SCHEDULE 2 – THE SERVICES

A. Service Specification

Service Specification No.	
Service	Tier 4 Bariatric Surgery
Commissioner Lead	NHS Lancashire and South Cumbria Integrated Care Board (ICB)
Provider Lead	TBC
Period	January 2023- December 2029 (5 year contract with an option to extend for 2 years)
Date of Review	January 2024

1. Population Needs

1.1 National/local context and evidence base

Obesity and overweight are a global epidemic. In 2016, the World Health Organisation (WHO) reported that more than 1.9 billion adults were overweight, and 650 million adults had obesity. At least 2.8 million people each year die because of being overweight or from obesity. The prevalence of obesity nearly tripled between 1975 and 2016. Once associated with high-income countries, obesity is now also prevalent in low- and middle-income countries (who.int).

The Health Survey for England (2019) examined the prevalence of overweight and obesity among adults and children in England in 2019. The key findings were as follows: -

- 27% of men and 29% of women had obesity (Body Mass Index (BMI) 30kg/m2 or over). Around two thirds of adults were overweight or had obesity; this was more prevalent among men (68%) than women (60%).
- Obesity increased with age from 13% of adults aged between 16 and 24, to 36% of those aged 65 to 74. It was lower among adults aged 75 and over (26%).
- 59% of men and 69% of women had a higher than desirable waist circumference (higher than 94cm for men or 80cm for women). This proportion increased broadly in line with age, from 29% of adults aged 16 to 24, to 83% of those aged 75 and over.
- Inequalities were seen for both obesity and raised waist circumference. Adults living in the most deprived areas were the most likely to have obesity. This difference was particularly pronounced for women, where 39% of women in the most deprived areas had obesity, compared with 22% in the least deprived areas (HSE 2019 Overweight and obesity in adult and child (digital.nhs.uk)).

BMI Definition	BMI range (kg/m2)
Underweight	Under 18.5
Normal	18.5 to less than 25
Overweight	25 to less than 30
Obesity	30 to less than 40
Obesity I	30 to less than 35
Obesity II	35 to less than 40
Obesity III/severe	40 and over
Overweight including obesity	25 and over
Obesity	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. In 2017, Public Health England estimated the NHS spent £6.1b on overweight and obesity related ill health in 2014/15. The overall cost of obesity to wider society is estimated at £27 billion (Health matters: obesity and the food environment - GOV.UK (www.gov.uk)).

As BMI increases the number of obesity-related comorbidities increases. The number of patients with ≥ 3 comorbidities increases from 40% for a BMI of < 40 to more than 50% for BMI 40-49.9 to almost 70% for BMI 50-59.9 and ultimately to 89% for BMI > 59-9.

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

Surgery to aid weight reduction for adults with class III 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 (NICE CG43 recommendations). The patient should in addition have been adequately counselled and prepared for bariatric surgery.

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

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

Bariatric surgery in the North West services will require that these patients fulfil the criteria within this specification. Selection criteria of patients for bariatric surgery should prevent perverse incentives for example patients should not become more eligible for surgery by increasing their body weight. Similarly, the selection criteria should not forbid bariatric surgery for patients who have lost weight with non-surgical methods.

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**	

2.2 Local defined outcomes

See 4.1 Applicable local standards

3. Scope

3.1 Aims and objectives of service

The main clinical aim of a Tier 4 Bariatric Service is to achieve a significant 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.

The provider of a Tier 4 Bariatric Service will, as part of a locally defined continuous pathway of care include the patient's GP (Primary Care); local (to the patient) services commissioned by local authority (LA) or the Integrated Care Board (ICB) and local district general hospital/tertiary care based interventions which may include private sector providers (e.g. those commercial slimming clubs with scientific directors), deliver a service providing specialised care, including both non-surgical interventions and surgical and interventions, for patients who have been unable to achieve and/or maintain significant weight-loss. The service will be provided in a complete and reproducible pathway that meets the required standards of care and achieves expected outcomes whilst remaining within proper consideration of cost and resource.

Providers will have clinical protocols and programmes of care that deal with the patient journey through assessment, medical or surgical intervention, post-surgical care (where appropriate), discharge and long term follow up, 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.

Providers will be required to demonstrate that they have multi-disciplinary teams that can provide such assessments and that clinically appropriate referrals to other specialties for further consultation and clinical management will be made.

Whilst bariatric surgery is a last-line intervention, the provision of follow up for complications, nutritional and weight maintenance support for the patient remains a lifetime commitment for the patient.

We describe an ideal service for severe and complex obesity which includes bariatric surgery. Various elements of this pathway will have different commissioning pathways and responsibilities.

3.2 Service description/care pathway

The services provided will cover in secondary and/or 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 based medical obesity services. Including but not limited to rare genetic syndromes, endocrine disturbances, and abnormalities.

- Assessment and treatment using non-surgical methods, or onward referral to other 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 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/m2.
- Specialist interventions (such as a very-low-calorie diet for extended periods),
- Pre-operative preparation, surgical intervention, and immediate post- operative follow-up.
- Life-long post-operative follow-up and specialist surveillance, in conjunction with community based medical obesity services, and primary care.

3.3 Shared Decision Making

It is expected that this will feature within all interactions with patients throughout the service offer of the Tier 4 Bariatric Service.

Shared Decision Making (SDM) is a process in which clinicians and patients work together to select tests, treatments, managements, and support packages, based on clinical evidence and patient's informed preferences. It involves the provision of evidence-based information about options, outcomes, and uncertainties,

together with decision support counselling and a system for recording and implementing patient's informed preferences.

The aim of SDM is to increase patient involvement in decisions about their care and treatment along the service pathways.

- To ensure **shared decision making** is embedded throughout every step of the patient's journey – "no decision about me without me" (Department of Health, 2012). The service will also adhere to the Commissioner's Shared Decision-Making plans.

- To deliver **patient centered care** where the patient is listened to and treated with dignity, respect, and sensitivity.

3.4 The Tier 4 Multi-Disciplinary Team (MDT)

All patients referred into Tier 4 services will be assessed by the Tier 4 MDT. The Tier 4 provider will have two pathways of care available for each patient: non-surgical and surgical. These pathways will be sequential, not parallel.

At referral the Tier 4 non-surgical MDT will determine whether a patient has progressed through appropriate local community-based Tier 3 services and liaise with Tier 3 to establish appropriateness and informed consent has been discussed to support the management of patient expectation. If appropriateness is not agreed Tier 4 will reject the referral.

The 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)
- to evaluate the modalities of weight loss that have been explored,
- to detect other diseases and
- to optimise their medical condition.

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

- Bariatric dietitian
- Bariatric physician
- Bariatric specialist nurse
- Psychotherapist / psychologist / psychiatrist - with an interest in obesity
- Other relevant medical specialist for referral and consultation e.g. endocrinologist / diabetologist / cardiologist / anaesthetist (unless already in the non-surgical MDT).

Following assessment, patients will be reviewed by a combined non-surgical and surgical Tier 4 MDT to consider the optimal therapy for individual patients. Only if the team feels that the patient fulfils the surgical selection criteria will they be referred onward to the bariatric surgery team.

The commissioner expectation is that the MDT stage (both non-surgical and surgical) of the pathway will normally take at least 6 months, however this will be dependent on the level of non-surgical intervention already received in the Tier 3 service. At the assessment stage, the Tier 4 MDT will determine what additional non-surgical intervention is required through liaising with the Tier 3 service.

If non-surgical therapies requiring Tier 4 interventions are considered optimal the non-surgical team will recommend and provide treatment with a view to discharging back to the Tier 3 as clinically appropriate.

The Tier 4 MDT pathway should also include regular, on-going non-surgical support for patients approved for surgery whilst they remain on the bariatric surgery waiting list.

Depending on local arrangements, the surgical Tier 4 MDT will undertake the psychology and preparation of patients assessed as appropriate for bariatric surgery.

The Tier 4 MDT will work, in conjunction with local commissioners and providers, within integrated care pathways and shared care protocols to ensure patients are receiving appropriate pre- and post- operative care and long-term follow-up regardless of location.

The 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.

3.5 Surgery

The specialist surgical MDT should include as a minimum:

- Bariatric surgeon
- Bariatric dietitian
- Specialist anaesthetist
- *Relevant medical specialist with an interest in obesity e.g. endocrinologist/diabetologist
- *Psychotherapist / Psychologist / Psychiatrist with an interest in obesity
- *Ideally on-site access to other relevant medical specialists for the diagnosis and management of co-morbidities.

**not necessary if part of the non-surgical MDT*

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.

Specialised complex obesity services will deliver primary bariatric surgery for all patients 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 guidelines
- There are no specific clinical or psychological contraindications to this type of surgery
- The individual is aged 18 years or above.
- The patient has engaged with non-surgical Tier 3/4 Services.
- The anaesthetic and other peri-operative risks have been appropriately minimised
- The patient has engaged in appropriate support or education groups/schemes to understand the benefits and risks of the intended surgical procedure. This should be provided by the Tier 4 service, following referral, 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 services prior to referral to Tier 4.
- The patient is likely to engage in the follow up programme that is required after any bariatric surgical procedure to ensure:
    - safety of the patient,
    - best clinical outcome is obtained and then maintained.
    - change in eating behaviour
    - change in physical behaviour
    - change in health promoting lifestyle
- The overall risk: benefit evaluation favours bariatric surgery.
- The MDT will meet physically/virtually, and minutes will be recorded of the patient management decisions.

Specialised complex obesity services will be able to provide the full range of routine bariatric procedures, including laparoscopic and open procedures and revision procedures. Providers will not restrict practice to one single method of operation.

It is expected that laparoscopic surgery will be the normal operating method used.

Specialised complex obesity services will be able to provide 24-hour emergency management of post-surgical complications, including the availability of 24-hour consultant bariatric surgeon cover or joint cover 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 is rapid access to bariatric surgery advice and attendance.

The majority of patients (including those undergoing malabsorptive and revisional surgery) can be safely nursed and closely observed/monitored with zero or single organ support in a surgical 'step down' unit for the first 24 hours. It is no longer considered *mandatory* for level 2/3 critical care facilities to be provided on-site, provided that (a) 24 hour consultant surgeon and anaesthetic cover is provided to support ward staff and junior doctors; (b) patients are accurately risk-stratified pre-operatively to identify those who might require elective admission to a level 2/3 critical care bed and (c) that robust arrangements are in place at every unit undertaking bariatric surgery for the safe transfer of patients requiring additional monitoring/support to a level 2 (or if appropriate level 3) critical care unit and (d) all units carrying out elective major surgery (not just bariatric surgery) should have a designated area that can be temporarily raised to a Level 2 critical care setting to enable stabilisation and subsequent transfer in the unlikely event that a patient develops an early complication (usually anaesthetic-related) that requires critical care admission. This is in line with the British Obesity & Metabolic Surgery Society (BOMSS) professional standards and commissioning guidance 2021 (update May 2019).

In order to allow for progression of Specialised Complex Obesity Services, 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 between themselves as part of the wider obesity care pathway, and cover the full range of surgical procedures and case complexity, education and training of post graduates and less experienced bariatric surgeons as well as multi-disciplinary training of other professionals (e.g. psychologists, dietitians etc.) with an interest in severe and complex obesity and bariatric surgery.

Falling volumes of NHS-commissioned bariatric surgery in recent years have made it difficult for many units to meet the BOMSS 2012 recommendations regarding surgeon and unit volume. BOMSS recognise that there is some evidence that supports better outcomes in high volume units, but they feel that a unit can deliver a safe service provided that the following criteria are met (a) an established MDT structure is in place (the bariatric MDT should as a minimum comprise bariatric surgeon(s), specialist dietician, bariatric specialist nurse and an experienced bariatric psychologist. It is strongly recommended that either a bariatric physician and/or a bariatric anaesthetist (acting as a peri-operative physician) should be present at bariatric MDT meetings); (b) the hospital engages at least two bariatric surgeons performing a minimum of 30 major procedures pa each (combined NHS and private experience); and (c) the unit (whether private or NHS) carries out a *minimum* of 30 major laparoscopic bariatric procedures per year (excluding gastric balloons) and ideally performs upwards of 100 major procedures pa . BOMSS strongly supports an expansion of bariatric surgery capacity in the UK and wish to re-emphasise previous advice that newly established units and surgeons should be supported within a network of more experienced bariatric MDTs and should aim to achieve the minimum unit volume of 30 cases pa within 3 years of service commencement.

The surgeons in the multidisciplinary team should have undertaken a relevant supervised training programme and have specialist experience in bariatric surgery (see International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) guidelines).

Specialised 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 as well as nursing is provided, due to the specific issues that this work presents. Therefore, a mix of specialism should be provided to match local requirements which will typically be ~1.5 WTE per 100 patients, with arrangements in place to ensure annual leave and sickness is always covered.

3.6 Non-surgical management (pre op)

There will need to be pathways for the management of:

- patients who require preparative therapy prior to bariatric surgery
- patients who have been assessed and found to be unsuitable for bariatric surgery but require Tier 4 specialist input.

These patients may need to be managed within the non-surgical MDT as described above for a period of up to 2 years. Where appropriate refer to Tier 3 or primary care.

3.7 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 to sign post patients to other patient support groups facilitated by different organisations or charities. Such groups are a vital source of peer support, 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. The provider will be expected to complete patient experience survey, to be designed to suit the service users, over and above the family and friend's test.

3.8 Follow Up Care

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 up to 2 years after surgery. Lifelong specialist follow up is also advocated via local services (GP and Tier 3).

Post-surgery follow up
Providers should ensure that all people are offered a post-surgery follow up within six weeks of the surgery date.

2 year follow up
Providers should ensure that all people are offered at least annual monitoring of nutritional status and appropriate supplementation according to need following bariatric surgery, as part of a shared care model of chronic disease management. The follow up should be for up for 2 years post-surgery should be organised to include:
NB: National guidance on nutritional monitoring following surgery (2020) https://onlinelibrary.wiley.com/doi/full/10.1111/obr.13087

- monitoring nutritional intake (including protein and vitamins) and mineral deficiencies
- monitoring comorbidities
- medication review
- dietary and nutritional assessment, advise and support
- physical activity and support
- psychological support tailored to the individual
- information about professionally led or peer support groups.

Lifelong specialist follow up

Lifelong specialist follow up is advocated and providers should have arrangements in place to discharge patients to the local community Tier 3 based obesity service within 2 years. The patients GP should be kept informed of the patient's ongoing progress.

"Lost to follow up" across the whole pathway should be minimised and a robust mechanism should be in place for early identification of post-operative complications. Rapid access to the specialised complex obesity Tier 4 MDT will be available for assessment of complications and post-operative care will be available to manage complications as they occur including revision surgery in line with NHS policies. Failure to lose 'sufficient' weight is not deemed a complication.

3.9 Population Covered

The service described in this specification is for patients ordinarily resident in the Lancashire, Cumbria, and Merseyside geographic areas.

Specifically, this service is for adults (aged 18 and over) with complex obesity requiring specialised interventions and management as outlined in this specification.

3.10 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 obesity.

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

Surgical interventions
https://www.nice.org.uk/guidance/cg189/chapter/1-recommendations#surgical-interventions (2014)

Bariatric surgery is a treatment option for people with obesity if all the following criteria are fulfilled:

- They have a BMI of 40 kg/m2 or more, or between 35 kg/m2 and 40 kg/m2 and other significant disease (for example, type 2 diabetes or high blood pressure) that could be improved if they lost weight.
- All appropriate non-surgical measures have been tried but the person has not achieved or maintained adequate, clinically beneficial weight loss.
- The person has been receiving or will receive intensive management in a Tier 3 service [10].
- The person is generally fit for anaesthesia and surgery.
- The person commits to the need for long-term follow-up.
- See recommendations 1.10.12 and 1.10.13 for additional criteria to use when assessing children, and recommendation 1.10.7 for additional criteria for adults. See also recommendations 1.11.1–1.11.3 for additional criteria for people with type 2 diabetes. [2006, amended 2014]
- The hospital specialist and/or bariatric surgeon should discuss the following with people who are severely obese if they are considering surgery to aid weight reduction:
    - the potential benefits
    - the longer-term implications of surgery
    - associated risks
    - complications
    - perioperative mortality.
    - The discussion should also include the person's family, as appropriate. [2006, amended 2014]
    - Choose the surgical intervention jointly with the person, taking into account:
    - the degree of obesity
    - comorbidities
    - the best available evidence on effectiveness and long-term effects
    - the facilities and equipment available
    - the experience of the surgeon who would perform the operation. [2006]
- There must be formalised Tier 4 Multidisciplinary Team led processes for the screening of co-morbidities and the detection of other significant diseases. These should include
    - identification, diagnosis, severity/complexity assessment, risk
    - Stratification/scoring and appropriate specialist referral for medical management. Such medical evaluation is mandatory prior to entering a surgical pathway.
- The individual has recently received and complied with a local specialist Tier 3 obesity service weight loss programme as set out in the NHS England commissioning policy.

Provide regular, specialist postoperative dietetic monitoring, including:

- Information on the appropriate diet for the bariatric procedure
- Monitoring of the person's micronutrient status
- Information on patient support groups
- Individualised nutritional supplementation, support, and guidance to achieve long-term weight loss and weight maintenance. [2006]

Arrange prospective audit so that the outcomes and complications of different procedures, the impact on quality of life and nutritional status, and the effect on comorbidities can be monitored in both the short and the long term.[11][2006, amended 2014]

- The surgeon in the multidisciplinary team should:
    - have had a relevant supervised training programme
    - have specialist experience in bariatric surgery
    - submit data for a national clinical audit scheme.[11] [2006, amended 2014]
    - Adults
- In addition to the criteria listed above, bariatric surgery is the option of choice (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m2 when other interventions have not been effective. [2006, amended 2014]
- Bariatric surgery for people with recent-onset type 2 diabetes

- Offer an expedited assessment for bariatric surgery to people with a BMI of 35 or over who have recent-onset type 2 diabetes[12] as long as they are also receiving or will receive assessment in a Tier 3 service (or equivalent). [new 2014]
- Consider an assessment for bariatric surgery for people with a BMI of 30–34.9 who have recent-onset type 2 diabetes [12] as long as they are also receiving or will receive assessment in a Tier 3 service (or equivalent). [new 2014]
- Consider an assessment for bariatric surgery for people of Asian family origin who have recent-onset type 2 diabetes[12] at a lower BMI than other populations (see recommendation 1.2.8) as long as they are also receiving or will receive assessment in a Tier 3 service (or equivalent). [new 2014]
- Revisional surgery (if the original operation has failed) should be undertaken only in specialist centres by surgeons with extensive experience because of the high rate of complications and increased mortality. [2006]

Exclusions to this specification (based on NICE Guidance (CG43)): This specification does not cover:

- Patients with a BMI under 35 kg/m2. *
- People with recent onset Type 2 diabetes who have not gone through appropriate Tier 3 services and do not meet the surgical acceptance criteria (all patients must have received intensive management in a Tier 3 service).
- Children and adolescents up to and including 17 years and 11 months.
- Routine follow-up after 2 years.

* There may be special clinical scenarios where urgent weight loss is required (prior to renal transplant or fertility treatment or cancer treatment or benign intracranial hypertension). These will arise from referral by another clinical MDT to a specialised complex obesity service. These patients may not have been through a Tier 3 service. However, if their clinical situation permits, they should undergo a minimum period of preparation, education, and clinical optimisation in the Tier 4 non- surgical specialised weight management service. These will be treated as exceptional cases and accelerated through the individual funding processes.

3.11 Interdependence with other services/providers

It is expected that appropriate communications will be in place between Tier 3 and Tier 4 providers pre-surgery; this is to include regular face to face/Microsoft Teams MDTs to discuss the treatment plan. Standardised documentation should be agreed (both ways) to ensure there are no missing components nor duplication of effort.

It is also expected that appropriate communications will be in place between Tier 4 and Tier 3 providers post-surgery.

Communications with primary care providers must also take place timely pre and post-surgery.

3.12 Facilities

Providers of Tier 4 Bariatric 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. Ideally, facilities for the complex obesity service will be separate from those for other patients 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 always maintained.

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 have class III obesity. The provider will make appropriate beds and scales available for patients with obesity and ensure that suitable imaging equipment is available.

The surgical service should have demonstrable arrangements for:

- Access to in-patient beds 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 where appropriate (if a patient is considered higher risk, and to have any real likelihood of needing level 2/3 care as part of their recovery, this patient should only be offered surgery at a facility with this resource available on-site). Where this is not the case providers will have robust plans in place for the safe transfer of patients requiring additional monitoring/support to a level 2 (or if appropriate level 3) critical care unit.
- Access to Intensive Therapy 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.
- Provision for revision procedures following assessment of previous outcomes for primary bariatric surgery.
- The training and education of all staff involved in the care and management of patients with class III obesity.
- The emergency assessment and treatment of post-operative complications (see 3.13 Emergency Pathway below).

3.13 Emergency Pathway (to be delivered by an NHS Acute Provider)

The following Emergency Pathway is to be delivered as part of the Tier 4 Bariatric Surgery Specification by an NHS Acute Provider with critical care facilities. For any other bariatric providers contracted to deliver this Specification, they must have robust links in place with the chosen Emergency Pathway provider.

The service should have robust arrangements for assessing and receiving Lancashire, Cumbria, and Merseyside patients with post-operative complications and their emergency management by a consultant bariatric surgeon, which should include;

- A clear point of contact and 24/7 access to a consultant bariatric surgeon for advice relating to post-operative complications

- Access to a fully staffed emergency theatre and critical care facilities on a 24 hour basis

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

- NICE Clinical Guideline 43: Obesity: the prevention, identification, assessment, and management of overweight and obesity in adults and children
- Obesity: identification, assessment, and management (CG189)
- National Bariatric Surgery Registry data standards and requirements accessed 2020 NBSR2020.pdf (e-dendrite.com)
- British Obesity & Metabolic Surgery Society (BOMSS) professional standards and commissioning guidance 2021 (update May 2019) https://bomss.org/wp-content/uploads/2021/08/Revised-BOMSS-Professional-Standards-and-Commissioning-Guidance-May-201....pdf
- 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 (2016)
- International Federation for the Surgery of Obesity: Guidelines for Safety, Quality, and Excellence in Bariatric Surgery (2008)

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

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

- https://www.eac-bs.com/site/index.php/ifso/sqe-guidelines

4.3 Applicable local standards

Key Service Outcomes

Commissioning Data and minimum data sets

The Commissioners require data on the services to benchmark the service against this specification and provide assurance on 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 will be required to have reporting systems in place and comply with the data requirements of the NHS National Obesity Audit due to introduced.

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.

Procedure mix undertaken, primary surgical procedures, revision procedures. Total and by ICB.

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.

Outcome Measures

For all patients referred to the Tier 4 bariatric surgery provider, there should be documentation of the patient's weight management history (engagement, attendance, duration, improvement in weight and co-morbidities) in specialised T3 weight management services and reasons for referral for bariatric surgery.

At least 90% of patients going for bariatric surgery should comply with all criteria as given in the Commissioning Policy document.

Patients are referred to Tier 4 Bariatric service when it is evident they meet the criteria as per NICE Clinical Guidance, including documentation of the patients weight management history (engagement, attendance, duration, improvement in weight and co-morbidities) in specialised Tier 3 weight management services and reason for referral. Options for treatment will include non-surgical and surgical pathways which will be assessed by the MDT in partnership with the patient. Performance of the Tier 4 Bariatric Service are therefore monitored by:

Co-morbidity improvement
Reduction in objective measures of identified co-morbidities, functional status improvement and lifestyle. To be monitored at 6-months, 12-months, 18-months, and 24-months post- surgery. Split by co-morbidity, e.g. type 2 diabetes, sleep apnoea, hypertension, asthma etc. Functional improvement can be monitored by increase in exercise tolerance, mobility. Life- style factors include increase in physical exercise, reduction/cessation of smoking and excessive alcohol intake.

Weight Loss
Weight should be recorded at onset of engagement with T3 weight management programme. Weight should be recorded at the time of assessment at surgical MDT and post-surgery (WL) by surgical procedure. Weight loss to be monitored at 6months, 12-months, 18-months and 24- months' post- surgery.
For patients undergoing surgery: At least 50% of excess weight should be lost at 12 -18 months and maintenance at 2 years.
Weight Loss for patients clinically unsuitable for surgery also to be monitored at 6months, 12-months, 18-months and 24-months post intervention.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements
See Schedule 4 of the draft contract.

5.2 **Applicable CQUIN goals**
The CQUIN scheme will be arranged in accordance with the latest published national guidance and contract technical guidance at the time of arranging the contract and will be set out in the relevant contract CQUIN schedule.

6. Location of Provider Premises

6.1 The Provider's Premises are located at:

TBC.

7. Individual Service User Placement

N/A.