity specialist or physiotherapist
- Psychotherapist / psychologist / psychiatrist - with an interest in obesity
- Other relevant medical specialists for referral and consultation e.g. endocrinologist / diabetologist / cardiologist / anaesthetist / radiologist (unless already in the surgical MDT)
- Co-ordinator support and administration

Following assessment, appropriate patients will be reviewed by a combined non-surgical and surgical obesity MDT to consider the optimal therapies which can/should be offered to the individual patient. If the team feels that the patient fulfils the surgical selection criteria and the patient wishes to consider this option, he/she will be referred onward for surgical assessment as to suitability for obesity surgery. If non-surgical therapies are considered optimal the non-surgical team will recommend, and/or provide treatment. The non-surgical and/or surgical MDT will also undertake, and re-enforce as appropriate, the counselling and preparation of patients assessed as appropriate for obesity surgery.

The multi-disciplinary team will work, in conjunction with local service providers (secondary care and community) and commissioners, within integrated care pathways and shared care protocols to ensure patients are receiving access to post - operative care, 2 year follow-up and arrange long term follow-up regardless of location.

The provider must demonstrate that systems that are in place to ensure that appropriate Tier 3 services are in place to allow collaborative comprehensive patient care for those in whom surgery of specialist Tier 4 non-surgical management is considered inappropriate. There will be formalised links in place (backed up by protocols) to refer and re-refer patients both pre and post-surgery between Tier 3 and Tier 4 services.

The provider will be able to offer support and information to patients through a designated contact person and in the form of a clear and comprehensive information pack in appropriate formats to comply with equality and diversity legislation.

4.5 Surgery

The specialist surgical MDT should include as a minimum:

- Obesity surgeon
- Physician with specialist obesity training
- Dietician with specialist obesity training
- Specialist obesity anaesthetist
- Specialist Mental Health Care professional with an interest in obesity
- Referral access to other relevant tertiary medical specialists for the diagnosis and management of co-morbidities.

This list is not exhaustive and the MDT should have access to/include the most appropriate group of health care professionals required to make a comprehensive and appropriate decision.

The surgical MDT should be supported by a radiologist and radiographer with a special interest in obesity. Patients will also have access to physiotherapy and occupational health professionals to assess and manage their levels of physical activity.

Severe and complex obesity services will deliver primary obesity surgery for all selected patients, who have been adequately informed, prepared, counselled and educated and who have demonstrated commitment and are deemed clinically suitable, and within the criteria defined in the commissioning policy which should take into consideration and be based upon NICE guidance.

The obesity surgery MDT will satisfy itself that:

- The patient is in accordance with relevant NICE guidelines and criteria
- there are no specific clinical or psychological contraindications to surgery
- the individual is aged 18 years or above.
- There is evidence that the patient has engaged with non-surgical Tier 3 services as outlined in the commissioning policy and has been assessed and referred by the obesity physician lead.
- the anaesthetic and other peri-operative risks have been appropriately explained and minimised

- that other clinicians providing care for the patient have been consulted where necessary and are kept informed (e.g. renal physician for those with renal failure)
- the patient has engaged in appropriate patient support or education groups/schemes to understand the benefits and risks of the intended surgical procedure. This will be organised by the surgical provider should the patient be assessed by the MDT as having not engaged prior to referral. However the expectation is clearly that the patient has accessed tier 3 weight management and patient support and education services prior to referral to Tier 4.
- the patient is judged as highly likely to engage in the follow up programme and life-style and dietary changes and behaviours that are required after any obesity surgical procedure to ensure
    - safety of the patient,
    - best clinical outcome is obtained and maintained.
    - sustained change in eating behaviour
    - sustained change in physical activity
    - sustained change in health promoting lifestyle and that the overall risk: benefit evaluation favours obesity surgery

The MDT will meet physically (not virtually) and minutes will be recorded of the discussion and the patient management decisions.

Specialist severe and complex obesity services will be able to provide the full range of routine obesity procedures, including laparoscopic and open procedures and revisional procedures (see advisory guidance for revisional procedures). Providers will not restrict practice to one single method of operation and a single procedure.

It is expected that laparoscopic surgery will be the main operating approach used. Specialist severe and complex obesity service providers will be able to provide 24 hour emergency management of post-surgical complications, including the availability of 24 hour consultant obesity surgeon cover solely or jointly with upper GI surgeons. In some models of care the surgical obesity service is part of the wider general surgery division and is clinically integrated with the upper GI surgical service. The critical factor for patient safety is rapid access to obesity surgical advice and obesity surgeon attendance for assessment. Services will also have appropriate on-site arrangements for critical care of the morbidly obese together with suitably trained and qualified ITU staff.

In order to allow for progression of specialisation, it is anticipated that there will be a need for two levels of service in the future (Units and Centres of Excellence - see International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) guidelines Annex 2 - units correspond to Institutions in IFSO). These levels will work as a clinical network to cover the entire patient pathway, and cover the full range of obesity surgical procedures, case complexity, education and training of post graduates and support for less experienced obesity surgeons as well as multi-disciplinary training of other professionals (e.g. psychologists, dieticians, physiotherapists etc.) with an interest in severe and complex obesity and obesity surgery.

For the present, obesity units will have a minimum of 2 consultant surgeons. Each surgeon will perform at least 50 procedures per annum and the provider unit will perform a minimum of 100 procedures per annum. Units will carry out all types of obesity procedures but will be restricted to an upper BMI/weight and complexity limit. Thresholds will be agreed in conjunction with the Commissioner and the Clinical network.

The surgeons in the multidisciplinary team should have completed a relevant supervised postgraduate training programme and have specialist experience in obesity surgery (see International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) guidelines – Annex 2
Specialist severe and complex obesity services will submit data on all patients treated to the National Bariatric Surgery Registry, using NSBR standard protocols for data compliance.

Patients must be appropriately supported. Support will vary between units, but it is essential that specialist dietetics and psychology, as well as nursing is provided, due to the specific issues that this patient group presents. Therefore a mix of specialisms should be provided to match local needs which will typically consist of ~1.5 WTE staff members per 100 patients with arrangements for annual leave.

4.6 Non-surgical management [within scope of Tier 4]

It is anticipated that some patients will be referred from areas with developed specialist weight management services i.e. Tier 3 [as defined in section 3.1] but will either not want surgery or not be suitable for surgery. Therefore, there will need to be pathways for the management of the following patient groups:

- patients who require preparative therapy prior to obesity surgery
- patients who have been assessed and found to be unsuitable for obesity surgery.
- patients whose medical state is too complex for Tier 3 services

These patients may need to be managed by the specialist non-surgical MDT as described above for a period of up to 2 years.

4.7 Patient Support

The Tier 4 provider will be able to offer support to the patients through a designated contact person and in the form of a clear and comprehensive information pack in appropriate formats to comply with equality and diversity legislation.
The provider will set up and maintain patient support groups and also signpost patients to other patient support groups facilitated by different organisations or charities. Such groups are a vital source of peer support, education, advice and information for patients. They may also be able, depending on their stage of development, to form an advocacy role, either at group or individual level, or as agents for change or service development.

4.8 Follow Up

The provision of after-care and weight management support for the patient remains a lifetime commitment. Structured, systematic and team based follow up should be organised by the Tier 4 (surgical) provider for a minimum of 2 years after surgery. Lifelong specialist follow up is advocated – various patterns of service provision will be described in 2016.

Follow up to include:

- continued specialist clinical, dietetic, behavioural and psychological advice. This support is to help patients modify their lifestyle to maximise weight loss/reduction, ensure nutritional replacement and to prevent or minimise complications.
- Follow up should provide early identification of complications and re-referral to the obesity surgeon and./or physicians.
- Long term follow-is the responsibility of the surgical provider but may be provided on a 'shared care' basis with the community based Tier 3 medical obesity services or secondary care specialist obesity clinics. Current practice is that patients are transferred from the surgical provider to local services after a period of no more than 24 months post-operatively although this period may be extended for patients undergoing duodenal switch procedures.
- Follow up arrangements will be procedure specific and surgical providers will have protocols for long term management of gastric bands
- Rapid access and re-referral to the specialist obesity MDT will be available for assessment of complications and their management. In some cases this will available as self-referral. The circumstances under which this is necessary will be included in the provider protocols and also patient discharge information.
- Post-operative care will be available to manage complications as they occur, including emergency revisional procedures. Failure to lose "sufficient" weight or weight regain is not deemed a complication.
- The "loss to follow-up" across the whole pathway for 2 years will be minimal. Follow-up rates must be collated and it is anticipated that a minimum of 75% follow up should be achieved assuming all reasonable efforts have been used to maximise follow up].I t is the responsibility of the obesity team to develop clear protocols for the required monitoring with local community or hospital based medical obesity services, including a robust mechanism ensuring early identification of post-operative problems.

Protocols for follow up from the obesity provider will be provided to primary and secondary care for shared care. This should include indications and pathways for removal of redundant skin.

4.9 General Paediatric care

Specifications for paediatric and adolescent obesity are not the remit of this specification and have been prepared by NHS England as separate specification for 2016/17.

5 Population Covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in *Who Pays?: Establishing the responsible commissioner* and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).
* - Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

Specifically, this service is for adults (aged 18 and over) with severe and complex obesity requiring specialist interventions and management as outlined in the guidance for this specification and in the Specialist Severe and Complex Obesity commissioning policy guidance.

5.1 Pathways of Care: Tiers 1 to 4

Responsibility for commissioning of obesity surgery services will change during 2016. After this time, preventative services and community-based services (Tiers 1 and 2) will be commissioned through PHE whereas the clinical services (Tiers 3 and 4) will be provided by Clinical Commissioning Groups.

The tiers of care are as below as defined in “Joined Up Clinical Pathways for Obesity”:

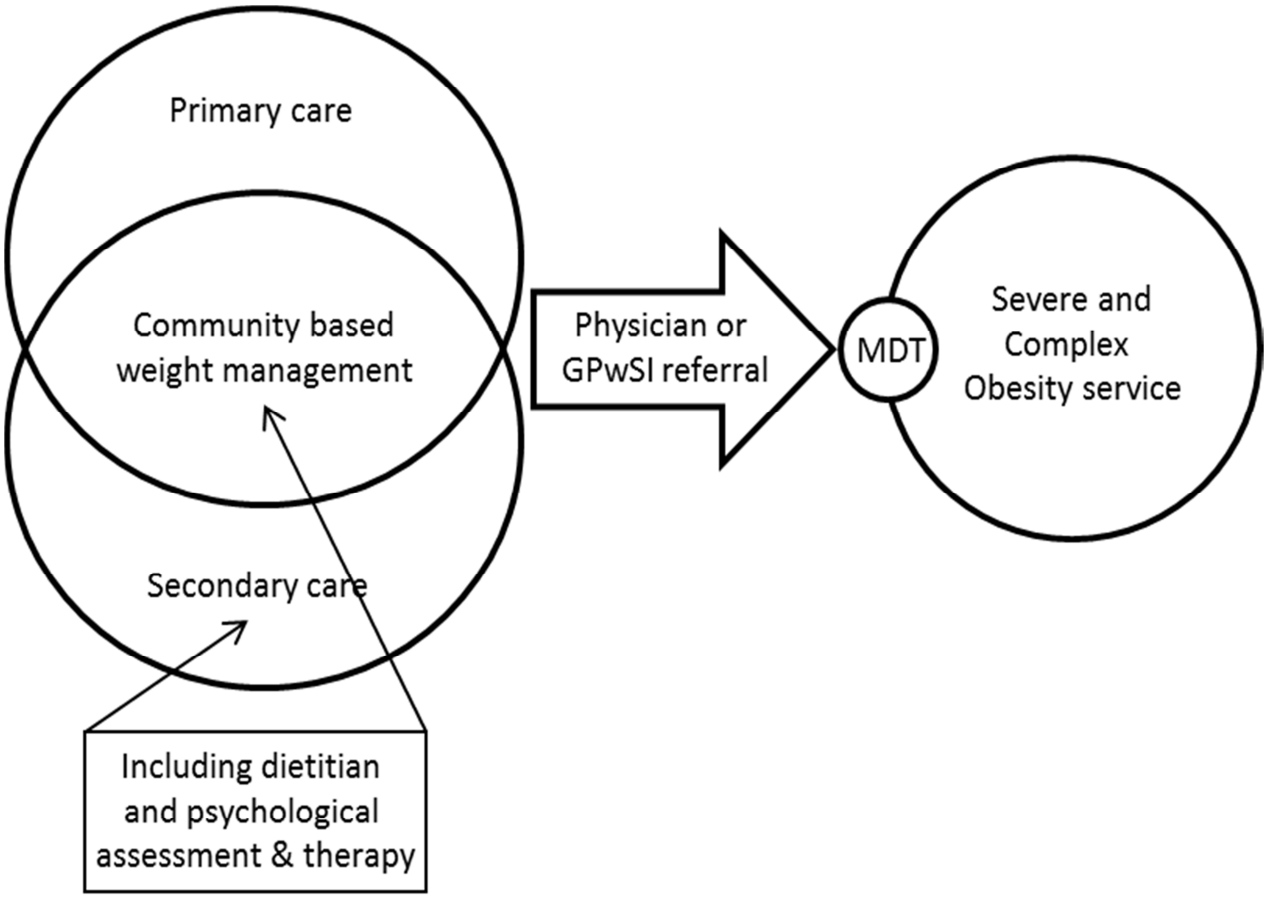
Tier 1 Preventative programmes: Public health interventions aimed at prevention and reinforcement of healthy eating and physical activity messages.

Tier 2 Weight management services: Lifestyle weight management advice. This may be given in Primary care as part of on-going personalised care. Weight management services delivered in the community led by a health care professional (e.g. dietician) trained in obesity. This may also include additional support by commercial weight management services. These commercial programmes will be well defined with scientific leadership and with clear protocols.

Tier 3 Specialist care: 1:1 management by a medically qualified specialist in obesity. This may be community or hospital based +/- outreach and delivered by a team led by a specialist obesity physician. Patient management will also include specialist dietetic, psychological and physical activity input. This will include group work and access to leisure services. There will be access to a full range of medical specialists as required for co-morbidity management

Tier 4 Specialist care: 1:1 management provided by specialist obesity medical and surgical MDTs with full access to a full range of medical specialists as required. All patients will be referred to Tier 4 by a Tier 3 service. The difference between the medical specialty at tiers 3 and 4 will be a qualitative level of experience in complex patient management. All surgical procedures will take place in tier 4.

These three aspects would be integrated as in the figure below:



This will ensure that selection for referral to the complex and severe obesity service by the medical lead of the Tier 3/4 service will consist of patients who have undergone an optimum level and duration of assessment and engagement with the tiered weight management service pathway described above and that the referral to specialist Tier 4 therapy is at the most appropriate time for the individual patient. Selected and referred patients will be expected to meet NICE Criteria. Community-based weight management falls in the overlap in this diagram as it may be under the clinical leadership of a secondary care based obesity physician or a primary care physician with a special interest in obesity.

We would assume that support from specialist dietetic, psychological and physical activities are longitudinal and parallel services rather than serial or single isolated events.

5.2 Interdependencies with other services/providers

Facilities:
Providers of severe and complex obesity services will be able to demonstrate that they have suitably equipped facilities and appropriately trained specialist staff to provide assessment; pre-operative; operative; and post-operative care for patients with severe, complex obesity. Ideally, facilities for the severe and complex obesity service will be separate from those for other patients in order to maintain the focus of the service on the special needs of the patients. However, irrespective of whether there are dedicated facilities, providers will ensure that privacy and dignity of patients is maintained at all times.

Consideration will be given to the services being delivered on the ground floor of the provider. Where this is not possible the commissioner will seek written assurances regarding access to lifts, including compliance with current legislation; emergency protocols for the event of power failure or rapid evacuation of patients in relation to other emergencies. Where this is not possible, the commissioner will seek written assurance regarding the physical structure of the relevant building and its load-bearing capabilities including access for bariatric wheelchairs and trolleys.

The service should have a physical environment that meets the needs of patient attending the service: toilet seats, grab rails, shower chairs, commodes, chairs, beds, lifting equipment etc. will be suitable for use by patients who are morbidly obese. The provider will make appropriate beds and scales available for obese patients and ensure that suitable imaging equipment is available for obese patients.

The surgical service should have demonstrable arrangements for:

- access to in-patient beds and for post-operative recovery;
- access to critical care facilities 24 hours a day, to at least high dependency (HDU) Level 2, and located on the same site at which surgical procedures are undertaken;
- access to Intensive care unit (ITU) Level 3 facilities on sites where surgical procedures are undertaken that are available 24 hours a day. Where this is not the case providers will have robust plans and procedures in place for patient transfers to local ITU level 3 critical care facilities that are available 24 hours a day. Procedures will include details of arrangements that the provider has with the receiving hospital for clinical liaison, hand-over during the patient transfer and post transfer/re-admittance to their surgical unit;
- access to suitably qualified doctor with sufficient training and experience in obesity surgery 24 hours a day for advice and treatment as necessary, and for the emergency assessment and treatment of post-operative complications;
- provision for emergency/urgent revisional procedures [specifications currently under development] following assessment of previous primary obesity surgery outcomes;
- the training and education of all staff involved in the care and management of morbidly obese patients.

6 Applicable Service Standards

6.1 Applicable national and international standards

Association of Upper Gastro-intestinal Surgeons: Provision of Services (2011)

BAPRAS Commissioning Guide: Massive Weight Loss Body Contouring (2014)

BOMSS Guidelines on perioperative and postoperative biochemical monitoring and micronutrient replacement for patients undergoing bariatric surgery. http://www.bomss.org.uk/bomss-nutritional-guidance/ accessed 29 Dec 2015

British Obesity and Metabolic Surgery Society Commissioning Standards. http://www.bomss.org.uk/wp-content/uploads/2014/04/Commissioning-guide-weight-assessment-and-management-clinics-published.pdf accessed 29 Dec 2015

Freid M et al. Interdisciplinary European guidelines on metabolic and bariatric Surgery. Obesity Facts 2013;6:449-68. http://easo.org/wp-content/uploads/2013/10/EASO-IFSO-EC-Guidelines-on-Metabolic-and-Bariatric-Surgery.pdf accessed 29 Dec 2015

Joined-up Clinical pathways for Obesity. PH England and NHS England 2014 https://www.england.nhs.uk/wp-content/uploads/2014/03/owg-join-clinc-path.pdf accessed 29 Dec 2015

MacLaughlin H et al. Development of the London Renal Obesity Network (LonRON): Protocol for Patients with CKD Referred for Bariatric Surgery. Br J Renal Med 2016 in press

Melissas J. International Federation for the Surgery of Obesity: Guidelines for Safety, Quality, and Excellence in Bariatric Surgery (2008) – see Annex 2 http://www.eac-bs.com/site_demo/images/ifso_guidelines_for_sqe_in_bariatric_surgery.pdf Accessed 26 Aug 2015

National Bariatric Surgery Registry data standards and requirements http://hostn3.e-dendrite.com/csp/bariatric/FrontPages/nbsrfront.csp accessed 29 Dec 2016

NICE Clinical Guideline 189: Obesity: identification, assessment and management of overweight and obesity in children, young people and adults. http://www.nice.org.uk/guidance/cg189 Accessed 29 Dec 2015

Safeguarding Adults: the Role of Health Service practitioners (Department of Health, 2011)

7 Annexes

ANNEX 1

Quality standards specific to the service

Quality Requirement	Threshold	Method of Measurement
There shall be an equal number of patients operated upon per unit of population.	50 per surgeon, 100 per unit.	Commissioning data NSBR NHS IC
Resolution of co-morbidities	20% of patients remaining on treatment for diabetes	Presence of diabetes at time 0 and 12 and 24 months after surgery
Re-admission within 28 days of discharge	100%	NHS IC
Patient views to be sought and actions taken as a result.	100% of patient per annum to be offered patient satisfaction questionnaire	Results of questionnaire to be shared with commissioners and actions taken (if any required) also shared.
Peri-operative mortality	As per national statistics for each type of surgery.	Data required as per contracting monitoring.

ANNEX 2

IFSO Guidelines for Safety, Quality, and Excellence in Bariatric Surgery

A. IFSO Guidelines for Primary Bariatric Institutions (PBIs) (i) Institutional requirements

For any medical institution considering the surgical management of morbidly obese patients, it would be necessary to:

1. Ensure that surgeons performing bariatric surgery have the appropriate certification, training, and experience to treat severely obese patients as described in the surgeon's credentials.

2. Ensure that individuals who provide services in the bariatric surgery programme are adequately qualified to provide such services.

3. Provide ancillary services such as specialist nursing care, dietary instruction, counselling, and psychological assistance if and when needed.

4. Have readily available consultants in cardiology, pulmonology, psychiatry, and rehabilitation with previous experience in treating bariatric surgery patients.

5. Have trained anaesthesiologists with experience in treating bariatric surgery patients.

6. Keep records of the adverse events that occur during the management of the patients.

7. Ensure that basic equipment necessary for the treatment of obese patients is available e.g. scales, operating room tables, instruments, supplies specifically designed for bariatric laparoscopic and open surgery, laparoscopic towers, wheelchairs, various other articles of furniture and lifts that can accommodate stretchers are available. There should also be available a recovery room capable of providing critical care to morbidly obese patients and an intensive care unit with similar capacity.

8. Ensure that radiology department facilities can perform emergency chest x-rays with portable machinery, abdominal ultrasonography, and upper GI series.

9. Ensure that blood tests can be performed on a 24hr basis.

10. Ensure that blood bank facilities are available and blood transfusion can be carried out at any time.

(ii) Surgeon's credentials

1. Appropriate certification to perform general surgery.

2. Training and experience in gastrointestinal open and/or laparoscopic surgery.

3. Successful completion of a training course in an existing Bariatric Institution or at least a minimum of two days on a bariatric training course including live demonstrations and laboratory hands-on training.

4. Testimonials by mentors (proctors) of satisfactory Bariatric surgical ability.

5. Careful maintenance of a database of all Bariatric cases, including outcomes, which can be audited by the appropriate national authorities.

6. Commitment to postoperative lifetime follow-up of the patients.

7. Carrying out of operations in approved facilities as described above.

Primary Bariatric Institutions (PBIs) should not accept super obese patients for the first one to two years of their practice.

During the early period of service development the management of morbidly obese patients should be confined to more simple bariatric procedures. PBIs may proceed to more complex bariatric techniques and to treat super obese patients only when significant experience has been gained (i.e. after performing a minimum of 50 cases). More technically demanding procedures requiring stapling and division of the stomach and gut and revisional surgery should not be carried out until the conditions described for existing Bariatric Institutions (BI)are completely reached.

B. IFSO Guidelines for Bariatric Institutions (BIs)

(i) Institutional Requirements

Any medical institution undertaking the management of morbidly obese, super obese, and super-super obese patients with laparoscopically adjustable gastric banding (LAGB) and/or procedures requiring stapling of the stomach and the gut, such as sleeve gastrectomy, Roux-en-Y gastric bypass (RYGBP) and biliopancreatic diversion (BPD)/duodenal switch (DS)* or revisional cases
should, apart from points described in guidelines for PBIs, ensure that they fulfil the following additional conditions:

1. Ensure that the director of bariatric surgery has at least five years' experience in the field and is capable of performing advanced bariatric procedures successfully.

2. Have comprehensive and full in-house consultative services required for the care of Bariatric surgical patients, including critical care services.

3. Have the complete range of necessary equipment, instruments, items of furniture, wheel chairs, operating room tables, beds, radiology facilities such as CT scan and other facilities specially designed and suitable for morbidly and super obese patients.

4. Have a written informed consent process that informs each patient of the surgical procedure, the risk for complications and mortality rate, alternative treatments, the possibility of failure to lose weight and his/her right to refuse treatment.

5. Maintain details of the treatment and outcome of each patient in a digital database.

6. Provide all necessary assistance and advise the staff to attend relevant meetings, subscribe to international journals and become members of a national Bariatric Society.

7. Have experienced interventional radiologists available to take over the non-surgical management of possible anastomotic leaks and strictures.

* Duodenal switch is associated with high morbidity and will normally be reserved for extreme cases.

(ii) Surgeon's credentials

Each interested surgeon should:

1. Have performed at least 50 bariatric cases per year.

2. Be able to perform revisional surgery by open and/or laparoscopic approach.

3. Be committed to a long-term (lifetime) follow up of his patients.

4. Attend bariatric meetings regularly, subscribe to at least one bariatric journal, and report his/her experience by presenting at local or international congresses or by publishing articles in peer-reviewed journals.

5. Perform advanced bariatric surgery at the appropriate facilities.

C. IFSO Guidelines for Centre of Excellence Bariatric Institution (COEBI) (i) Institutional requirements

Apart from the described requirements for BIs, every medical centre willing to be evaluated and approved as an IFSO Centre of Excellence Bariatric Institution, should prove to the IFSO authorised Review Committee that:

1. It is committed to the highest level of excellence in bariatric surgical patient care and maintains a regular programme of education for medical, nursing, administrative and allied health staff in bariatric surgery.

2. Performs at least 100 bariatric surgical cases per year including revisional cases. The perioperative care and the surgical procedures have to be standardised for each surgeon.

3. Has a bariatric surgeon who spends the main portion of his or her effort in the field of bariatric surgery.

4. Has supervised support groups for bariatric patients.

5. Provides lifetime follow up for the majority and not less than 75% of all bariatric surgical patients. Details of the patients' outcome should be included in a digital database and confidential information should be available on request by IFSO authorities.

(ii) Surgeon's credentials

Each surgeon in addition to the above described BIs credentials should:

1. Perform at least 50 bariatric cases per year including a number of revisional cases among them.

2. Be involved in the training and the accreditation of less-experienced bariatric surgeons.

3. Be committed to complete life time follow up of his/her patients and prove that his/her follow up is for at least five or more years.

4. Report his/her results in international conferences and publish articles in international peer-reviewed journals.

ANNEX 3

Obesity Surgery Mortality Risk Score

Risk factor	**Points**
Age > 45 years	1
Hypertension	1
Male sex	1
Risk factors for pulmonary embolism	1
Body mass index ≥ 50 kg per m2	1

Risk Group

Low	0 or 1 points
Moderate	2 or 3 points
High	4 or 5 points

References:

DeMaria EJ, Portenier D, Wolfe L. Obesity surgery mortality risk score: proposal for a clinically useful score to predict mortality risk in patients undergoing gastric bypass. Surg Obes Relat Dis 2007;3:134-40.

Demaria EJ, Murr M, Byrne TK, Blackstone R, Grant JP, Budak A Wolfe L. Validation of the Obesity Surgery Mortality Risk Score in a multicenter study proves it stratifies mortality risk in patients undergoing gastric bypass for morbid obesity. Ann Surg 2007;246:578–582.

ANNEX 4

Person specifications of specialists comprising multi-disciplinary team (MDT)

Bariatric Surgeons
Surgeons in the multidisciplinary and be on the specialist register for general surgery and have undertaken a relevant supervised training programme and have specialist experience in bariatric surgery. See IFSO guidelines Annex 2. They should be members of BOMMS.

Bariatric Physicians
Bariatric physicians in the multidisciplinary team will be on the specialist register and have undertaken a relevant supervised training programme and have specialist experience in bariatric medicine. Formal training in obesity is a component of the training requirement for diabetes & endocrinology and metabolic medicine. This should entail a minimum of MRCP (or equivalent), membership of APSO and SCOPE fellowship.

Primary Care Bariatric Specialists
Primary care specialists in the community based multidisciplinary team should be on GP register and a member of SCOPE and/or be a GP with a special interest in obesity. They should have undertaken a relevant supervised training programme.

Dieticians
All dieticians should be HPC (Health and Care Professions Council) registered and have undergone appropriate training in the management of obesity. Junior dieticians should have the support of a senior colleague with appropriate experience. Training should include both an understanding of psychological factors and readiness to change and motivational interviewing and counselling skills. They should be a member of BOMMS.

Psychologists
All psychologists should have HCP registration and be chartered with British Psychological Society. Psychologists should be sufficiently experienced in weight loss surgery, mental health and disordered eating behaviour. Ability to conduct an assessment to establish the individual's ability to implement necessary health behaviour changes for weight loss post-surgery through therapeutic approaches such as motivational interviewing and stages of changes. Experienced in identifying the individual emotional, cognitive and behavioural factors that may influence weight loss and be able to provide individual recommendations to improve weight loss and QoL outcomes. Ability to make recommendations for more complex patients that potentially may require psychological intervention pre and/or post-surgery for anxiety, depression and binge-eating. Able to train other health professionals in facilitation of health behaviour change.

Specialist nurses
All nurses should hold state registration, have undergone appropriate training within their specialist field and attended an obesity training course. Nurses involved in obesity management should have attended an obesity training course. They should be a member of BOMMS.