NHS England

## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

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|---|---|
| **Service Specification No.** | A05/S/a |
| **Service** | Severe and Complex Obesity |
| **Commissioner Lead** | |
| **Provider Lead** | *The name of the individual leading on the service for the provider* |
| **Period** | *12 months* |
| **Date of Review** | |



### 1. Population Needs

**1.1 National/local context and evidence base**

Obesity and overweight are 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. 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/$m^2$ or over). 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. 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%.

| 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 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 (Department of Health)

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. Mortality is related to the number of co-morbidities.

The treatment of obesity should be multi-component. All weight management programmes should include medical assessment of patients, non-surgical 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 specialised 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) CG43 recommendations). The patient should in addition have been adequately educated, 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 premature mortality, is commonly known as bariatric surgery. However patients need to be appropriately selected and must be able to adapt to post-surgical capacity restriction and comply with follow-up support and monitoring to optimise surgical outcomes.

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/m2 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/m2. Other groups have been less well studied but bariatric 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.

Bariatric 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, bariatric surgery has been shown to be a highly cost effective therapy that prevents the development of co-morbidities.

Bariatric surgery was 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 following criteria. For patients with BMI > 50 attending a specialist bariatric service, this period may include the assessment, stabilisation and preparation period prior to bariatric surgery. Selection criteria of patients for bariatric surgery 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 forbid bariatric 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.

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

## 2. Outcomes

### 2.1 NHS Outcomes Framework Domains & Indicators

| | | |
|---|---|---|
| **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** | √ |

### 2.1.1 Commissioning Data and minimum data sets

The Commissioners 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.

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

The outcome measures listed below will be derived from information collected at individual patient level. The outcome measures are to be collected for all patients.

### 2.1.2 Outcome Measures

In addition to the measures in the paragraphs above, there should be documentation for all patients referred to the secondary care provider, of their weight management trajectory in non-surgical services, information about reasons for referral for bariatric 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 bariatric physician (Tier 3/4 service). Ideally referral for surgery should be made by the bariatric physician lead for the Tier 3 service.

### 2.1.3 Co-morbidity improvement (domain 1, 2 and 3)

### 2.1.3.1 Reduction in objective measures of identified co-morbidities.

**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 to be recorded at 6 months, 12 months, 18 months and 24 months post-surgery by type of surgery. Weight loss parameters to be calculated include BMI reduction, %

Weight loss to be monitored at 6 months, 12 months, and 24 months post intervention for

non-surgical interventions (for patients clinically unsuitable for surgery).

100% data submission to National Bariatric Surgery Registry: all procedures carried out will be entered into the NBSR as per Dendrite data entry criteria.

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

% patients within 18 weeks; the percentage of patients achieving a maximum wait of 18 weeks between referral and first definitive treatment/clock-stop on both admitted and non-admitted pathways. Minimum expectations of 90% admitted patients and 95% non-admitted patients within 18 weeks. (Please be aware that this does not mean surgery within 18 weeks of referral, first definitive treatment might be any non-surgical intervention deemed clinically necessary).

**Resolution of co-morbidities**

To be monitored at 6 months, 12 months, 18 months and 24 months post-surgery. Described by co-morbidity, e.g. type 2 diabetes, hypertension. Parameters recorded could include reductions in disease severity and treatment/medication requirements.

**2.1.3.2 Morbidity and Mortality (domain 4, 5)**

Post-operative complication rates 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.

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

Numbers of patients who present for revision by primary bariatric procedure type.

## 3. Scope

### 3.1 Aims and objectives of service

The main clinical aim of a Tier 4 specialised bariatric surgical and medical 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 Tier 4 service providing specialised care, including both specialised non-surgical interventions and surgical interventions, for patients who have been unable to achieve and/or maintain significant weight-loss. This will be at the end of a patient pathway. The service will also provide/arrange follow-up on a hub and spoke model with a secondary care specialised obesity clinic with agreed protocols including criteria for re-referral.

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 specialised weight management service local to the patient's home, as part of a life-long shared care arrangement of follow-up and surveillance.

Surgical providers will be required to demonstrate that they have specialist multi-disciplinary bariatric (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 bariatric surgery is an intervention used after persistent failure of non-surgical weight management programmes, the provision of structured follow up by professionals for weight loss progress, medical and surgical complications, nutritional monitoring and supplementation and life-style weight maintenance support for the patient remains a lifetime commitment for the patient.

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

**3.2 Service description/care pathway**

The services provided will cover 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).

Assessment and treatment using specialised 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;
- Treatment for those where drug therapy is being considered for a person with a BMI more than 50 kg/m$^2$
- Specialist interventions
- Bariatric MDT and pre-operative assessment, surgical intervention and immediate post-operative follow-up.
- Life-long post-operative follow-up and specialist surveillance, in conjunction with medical obesity services (Tier 3 services, specialised obesity clinics), in collaboration with primary care and secondary care.
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**3.2.1 The Multi-Disciplinary Team (MDT) (see appendix 4)**

The provider will have two pathways of care available for each patient; bariatric medical/ (non-surgical) and surgical. These pathways will be sequential, not parallel.

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 appendix 3),
- to evaluate the adequacy of modalities of weight loss and weight loss management experience, that have been trialled by the patient,
- to detect other diseases and to optimise their medical condition.

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

- Bariatric physician
- Bariatric dietitian
- Bariatric specialist nurse
- Psychotherapist / psychologist / psychiatrist - with an interest in obesity
- Other relevant medical specialists for referral and consultation eg 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 bariatric MDT to consider the optimal therapy for individual patients. If the team feels that the patient fulfils the surgical selection criteria they will be referred onward for bariatric surgery. If non-surgical therapies are considered optimal the non-surgical team will recommend, and 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 bariatric 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 patient assessment, preparation, education and intensive management is implemented in a community or hospital based Tier 3 service. This will also address psychological and medical co-morbidities for all referred patients and specialised weight management of patients for whom surgery is not the most appropriate form of therapy unless Tier 4 non-surgical is required. There will be formalised links in place (backed up by protocols) to refer and re-refer patients both pre and post-surgery.

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.

### 3.2.2 Surgery

The specialist surgical MDT should include as a minimum:

- Bariatric surgeon
- Bariatric physician / relevant medical specialist with an interest in obesity e.g. endocrinologist / diabetologist / chemical pathologist
- Bariatric dietitian
- Specialist bariatric anaesthetist and radiologist
- Specialist Psychotherapist / Psychologist / Psychiatrist with an interest in obesity
- Ideally on site referral access to other relevant tertiary medical specialists for the obesity 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 will 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 bariatric surgery for all selected patients, who have been adequately informed, prepared, counselled and educated and who have demonstrated commitment and are deemed clinically appropriate, and within the criteria defined in the commissioning policy.

The bariatric surgery MDT will satisfy itself that:

- bariatric surgery is in accordance with relevant NICE guidelines and criteria
- there are no specific clinical or psychological contraindications to this type of 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 bariatric physician lead.
- the anaesthetic and other peri-operative risks have been appropriately minimised
- 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 Tier 4 service 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

bariatric 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 bariatric 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 bariatric procedures, including laparoscopic and open procedures and revisional procedures (a national policy for revisional procedures will be developed). 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 method 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 bariatric surgeon cover solely or jointly with upper GI surgeons. In some models of care the surgical bariatric 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 bariatric surgical advice and bariatric 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 appendix 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 bariatric surgical procedures, case complexity, education and training of post graduates and support for less experienced bariatric surgeons as well as multi-disciplinary training of other professionals (e.g. psychologists, dieticians etc) with an interest in severe and complex obesity and bariatric surgery.

For the present, bariatric 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 bariatric 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.

Bariatric Centre Requirements for revision surgery are currently being developed.

The surgeons in the multidisciplinary team should have completed a relevant supervised postgraduate training programme and have specialised experience in bariatric surgery (see International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) guidelines – appendix 2).

Specialised severe and complex obesity services will submit data on all patients treated to the National Bariatric Surgery Registry, using their standard protocols for data compliance.

Patients must be appropriately supported. Support will vary between units, but it is essential that specialist dietetics, psychology, pharmacy, 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 be ~1.5 wte per 100 patients with arrangements for annual leave.

### 3.2.3 Non-surgical management [within scope of Tier 4]

It is anticipated that some patients will be referred from areas with developed specialised 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 bariatric surgery
- patients who have been assessed and found to be unsuitable for bariatric surgery.
- patients whose medical state is too complex for Tier 3 services

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

### 3.2.4 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 sign post 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.

### 3.2.5 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 provider for a minimum of 2 years after surgery. Lifelong specialist follow up is advocated – a policy for this will be developed in 2014/15.

Patients will continue to receive specialist clinical, dietetic, behavioural and psychological advice and support to help them modify their lifestyle to maintain weight loss/reduction, nutritional replacement and to prevent or minimise complications. A further role will be the early identification of complications and re-referral to the bariatric surgeon and./or physicians.

Long term follow-up and supervision will be provided by the surgical provider for 2 years post-operatively. This may be provided on a ‘shared care’ basis with the community based Tier 3 medical obesity services or secondary care specialised obesity clinics. The Commissioners intend that the transfer of care from the surgical provider to local services would take place no more than 24 months post-operatively although this period may be

extended for patients undergoing duodenal switch procedures. Follow up arrangements will however be procedure specific and surgical providers will have protocols for long term surveillance (e.g. gastric band adjustment and monitoring to avoid nutritional deficiencies). The specialised service will at all times maintain links with patient's local services ensuring that they are aware of the patients' on-going progress. The "loss to follow-up" across the whole pathway for 2 years will be minimal [a minimum of 75% follow up achieved assuming all reasonable efforts have been used to maximise follow up].

It is the responsibility of the bariatric 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. Rapid access and re-referral to the specialised Bariatric 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.

Protocols for follow up from the bariatric provider will be provided to primary and secondary care for shared care.

### 3.2.6 General Paediatric care

Specifications for paediatric and adolescent obesity are not the remit of this specification but will be prepared as separate specification in 2014/5.

### 3.3 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 specialised interventions and management as outlined in this specification and in the Specialised Severe and Complex Obesity commissioning policy.

### 3.4 Any acceptance and exclusion criteria and thresholds

Referrals will 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 criteria laid out in the clinical commissioning policy. The clinical commissioning policy needs to be read in conjunction with the service specification.

Services for children and adolescents (aged up to and including 17 yrs and 11 months) with severe and complex obesity are considered to be highly specialised and will be delivered from very few centres dedicated to the provision of Paediatric obesity services,

and co-ordinated under the supervision of a national clinical supervisory programme. A separate policy and service specifications is being prepared for 2014/15

Bariatric 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 undergone an appropriate period of self-management and weight management advice and support by specialist professionals, both before and after any surgical intervention. Whilst it is not within the scope of this specification, it is anticipated that specialised weight management/pathway services will be locally commissioned to provide a pattern of resources similar to that described below to which patients can be referred to and with which patients can engage.

**Tier 1 Primary care** – 1:1 management by the primary care team and self-management supported by commercial slimming clubs.

**Tier 2 Community care** – Primary care group management 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 will be defined programmes with scientific leadership and with clear protocols.

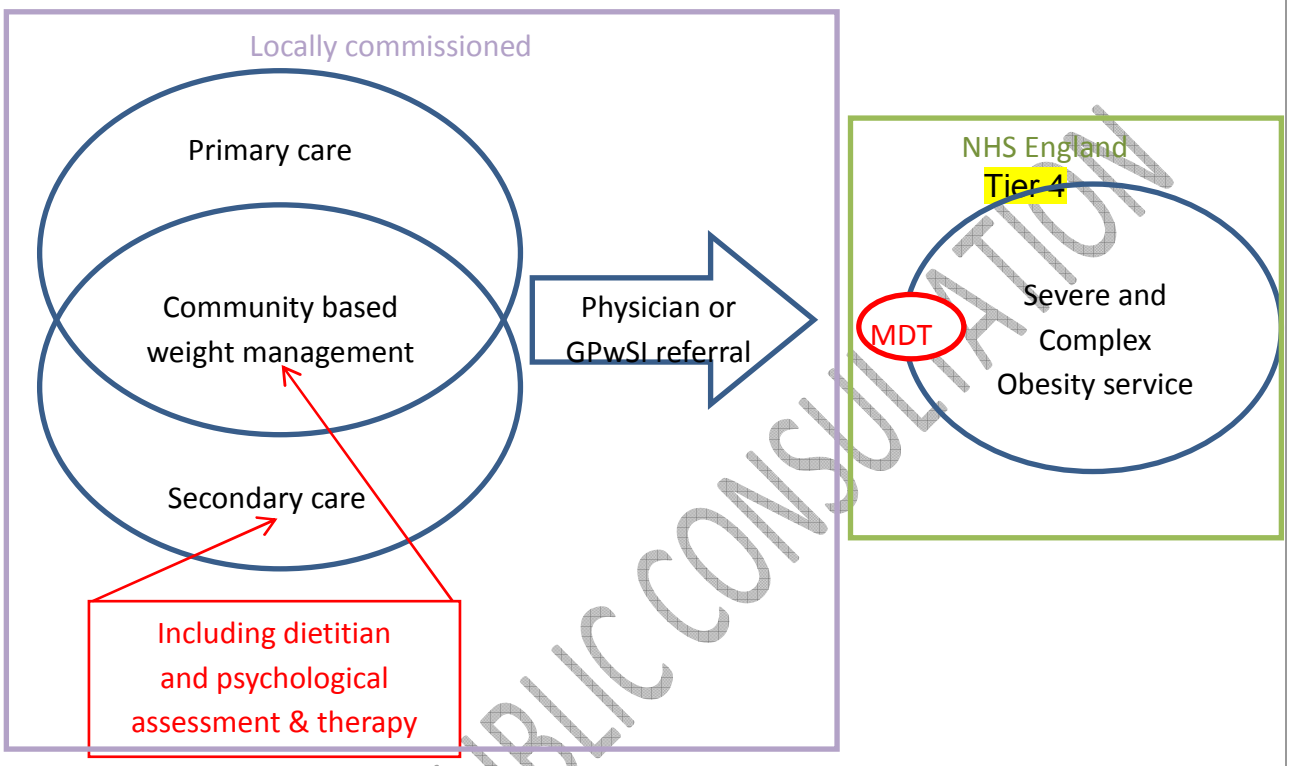
**Tier 3 Specialist care** – 1:1 management by a medically qualified specialist in obesity. This may be community or hospital based +/- outreach and delivered by a team led by a specialist bariatric physician. Patient management will also include specialised dietetic and psychological professional input. 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 Specialised care** – 1:1 management provided by specialised bariatric 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.

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.

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

Tiers 1, 2 and 3






Community based weight management falls in the overlap in this diagram as it may be under the clinical leadership of a secondary care based bariatric physician or a primary care physician with a special interest in obesity.

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

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

This specification does not cover:

Patients with a BMI under 35 kg/m$^2$. There may be rare occasions when special factors (e.g. prior to renal transplant or fertility treatment) necessitate referral to a specialised complex obesity service; these will be treated as exceptional cases and managed through the individual funding processes.

Ethnic groups with increased risk of obesity related co-morbidities at lower BMI than Caucasians

Children and adolescents

Revisional surgery

Follow-up after 2 years

Metabolic surgery for severe insulin resistant diabetes

Any body contouring required post surgery.

**3.5 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.

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 bariatric surgery 24 hours a day for advice and treatment as necessary, and for the:-
- the emergency assessment and treatment of post-operative complications;
- provision for emergency/urgent revisional procedures [specifications currently under development] following assessment of previous primary bariatric surgery outcomes ;
- the training and education of all staff involved in the care and management of morbidly obese patients.

## 4. Applicable Service Standards

### 4.1 Applicable national standards e.g. NICE

Core Standards: to be in place at commencement of the contract

NICE Clinical Guideline 43: Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children

National Bariatric Surgery Registry data standards and requirements http://hostn3.e-dendrite.com/csp/bariatric/FrontPages/nbsrfront.csp accessed 26 Aug 2012
http://www.bomss.org.uk/pdf/Pages_from_NBSR_2010.pdf accessed 26 Aug 2012

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

British Obesity and Metabolic Surgery Society Commissioning Standards

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

International Federation for the Surgery of Obesity: Guidelines for Safety, Quality, and Excellence in Bariatric Surgery (2008) – see Appendix 2 http://www.eac-bs.com/eacbs/en/4/58.html. Accessed 26 Aug 2012.

### 4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

## 5. Applicable quality requirements and CQUIN goals

### 5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

### 5.2 Applicable CQUIN goals (See Schedule 4 Part E)

## 6. Location of Provider Premises

**The Provider's Premises are located at:**

**Appendix 1**

**Quality standards specific to the service using the following template**

| Quality Requirement | Threshold | Method of Measurement | Consequence of breach |
|---|---|---|---|
| **Domain 1: Preventing people dying prematurely** | | | |
| There shall be an equal number of patients operated upon per unit of population. | 50 per surgeon, 100 per unit. | Commissioning data<br>NSBR<br>NHS IC | As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan |
| **Domain 2: Enhancing the quality of life of people with long-term conditions** | | | |
| 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 | As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan |
| **Domain 3: Helping people to recover from episodes of ill-health or following injury** | | | |
| Re-admission within 28 days of discharge | 100% | NHS IC | As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan |
| **Domain 4: Ensuring that people have a positive experience of care** | | | |
| 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. | As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan |
| **Domain 5: Treating and caring for people in a safe environment and protecting them** | | | |

| Quality Requirement | Threshold | Method of Measurement | Consequence of breach |
|---|---|---|---|
| **from avoidable harm** | | | |
| Peri-operative mortality | As per national statistics for each type of surgery. | Data required as per contracting monitoring. | As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan |

## APPENDIX 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 specialised 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.

## APPENDIX 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.

## APPENDIX 4

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

### Bariatric Surgeons

Surgeons in the multidisciplinary team will hold GMC (General Medical Council) registration, 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 appendix 2. They should be members of BOMMS.

### Bariatric Physicians

Bariatric physicians in the multidisciplinary team will hold GMC registration, 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 hold GMC registration, be on the 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.

### Dietitians

All dietitians should be HPC (Health profession Council) registered and have undergone appropriate training in the management of obesity. Junior dietitians 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 HPC 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.