1 SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No:	**SSX-LCS022**
Service	Tirzepatide Prescribing for Obesity 2025-26 (Implementation of NICE Funding Variation Cohort One in General Practice 2025-26)
Commissioner Lead	Garry Money Primary Care Director Dr Stephen Pike Clinical Director Dr Bruce Allan Clinical Director
Period	1.7.25 - 30.6.26
Date of Review	1.12.25

1. Population Needs
1.1 National/local context and evidence base All practices are expected to provide essential and those additional services they are contracted to provide to all their registered patients. This Locally Commissioned Service (LCS) specification for Tirzepatide Prescribing in General Practice outlines the more specialised services to be provided. No part of this specification by commission, omission or implication defines or redefines essential or additional services. This service must be provided in a way that ensures it is equitable in respect of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation. NHS England has published Interim Commissioning Guidance for the implementation of the NICE Technology Appraisal (NICE TA1026) and NICE Funding Variation for Tirzepatide (Mounjaro®) prescribing which describes management during the first three years of delivery within the NHS. The document details eligible patient cohorts, prioritisation strategy and phased implementation of Tirzepatide prescribing across specialist weight management services and primary care settings. Additionally, it outlines the funding allocations to Integrated Care Boards

(ICBs) to ensure effective delivery and equitable access to treatment across NHS systems in line with the NICE Funding Variation implementation approach.

The funding variation agreed for the implementation of NICE TA1026 recommends the roll-out of Tirzepatide prescribing in the NHS over a 12-year timeframe. Initially there will be identification of an eligible cohort of 220,000 individuals over the first three years as part of a phased introduction with the total eligible population having access within the maximum period of 12 years, based on cohort prioritization led by clinical need. Details of the initial cohorts in the first 3 years are detailed in the tables below.

Key points summary

- 23 June 2025 will see the beginning of access to the drug Tirzepatide (Mounjaro®) for the management of obesity in primary care settings to eligible patients.
- Tirzepatide will not be accessible to everyone who wishes to use it. People with the highest health risks and who meet the clinical criteria will be prioritised.
- From 23 June 2025, people who meet the qualifying criteria (a BMI of at least 40 and four of the five stated weight related comorbidities), will be able to gain access to the drug via primary care, if both patient and clinician agree it is the most appropriate treatment option.
- 'Access' on 23 June does not mean people will be able to get a prescription for Tirzepatide on that day. People living with obesity who meet the criteria will be able to explore with their healthcare professional whether this is the right treatment for them.
- Access to Tirzepatide via the NHS is for those at greatest risk of ill health, or who are experiencing severe ill health due to living with obesity. Access to the drug must be accompanied by wraparound care which will include support for people to make dietary changes and to increase physical activity.
- According to NICE's calculations, as part of its Technical Appraisal for Tirzepatide, 3.4 million patients would potentially be eligible for the drug, however the NHS does not have the services or existing resources to manage this number of people.
- Access to Tirzepatide will be phased in gradually through a special agreement (funding variation) between NICE and the NHS in England, to make sure primary care services are not overwhelmed and can manage the extra demand safely.
- The agreement between NICE and the NHS in England means 220,000 people living with obesity and obesity related comorbidities will be prioritised for access to Tirzepatide over the first three years.

- Tirzepatide might not be considered clinically suitable for everyone, and not everyone who meets the eligibility criteria will want to use it to support their weight loss. Other options are available including weight loss programmes which use tried and tested methods such as lifestyle changes and nutrition and physical activity advice; such as the NHS Digital Weight Management Programme, NHS Type 2 Diabetes Path to Remission Programme or the NHS Diabetes Prevention Programme

- This LCS is intended to fund the first 12 months of implementation (Cohort One - see table below). Implementation for Cohorts 2 and 3 will be supported by an updated LCS specification in June/July 2026.

National Context

Obesity is a growing public health concern in England. In 2022, 29% of adults were living with obesity (BMI ≥30 kg/m²), and 64% were overweight or living with obesity. The prevalence of obesity continues to rise. Obesity significantly increases the risk of developing several chronic conditions, including type 2 diabetes, cardiovascular disease, certain cancers, and musculoskeletal disorders, as well as being associated with reduced quality of life and increased mortality rates.

Despite public health initiatives and lifestyle interventions to address the rising prevalence of obesity and associated comorbidities, progress has been slow. For many adults, obesity is a chronic, relapsing condition, and while dietary changes, physical activity, and behavioural therapy play a role, achieving and maintaining substantial long-term weight loss can be a significant challenge. However, any period of weight reduction, for people living with obesity brings meaningful health benefits, including improved metabolic health, reduced cardiovascular risk, and enhanced quality of life. This underscores the importance of adjunctive therapies that complement lifestyle changes, offering individuals greater support to achieve sustained weight loss and long-term health improvements.

Pharmacotherapy for weight management - eligibility and funding variation

New pharmacotherapies for weight management offer a promising option for individuals who have not achieved clinically significant weight loss or sustained weight management with lifestyle and behavioural interventions alone. Given the impact on NHS resources, eligibility needs to be phased in across the entire eligible patient population as set out below.

Tirzepatide is recommended for managing obesity alongside a reduced calorie diet and increased physical activity in adults, in primary care settings and specialist weight management services, only if they have:

- an initial body mass index (BMI) of at least 35 kg/m2

(use a lower BMI threshold (usually reduced by 2.5 kg/m2) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds)
AND

- at least 1 weight-related comorbidity.

According to the eligible cohort outlined by NICE above, ICBs would have been required to meet the cost for funding access to Tirzepatide for an estimated 3.4 million people from 24 March 2025 (90 days from publication of the NICE TA1026). Accordingly, NHS England submitted a funding variation request, on behalf of NHS providers and ICBs, to extend the time needed to comply with the recommendations. NICE's guidance executive accepted that NHS England's funding variation request was justified and made amendments, as outlined in Section 4 "Implementation" of NICE TA1026.

Eligible patient cohort phasing and related setting of care

ICBs are required to meet the costs of funding access to Tirzepatide for the treatment of obesity in primary care settings from 23 June 2025, alongside other available treatment options, to certain patient cohorts on a phased basis. Tirzepatide will be made available **only** to prioritised cohorts (see tables below) in primary care settings during an initial phased implementation period, which reflects the available capacity in primary care. It will not be available for the treatment of obesity outside the prioritised cohorts.

The NICE Funding Variation recommends the identification of an eligible cohort (of 220,000 individuals) over the first three years as part of a phased introduction for delivering Tirzepatide. The total eligible population (estimated 3.4 million NICE TA1026) should have access within the maximum period of 12 years, based on cohort prioritisation led by clinical need. This approach to implementation focuses on managing primary care capacity and enabling access for patients with the highest clinical need. The approach considers comorbidities as the main qualifier in clinical prioritisation, in association with BMI, to phase access.

See table below for the phasing proposal for the initial 3 years of Tirzepatide implementation.

Table 1. Cohort Access Groups for Implementation in primary care Settings.

Funding Variation Year*	Estimated Cohort Duration	Cohorts	Cohort Access Groups	
			Comorbidities	BMI**
Year 1 (2025/26)	12 months	Cohort I	≥4 'qualifying' comorbidities hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, type 2 diabetes mellitus	≥ 40
Year 2 (2026/27)	9 months	Cohort II	≥4 'qualifying' comorbidities hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, type 2 diabetes mellitus	≥35 – 39.9
Year 2/3 (2026 and 2027/28)	15 months	Cohort III	3 'qualifying comorbidities hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, type 2 diabetes mellitus	≥ 40

** **Ethnicity:** There is an increased risk of health conditions at lower BMI thresholds in certain populations. The BMI applied to assess eligibility for Tirzepatide is adjusted by 2.5 kg/m2 in people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds to ensure equitable clinical prioritisation and access to appropriate treatment.

'Qualifying' comorbidities definitions

See table below

Table 2. Qualifying Comorbidities and Definitions for initial assessment.

Qualifying Comorbidities	Definition for Initial Assessment
Atherosclerotic cardiovascular disease (ASCVD)	Established atherosclerotic CVD (ischaemic heart disease, cerebrovascular disease, peripheral vascular disease, heart failure)
Hypertension	Established diagnosis of hypertension and requiring blood pressure lowering therapy
Dyslipidaemia	Treated with lipid-lowering therapy, or with low-density lipoprotein (LDL) ≥ 4.1 mmol/L, or high-density lipoprotein (HDL) <1.0 mmol/L for men or HDL<1.3 mmol/L for women, or fasting (where possible) triglycerides ≥1.7 mmol/L
Obstructive Sleep Apnoea (OSA)	Established diagnosis of OSA (sleep clinic confirmation via sleep study) and treatment indicated i.e. meets criteria for continuous positive airway pressure (CPAP) or equivalent
Type 2 diabetes mellitus	Established type 2 diabetes mellitus *

Tirzepatide for the management of obesity must not be prescribed outside this guidance.

Tirzepatide and Diabetes

People with type 2 diabetes can be prescribed Tirzepatide for glycaemic management but there are different eligibility criteria from those that apply to obesity.

- Tirzepatide for managing overweight and obesity (NICE Funding Variation)
- Tirzepatide for treating type 2 diabetes (NICE TA924)

The treatment goal is also different. In diabetes it is to use the dose that achieves glycaemic control. Where the indication is obesity, it is to achieve the maximum or maximally tolerated dose of Tirzepatide.

Some of those who qualify in the obesity cohorts may already be being treated with Tirzepatide for diabetes. As the dosing for obesity is to achieve the 'maximally tolerated dose' and the

dosing for diabetes is to 'achieve glycaemic control', it may still be appropriate to offer Tirzepatide to achieve 'maximally tolerated dosing' for obesity in those who qualify for obesity treatment but are already being treated (at lower doses) for diabetes.

See section 3.2

Financial allocations for implementation

Funding has been allocated in 2025/26 for the implementation of the NICE Funding Variation for the agreed (prioritised) patient cohort. All ICBs will receive a funding allocation for 2025/26 to cover the estimated additional cost, calculated to take account of two different components:

- Drug Costs: the cost of weight loss drugs in both primary and secondary care for the identified priority cohorts.
- Primary care patient management costs: funding to support service delivery within primary care, as a new setting of care.

The allocation is calculated based on obesity prevalence rates at ICB level. The allocation is fixed and will not be adjusted to take account of actual take up in year. It will not be ring fenced.

Separate funding will be retained centrally by NHS England to deliver the wraparound care required in primary care efficiently and quickly across all ICBs in 2025/26.

Models of Care for Primary Care Access

NICE TA1026 recommends primary care as a new care setting and point of access for Tirzepatide. To implement the NICE Funding Variation in primary care, NHS England suggests four implementation models for the safe and effective delivery of Tirzepatide for weight management in primary care, as follows:

1. Community / Local based delivery model
2. General Practice delivery model
3. Specialist weight management services provision of community outreach delivery model
4. Specialist weight management services Community & General Practice shared care model

ICBs have flexibility to select the model(s) which best meets their population's needs. NHS Sussex is pursuing option 2: the General Practice delivery model.

Wraparound care provision and access

For the delivery of the NICE Funding Variation in England all patients must be provided wraparound support which incorporates nutritional and dietetic advice as a minimum and access to behavioural change components, as a mandatory requirement to access treatment.

For 2025/26 the wraparound care service will be centrally funded, accessible from primary care settings from the 23rd June 2025 and will be exclusively for use by the identified priority cohort. Individual ICB funding for the wraparound care will be limited to the NHSE estimate of numbers eligible in each cohort.

The provider of wraparound care services in Sussex will be Xyla (the current provider of the National Diabetes Prevention Programme in Sussex) and the service will be known as the *NHS Behavioural Support for Obesity Prescribing Programme (BSOP)*

Patient management

For the management of patients in primary care, monthly face to face appointments with a suitably trained healthcare professional should be conducted during the titration phase, with structured medication reviews incorporated in the management pathway for at least the first 12 months of prescribing. All patient reviews should take a holistic approach, monitoring physical outcomes such as weight loss and associated recording of BMI, comorbidity indicators, consideration of de-prescribing, as well as potential adverse effects, including psychological impacts.

Prescribing and titration guidance

Prescribing of Tirzepatide for the management of obesity should align with the following guidance

- British National Formulary (BNF): Tirzepatide
- NICE TA1026 eligibility criteria
- NICE Funding Variation Tirzepatide
- NICE prescribing information for Tirzepatide
- Summary of product characteristics: Tirzepatide

Important advice on Tirzepatide and oral contraceptives

- FSRH statement: Glucagon-like peptide-1 (GLP-1) agonists and oral contraception
- glp1_contraception_hrt_article.pdf

Further information on initial assessment can be found in

- NICE “Practical guide to using medicines to manage overweight and obesity”
- NICE ”Initial assessment checklist”

Due to the current Black Triangle status of Tirzepatide, commissioners and prescribers are required to exercise extra caution to ensure the drug is appropriate and safe for each patient; prioritising comprehensive clinical evaluation and ongoing monitoring throughout the course of treatment. Healthcare professionals, the public, and pharmaceutical companies must report all suspected adverse drug reactions via the Yellow Card Scheme.

Further information on the follow up and monitoring required for Tirzepatide can be found in NICE “Practical guide to using medicines to manage overweight and obesity”

Reviewing and stopping prescribing

Unlike other NICE-recommended weight management medicines, which currently have a maximum prescription duration of 2 years, Tirzepatide does not have a set "stopping rule" or maximum treatment period, allowing for indefinite prescribing.

The decision to continue long-term prescribing should be made on a case-by-case basis. This decision must consider the clinical benefits and risks of treatment. If at least 5% of initial body weight has not been lost after 6 months at the highest tolerated dose, healthcare professionals should reassess the appropriateness of continuing treatment and consider alternative therapies.

Where a person has lost less than 5% of their initial weight after 6 months on the highest tolerated dose, the risks of treatment are likely to outweigh any benefits and discontinuation would be recommended.

Prescribing, reviewing and stopping Tirzepatide | Tools and resources | Tirzepatide for managing overweight and obesity | Guidance | NICE

Severe mental health, learning disabilities and autism

People with severe mental health conditions, a learning disability or who are autistic, are at higher risk of cardio-metabolic disease and will potentially benefit from weight management support and/or treatment through weight loss therapies, including Tirzepatide. These patients should be actively supported to access treatment unless there is a clinical reason not to do so. However, because people with severe mental health conditions, a learning disability, or who are autistic are not well represented in clinical trials, caution and heightened vigilance is advised.

Clinicians should be particularly aware of gastrointestinal side effects and the need to avoid constipation, which might be anticipated to be more severe and are commonly experienced by some patients who are co-prescribed antipsychotics.

Housebound

ICBs, and practices, should ensure appropriate delivery and support of equitable access to Tirzepatide for those who are housebound.

Recording and reporting of implementation and access

A national GP IT data entry template has been published to provide a structured approach for capturing essential data within current GP IT systems (EMIS and SystmOne).

Aggregated data (details awaited) will be requested by NHS England from ICBs in a standardised format, at four points in the first year of implementation, to inform on the prescribing of Tirzepatide for obesity.

Data collection timeframes are:

- Activity to end September 2025
- Activity to end December 2025
- Activity to end February 2026
- Complete 2025/26 activity

NICE will conduct a formal review of the implementation of the NICE Funding Variation to be completed within 3 years from the date of final guidance publication.

1.2 Implementation within Sussex / Possible limitations on service capacity

The preferred model of care for implementation in Sussex is through General Practice via a Locally Commissioned Service (LCS). This LCS will run from the 23rd June 2025 to 30th June 2026 to support implementation for Cohort One. Cohorts 2 and 3 will be supported by an updated LCS from June/July 2026.

NHSE have estimated that the number of patient numbers for Cohort One 2025/26 (see table 1 above), in Sussex is 884. NHSE have assumed 70% take-up making a treatment cohort of 619 for Sussex in 2025/26 and provided funding and wraparound care for that number.

Initial scoping searches in Sussex practices have provided an estimate of 1,962 eligible persons (0.11% of the population) for the whole of Sussex, which would equate (at 70% take-up) to a treatment cohort of 1,373.

NHSE provided wraparound care is a mandatory requirement of this pathway. At the time of publication NHSE intends to cap the capacity of wraparound care for Sussex in 2025/26 to their estimate of 619 persons.

It is likely therefore that, at some point during the 12 months of this LCS, the wraparound care capacity may be exceeded. NHS Sussex is working with NHSE on potential solutions to this issue and will be monitoring the activity under this LCS very closely.

In the event that there is a risk that the capacity of NHSE wraparound care is exceeded, NHS Sussex will inform practices in advance and request that further assessments and on-boarding is paused. Practices will be informed if further wraparound care capacity becomes available.

In addition, in order not to overwhelm the available wraparound service in year, practices are requested, where possible, to spread practice activity evenly throughout the year.

2. Outcomes

2.1 NHS Outcomes Framework Domains and 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

- That all those qualifying for NHS funded Tirzepatide for weight loss as defined in the NICE Funding Variation shall be identified and, where appropriate, offered treatment.

3. Scope

3.1 Aims and objectives of service

The aim of this LCS is to implement Tirzepatide treatment for weight loss in general practice according to NHS England guidance, as follows

- Interim commissioning guidance
- NICE Technology Appraisal (NICE TA1026)
- NICE Funding Variation

3.2 Population covered, exclusions and eligibility

All patients registered with any Sussex GP practice are eligible.

This LCS applies to Cohort One only (see Tables 1 & 2 above) as per the NICE Funding Variation It is intended that a further amended LCS will be published for Cohorts 2 and 3 in June/July 2026.

3.2.1 Patients already treated with Tirzepatide for a Diabetes indication, or Privately for an Obesity indication

Some of those identified in the eligible cohorts may already be being treated with Tirzepatide (or another GLP-1 inhibitor), either for a diabetes indication (usually on the NHS) or obesity indication (privately). The aim of the pathway supported by this LCS, for the cohorts described, is specifically to prescribe Tirzepatide in a maximum dose (15mg), or maximally tolerated dose, for the indication of obesity.

Where current treatment is Tirzepatide, but not in a maximal dose, patients are eligible for the service described in this LCS if they meet the NHSE cohort criteria. This is described in more detail and in the table below.

- Those already on a maximum (or maximally tolerated) dose of Tirzepatide are not eligible for this LCS but, if this is currently prescribed privately, and eligibility criteria are met, may continue Tirzepatide prescriptions on the NHS (under GMS, no special monitoring required)

- Those already prescribed Tirzepatide for a diabetes indication who are not on the maximum (or maximally tolerated) dose are eligible for assessment and treatment under this LCS **only** if they meet the NHSE cohort criteria.

- Those being prescribed Tirzepatide privately who are not on the maximum (or maximally tolerated) dose are eligible for assessment and treatment under this LCS but must provide evidence of their initiation BMI from their private provider.

- Those already prescribed another GLP-1 inhibitor are eligible to be assessed and treated under this LCS.

Patient meets NHSE cohort criteria (BMI > 40 and 4 out of 5 comorbidities)	No GLP-1 inhibitor	Eligible for LCS
	Tirzepatide (diabetes indication): NOT maximum or maximally tolerated dose	Eligible for LCS
	Tirzepatide (diabetes indication): on maximum or maximally tolerated dose	Not eligible for LCS Continue prescribing (Diabetes LCS / GMS)
	Other GLP-1 inhibitor	Eligible for LCS
	Private Tirzepatide: maximum or maximally tolerated dose	Not eligible for LCS Eligible for continued NHS prescribing (GMS)
	Private Tirzepatide: not maximum or maximally tolerated dose	Eligible for LCS

- Patients on Tirzepatide for a diabetes indication who do not meet the cohort eligibility criteria for an obesity indication must not have dose increases beyond those that achieve HbA1c reduction.

3.3 Addressing inequalities

NHS Sussex is committed to reducing health inequalities, particularly in Sussex's most deprived communities and amongst population groups which have the poorest health outcomes.

Obesity is more common in lower socioeconomic groups and is associated with reduced workforce participation and social mobility, lower earnings and barriers to career progression thus compounding socioeconomic inequalities. These interventions aim to improve health outcomes, reduce long-term costs to both the NHS and society, ultimately striving to improve both individual well-being and economic sustainability.

There is an increased risk of health conditions at lower BMI thresholds in certain populations. The BMI applied to assess eligibility for Tirzepatide is adjusted by 2.5 kg/m2 in people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds to ensure equitable clinical prioritisation and access to appropriate treatment.

This service must be provided in a way that ensures it is equitable for patients in respect of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation.

Additional resources: Translation and interpreting - NHS Sussex (ics.nhs.uk)

3.4 Service description / care pathway

3.4.1 Practice Clinical Lead and Training

The practice must nominate a clinical lead who has overall responsibility for ensuring the clinical requirements of this specification are met, and that all clinicians delivering direct patient care are suitably trained. As Tirzepatide is already available for a diabetes indication practices may wish to consider their diabetes clinical lead for this role. The clinical lead does not need to be a GP but should be a prescriber.

It is the responsibility of clinical lead and practice to stay informed and up to date with the latest guidelines and prescribing recommendations for weight management treatments, including Tirzepatide.

NHS Sussex intends to provide an educational webinar (which will be recorded). This is intended to assist training, but attendance is not a mandatory requirement for the provision of this LCS

3.4.2 Guidance

All clinicians delivering this service should be familiar with, and adhere to, the following guidance

National

- British National Formulary (BNF): Tirzepatide
- Overview | Overweight and obesity management | Guidance | NICE
- Tirzepatide: NICE Technology Appraisal (NICE TA1026)
- NICE Funding Variation
- Tirzepatide interim commissioning guidance
- NICE prescribing information for Tirzepatide
- Summary of product characteristics: Tirzepatide
- NICE "Initial assessment checklist"
- NICE TA924: Tirzepatide for treating type 2 diabetes

Sussex

- Weight management - NHS Sussex
- Sussex Health and Care: Support to manage your weight

Important safety information

- FSRH statement: Glucagon-like peptide-1 (GLP-1) agonists and oral contraception
- Drug Safety Updates (GOV.UK)
    - GLP-1 and dual GIP/GLP-1 receptor agonists: potential risk of pulmonary aspiration during general anaesthesia or deep sedation (GOV.UK)
    - GLP-1 receptor agonists: reminder of the potential side effects and to be aware of the potential for misuse (GOV.UK)
    - GLP-1 receptor agonists: reports of diabetic ketoacidosis when concomitant insulin was rapidly reduced or discontinued (GOV.UK)

Further information

- BMA Focus on Tirzepatide for Weight Management
- NHS England: Patient information Weight management injections

3.4.3 Cohort identification

The tables above (tables 1 and 2) describe the population cohorts to be assessed and offered Tirzepatide treatment for weight loss in the first 3 years.

Searches are provided (via Ardens) to identify each cohort which can be accessed as follows,

EMIS Web:

Population Reporting > Ardens Searches > 5.30 Contracts - National (Misc) > Obesity Medication Pathway

SystmOne:

Clinical Reporting > Contracts | 2025 26 | NHSE | Obesity Medication

According to NHS Sussex estimates, a practice with a list size of 10,000 might expect to identify 11 persons in cohort 1 although there is likely to be wide variation.

As the patient cohorts are likely to be small, practices may wish to consider providing the service in buddying arrangements or in PCN footprints.

3.4.4 Service capacity management

NHSE provided wraparound care is a mandatory requirement of this pathway. NHSE currently intends to cap the capacity of wraparound care for Sussex in 2025/26 to their estimate of 619 persons, whereas NHS Sussex estimates suggest that there may be significantly more people eligible.

It is possible therefore that, at some point during the 12 months of this LCS, the wraparound care capacity may be exceeded, at which point practices would not be able to commence prescribing without wraparound care. NHS Sussex is working with NHSE on potential solutions to this issue.

NHS Sussex will monitor activity under this LCS closely and, in the event that there is a risk that the capacity of NHSE wraparound care is exceeded, will inform practices in advance and request that further assessments and on-boarding is paused. Practices will be informed if further wraparound care capacity becomes available.

In addition, in order not to overwhelm the available wraparound service in year, practices are requested to spread activity evenly throughout the year where possible and at their own discretion.

3.4.5 Pathway

The pathway followed for those who are new to Tirzepatide and those who are already prescribed, either privately or for a diabetes indication (see section 3.2.1), will differ. In essence, those already prescribed are likely to

- Only require abbreviated initial assessment and follow-up
- Not require self-administration education

The pathway should be tailored to the individual patient circumstances at the discretion of the practice.

Background

Tirzepatide (Mounjaro) is administered via pre-filled pens. The medication is injected under the skin, typically in the abdomen, thigh, or upper arm. The recommended starting dose is 2.5 mg, with gradual dose increases of 2.5 mg every 4 weeks until the target dose is reached. If gastrointestinal side effects become intolerable, the dose may be reduced. The goal is to reach the highest tolerated dose, which is often the maximum dose of 15 mg for most individuals. Dose escalation and de-escalation should be carefully monitored.

Tirzepatide treatment for weight loss must be part of a broader wraparound obesity management service, which includes lifestyle counselling, diet and exercise support, and other necessary interventions.

Tirzepatide for weight loss must only be prescribed on the NHS according to the cohort identification criteria above. It must not be prescribed outside these guidelines.

Implementation in general practice

For payment purposes (see sections 5/6) the pathway can be considered to be in two parts,

- Assessment and on-boarding
- Follow-up and completion

The pathway is over a 12 month timeframe.

1: Assessment and On-boarding

Having identified the cohort (using searches provided), the following steps should be followed.

- Offer assessment to those identified as eligible (unless there is a clear reason for not doing so). Practices are requested, where possible, to spread on-boarding activity evenly over the year

- Arrange bloods (unless done recently)
    - FBC Elecs LFT TFT
    - HbA1c Lipids

- Face to face assessment with a suitably trained clinician (usually but not limited to a GP but must be a prescriber). The aim is to enable the patient to make an informed decision regarding the treatment of obesity. Recommended 30 mins.

  Other treatment options should be discussed (for example bariatric surgery where appropriate).

The NICE "Initial assessment checklist" may be helpful.

The initial assessment should include the following.

- An assessment as to the suitability of treatment
- A full medication review, including review of HRT and contraception if appropriate
- Contraception/HRT:
    - Those taking Tirzepatide should switch to a non-oral method, or add a barrier method, for four weeks after initiation and four weeks after each dose increase. If appropriate, discuss any plans for pregnancy.
        - NICE guidance: pregnancy and contraception section for further information. Tirzepatide is not recommended in pregnancy and should be stopped if pregnancy occurs or is planned.
        - FSRH statement: Glucagon-like peptide-1 (GLP-1) agonists and oral contraception
    - Transdermal oestrogen is preferred in women with obesity and in those using GLP-1 agonists. This is because of risks resulting from the obesity and the lack of interaction if this route is used.
      There is little data on the interaction between GLP-1 agonists and progestogens used in HRT; transdermal or vaginal routes are unlikely to interact, but GLP-1 agonists delay gastric emptying and may therefore reduce absorption of oral progestogens.
- Advise people on potential adverse effects.
    - There is a risk of gastrointestinal adverse effects with Tirzepatide, which are common but usually non-serious. Some adverse effects can lead to serious complications such as severe dehydration, resulting in hospitalisation. Advise people to stay well hydrated to avoid dehydration, especially after any vomiting or diarrhoea. The incidence of nausea, vomiting and diarrhoea are usually higher during the dose escalation period and decreases over time. Other serious but less common adverse effects include gallstone disease and allergic reactions.
    - Acute pancreatitis has been reported in people having Tirzepatide treatment. Inform the person about the symptoms of acute pancreatitis and advise them to seek immediate medical help if they develop sudden, severe abdominal pain.
    - Because of the potential risk of pulmonary aspiration during general anaesthesia or deep sedation, tell people using Tirzepatide to inform their

healthcare team, including the anaesthetist, about this before any surgical procedure.

- Provision of written patient information such as the Mounjaro patient booklet

If patient suitable, fully informed and consents to treatment, enrol patient on Tirzepatide treatment programme:

- Referral to NHS wraparound support service (mandatory).
  Sussex patients should be referred by sending the 'NHS Behavioural Support for Obesity Prescribing' (BSOP) form (published in Ardens) to scwcsu.sussexeastsurrey-bsop@nhs.net

  (This service will report to practices at the following points

  - Referral received
  - Programme start
  - Not started – discharged
  - Not completed – discharged
  - Completed)

- Prescribe starting dose of Tirzepatide (2.5mg) informing the patient that each pen contains 4 doses.

- Prescribe compatible needles and supply Sharps bin.
  The most cost-effective needle should be selected.
  Please refer to the Sussex Partner Formulary and the following guidance.
  - PrescQIPP Bulletin 229 - Diabetes pen needle prescribing for pre-filled and reusuable insulin and GLP-1 receptor agonist pens
  - PrescQIPP Bulleitn 229 - Diabetes pen needle prescribing for pre-filled and reusable insulin and GLP-1 receptor agonist pens briefing
  - What needles are recommended for the Mounjaro® KwikPen®?

At this point practices may wish to await confirmation that the patient has been enrolled successfully in the wraparound support service before proceeding to make the next appointments, as follows

- GLP-1 self-administration education and first dose (for GLP-1 naive patients only)

- Follow up appointment 4 weeks after first dose (or after enrolment if already on Tirzepatide)

2: Follow-up and Completion

- Appointment for GLP-1 self-administration education and first dose (if required).

    - This should be with a suitably trained clinician who is likely to be a trained diabetes nurse. Recommended 15 minutes.

      GLP-1 initiation is also part of the NHS Sussex: Improving diabetes care LCS | SSX-LCS033. In line with the Diabetes LCS,

        - *GLP-1 (Glucagon-like peptide-1) analogue initiation can be provided safely and conveniently in General Practice.*
        - *Practices who do not provide this service directly are encouraged to ensure access to this service for their registered patients through buddying arrangements with other practices or via PCN provision.*
        - *Appointments must be with a suitably qualified clinician (see section 3.4.1 NHS Sussex: Improving diabetes care LCS | SSX-LCS033) who must provide 6 or more initiations per annum*
        - *The first injection should be given in the presence of the healthcare professional*
        - *Provision of Sharps bin and relevant information.*

    - Refer patients to the Tirzepatide user manual

    - The company has also produced a document for healthcare professionals to help troubleshoot common KwikPen issues.

    - GLP-1 training resources if required will be published in the Sussex Training Hub

- Up to 12 follow up appointments at 4-week intervals with a suitably trained clinician. Recommended 10 minutes each

    - This does not need to be with a GP but, as a minimum requirement, the clinician must be suitably trained and there should be easy access to, and clinical oversight from, a prescriber as part of the appointment.

    - The appointment may be remote or face to face, but patient preference should be considered.
        - Where the clinician needs to verify the weight, the patient should be weighed at the practice.

    - Commissioning guidance states that during dose titration the patient should be followed up every 4 weeks for 12 months. For the purposes of this LCS a **flexible approach** may be taken to the actual number of follow up appointments required for an individual patient. The aim is to achieve the maximum (15mg), or maximally

tolerated dose, with a final assessment of efficacy after 6 months on maximal dose and this principle should be adhered to wherever possible. However, there may be individual circumstances where patient and clinician agree follow up after 8 or 12 weeks for example.

The review should cover the following issues. The NICE: Tirzepatide monitoring checklist may be helpful.

- Check patient remains engaged with wraparound service. Patients who do not engage with this part of the service should be withdrawn from this pathway / LCS and no further prescriptions issued. Continued engagement with the wraparound service is mandatory.

- Wellbeing check, Weight, BMI, %weight loss

- Side-effects

- Medication review

    - Dose of concomitant insulin or sulfonylurea may need to be reduced

    - Tirzepatide delays gastric emptying, particularly following the first dose. This has the potential to slow the rate of absorption of concomitant oral medicines. The risk of a delayed effect should be considered for oral medicines where a rapid onset of action is important. Monitor patients on oral medicines with a narrow therapeutic index, especially at the start of Tirzepatide treatment and after dose increases (BNF).

- If appropriate, discuss contraception and any plans for pregnancy. See

    - NICE guidance: pregnancy and contraception section
    - FSRH statement: Glucagon-like peptide-1 (GLP-1) agonists and oral contraception

  Tirzepatide is not recommended in pregnancy and should be stopped if pregnancy occurs or is planned.

- Discuss realistic and safe weight loss goals. Weight loss of 0.5 kg to 1 kg a week is generally considered to be safe and sustainable but should be tailored to the individual. For example, people with type 2 diabetes may lose weight at a slower rate than people without the condition. In older people, a slightly higher BMI can have a protective effect (for example,

reducing the risk of all-cause mortality). When discussing weight loss goals with the person, consider comorbidities the person has that may improve, and any personal goals the person has discussed with you (such as having more energy to do the things they enjoy or to find it easier undertaking personal care).

- Where appropriate consider treatment to target for hyperlipidaemia and hypertension.
- Increase Tirzepatide dose by 2.5mg if tolerated (to maximum 15mg).
- Provision of next prescription(s).

  No repeat prescriptions should be accessible during the first 12 months of treatment (although it is acceptable to provide 8- or 12-weeks medication if the next follow up has been arranged for 8 or 12 weeks).

- Completion
  - At the end of 12 months the benefit of continuing treatment should be assessed. A face-to-face appointment at this stage is recommended (but not mandatory).
  - Discontinuation is recommended if at least 5% of initial body weight has not been lost after 6 months at highest tolerated dose. See the following guidance,

    Prescribing, reviewing and stopping Tirzepatide | Tools and resources | Tirzepatide for managing overweight and obesity | Guidance | NICE

    If a person has lost less than 5% of their initial weight after 6 months on the highest tolerated dose, the risks of treatment are likely to outweigh any benefits.

    The continuation of Tirzepatide prescribing after this pathway has completed,

    - requires no special monitoring other than appropriate medication review at least annually
    - is a GMS service

Summary of Practice Requirements

- *Clinical Service Lead*
- *All clinicians delivering service to be suitably trained*

- *Service compliance with guidance and pathway as described*
- *Spread practice activity evenly over the year if possible*
- *Data returns, monthly*
- *Claims must be accurate*
- *Annual quality assurance self-declaration*

3.5 Data requirements, Audit and Quality Assurance

Aggregated data will be requested by NHS England from ICBs in a standardised format, at four points in the first year of implementation, to inform on the prescribing of Tirzepatide and the management of patients.

The NHSE data collection timeframes are:

- Activity to end September 2025
- Activity to end December 2025
- Activity to end February 2026
- Complete 2025/26 activity

The data requirements are currently unknown. This specification will be updated when they are known. Where possible data will be submitted by practices through Apex Contract Manager.

Data must be submitted by practices monthly.

3.6 Interdependence with other services/providers

All LCSs, as they are list-based services, are offered to individual practices in the first instance.

To ensure LCSs are accessible to as many patients in Sussex as possible,

- Practices may choose to put buddying arrangements in place, in agreement with another practice (or practices) where it is appropriate to do so.
- Practices may choose to deliver services at PCN level (with the agreement of the other practices in the PCN).

In each case, the practice delivering the service (or the lead practice if PCN based) should claim for the service delivered.

Practices may also subcontract LCSs to GP federations, but this will require prior approval from the commissioner.

As initial patient numbers in this LCS are relatively low, practices may wish to explore delivering the service at PCN level.

4. Applicable Service Standards

The Practice is responsible for ensuring that,

- **Premises** used are registered with the Care Quality Commission (CQC) and the service is provided in a suitable setting
- **Equipment** meets all criteria set out in national and local guidance and is maintained in line with manufacturer's guidance
- **Training** meets all relevant criteria set out in national and local guidance
- **Serious Incidents** within this service are reported to NHS Sussex
- **Infection Control Guidance** is adhered to
- **Privacy and Dignity Guidance** are adhered to
- **Health and Safety** standards are met
- **Information Governance** standards are met
- **Safeguarding Adults, Children and Looked After Children Guidance** is adhered to including statutory training
- **Mental Capacity Act** - the Mental Capacity Act 2005 (MCA) is designed to protect and empower people who may lack the mental capacity to make their own decisions about their care and treatment. It applies to people aged 16 and over.

4.1 Applicable national standards (e.g., NICE)

See service specification

4.1.1 Infection control

Practices must ensure that latest national infection control and prevention guidance is adhered to. Please follow current national guidance which includes, but not exclusive of the following:

- Infection Prevention Society Guidance – National Guidance for England
- Healthcare associated infections- Prevention and Control in Primary and Community Care – National Institute for Health and Care Excellence (NICE) [CG139]
- Infection Prevention and Control Quality Standards – NICE [QS61]
- Health and Social Care Act 2008: code of practice on the prevention and control of infections – Department of health and Social Care
- Coronavirus Primary Care – National Health Service England and NHS Improvement
- National Standards of Healthcare Cleanliness

Other resources and information can be found locally at NHS Sussex intranet page:
Infection prevention and control - NHS Sussex (ics.nhs.uk)

4.1.2 Chaperoning, privacy, and dignity

- GMC guidance: Intimate examinations and chaperones
- CQC guidance: Chaperones

4.1.3 Quality

Practices must comply with all the National Quality Requirements as set out in the NHS Standard Contract

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

See service specification

4.3 Applicable local standards

See service specification

4.3.1 Quality Requirements

- Significant Event incidents related to this service should be reported as SEAs (Significant Event Audit) and learning shared within the practice.
- Serious incidents related to this service must be reported to the NHS Sussex Patient Safety Team
- GP practices should adopt and apply the Patient Safety Incident Response Framework (PSIRF) principles, as outlined in the NHS Sussex PSRIF Policy:
    - Compassionate engagement and involvement of those affected
    - A system-based approach to learning
    - Considered and proportionate responses
    - Supportive oversight focused on strengthening response systems and improvement
- Practices should report patient safety events on the Learn from Patient Safety Events (LFPSE) service
- Important, potentially recurrent, problems involving other providers should be submitted to PQIT (Provider Quality Improvement Tool)
- Clinical Governance arrangements for this service are as set out in Schedule 5 of the NHS Standard Contract. In addition, the practice is required to evidence an effective system of clinical governance and put in place appropriate and effective arrangements for quality assurance, continuous quality improvement and risk management.
- Where appropriate, patient satisfaction feedback about the service should be offered to all patients accessing this service and quality improvements should be made as an outcome of this feedback.

- As part of the annual quality assurance process, the practice is required to make an annual

quality assurance self- declaration that it has met the requirements of this LCS. A copy of the self-declaration form will be available on the NHS Sussex intranet. This may cover elements pertaining to the

- Service specification
- Service standards
- Training
- Audit standards

NHS Sussex is responsible for commissioning high quality, safe and effective care for the population of Sussex. It is vital that the organisation maintains good governance in the decisions it makes.

To ensure that NHS Sussex receives assurance that the services it commissions are provided according to specifications, and that practices fulfil the requirements within, an annual Quality Assurance Self-Declaration for LCSs has been developed whereby GP-practices are required to complete and return to NHS Sussex.

The Quality Assurance Self-Declaration was developed in collaboration with NHS Sussex Quality Team, and is aligned to the three main quality domains:

- Patient safety
- Patient experience
- Clinical effectiveness

The annual Quality Assurance Self-Declaration for LCSs aims to provide GP practices with a system for identifying areas for improvement and a support mechanism to make those improvements.

The self-declaration will enable practices to identify areas requiring improvement and will enable NHS Sussex to focus on identifying possible areas requiring further development, training, and support.

Practices are required to submit the Quality Assurance Self-Declaration annually, and upon review, in conjunction with the Quality Team, feedback reports will be provided to primary care to encourage engagement and a culture for improvement.

Where forms have not been received by the required deadlines (as published with the annual QASD), NHS Sussex reserves the right to pause LCS payments to the practice pending receipt.

4.3.2 Equipment

- The handling of consumables and associated activities (e.g., procurement, storage, prescribing, decontamination, and disposal of consumables) must be safe and in line with current legislation, licensing requirements, good practice, and any national guidelines
- Equipment must meet all criteria set out in national and local guidance and be maintained in line with manufacturer's guidance
- The provision of bariatric scales, if required, is the responsibility of the practice.

4.3.3 Safeguarding

Practices must have appropriate Safeguarding Policies, Procedures and Governance arrangements in place which comply and reflect the principles of the Pan Sussex Safeguarding Procedures (Children and Adults) and adhere to all Safeguarding and Looked After Children related Legislation. In addition, Practices must meet all regulatory safeguarding requirements (including CQC Regulation 13) and those as specified within the Sussex NHS Commissioners Primary Care Safeguarding Standards.
Mental Capacity guidance available on NHS Sussex intranet: Mental Capacity - NHS Sussex (ics.nhs.uk).

4.3.4 Medicines

Practices should be familiar with and comply with local guidance

- Sussex formulary

Each multiple dose pre-filled pen of Tirzepatide (irrespective of strength) contains 4 doses of 0.6ml solution which can be administered. Tirzepatide is administered weekly, therefore each multiple dose pre-filled pen provides sufficient medicine for one month (28 days).

4.4 Training requirements

It is the practice's responsibility to ensure that all personnel involved in delivery of this LCS are familiar with the requirements and any relevant guidance.

Training should be recorded and made available as evidence if required. Practices should update training as per LCS speciality and specification.

Professionals delivering any part of this LCS must be suitably trained and accredited. This can be achieved through

- Self-directed learning
- In house practice or PCN learning events
- NHS Sussex educational events (where available)

There are no specific training requirements for this LCS other than those described in section 3.4.1

Practices are expected to complete an annual self-declaration stating that all relevant staff and clinicians have been, or are planning to be, appropriately trained (see section 4.3.1).

The Sussex Training Hub (STH) will support training requirements for Locally Commissioned Services by providing, commissioning or sign-posting relevant education and training resources. Practices are not obliged to access training from STH and may obtain relevant training from other (ICB approved) sources.

Training and familiarisation costs are provided to the practice as part of this specification as per section 6.

5. Coding, Records, Data Quality and Audit

5.1 Coding

Practices must use the NHS Sussex approved code set as described below

NHS obesity medication pathway started *This code should be used to indicate that a patient is eligible for payment B under 'Assessment and On-boarding' (see section 6)*	2386231000000101
Referral to NHS obesity medication wraparound support pathway	2386201000000107
NHS obesity medication pathway declined	2386241000000105
Unsuitable for NHS obesity medication pathway	2386221000000103
Incretin mimetic therapy started *This code may be used to indicate GLP-1 initiation. The code 'Enhanced services administration' should NOT be entered on the same day as part of this pathway or may trigger 'double' payment under the Diabetes LCS*	702542006
Review of anti-obesity drug therapy *This code should be used to indicate each follow up appointment*	2386251000000108
NHS obesity medication wraparound support pathway completed *This code should be used to indicate completion of the pathway and eligibility for payment C 'Follow up and Completion' (see section 6)*	2386261000000106
Codes included in the Ardens 'NHS Obesity Medication Pathway' template	

At present practices must make claims manually monthly using the manual claim form provided (see section 6). It is expected that the first claims will be submitted in August for all activity from 1st July 2025 and the link to the claim form is provided here.

Practices must have systems in place to ensure that claims data is accurate.

5.2 Records

Adequate records must be maintained to provide an audit trail for post payment verification purposes.

5.3 Data Quality

Practices are recommended to use the 'NHS Obesity Medication Pathway' data entry template provided through Ardens.

5.4 Audit and Data submission requirements

Practices must submit claims and data submissions monthly via the agreed NHS Sussex electronic payment and submissions portal (Apex Contract Manager).

Regarding the submissions' portal,

- No patient identifiable information is submitted.
- Code-sets submitted are and will be absolutely limited to those described in this specification. No additional codes or data not specified in this LCS will be submitted or collected.
- Practices must ensure that data is accurate before submission.
- Data submitted via the electronic portal may be
    - used to feedback to practices on their performance
    - shared with other practices/PCNs

6. Payment/Claiming

Claims for payment must be submitted monthly using the manual claim form available here

Practices must also submit data monthly via Apex Contract Manager. This data will not (at least initially) be used for payment purposes but will be used to inform future commissioning decisions.

Practices will be paid as follows.

Payment will be in 3 parts,

A: Engagement Preparation and Implementation	£360.87 per practice
B: Assessment and Onboarding	£66.20 per patient
C: Follow up and Completion	£112.86 per patient

A. Practice engagement preparation and implementation will be paid on sign-up and includes the following
    - Clinical lead time
    - In house training and familiarisation
    - Running initial reports and initial review of records

B. Initial assessment and on-boarding fee payable on completion of the initial assessment (whether the patient continues to treatment or not), and includes
    - Service offer
    - Initial assessment

C. Follow up and completion will be paid for all patients completing the treatment pathway (regardless of how many appointments are required to reach 'completion') and includes the following,
    - GLP-1 administration education appointment (where appropriate)
    - Review appointments (maximum 11)
    - Completion appointment

    There will be patients who may enter or leave this part of the pathway at different points, for example
    - Those already on a lower dose of tirzepatide (diabetes indication or privately) who do not require the GLP-1 appointment and only require a reduced number of follow-up appointments to reach maximum dose
    - Those who were tirzepatide naive but drop out due to side effects or disengage from the wraparound support
    - Those who were tirzepatide naive and require a GLP-1 appointment, all 11 follow up appointments and a completion appointment
    - Those who leave the practice during the pathway
    - Those who newly register with the practice when part way through part C of the pathway

    For the avoidance of doubt, this fee (C) is payable for any patient who has entered this part of the pathway and engaged with the wraparound support service, regardless of how many appointments actually take place. The fee becomes payable when the patient leaves the pathway (or practice).

Practices whose claims are at variance with expectations may be asked to submit additional evidence to support past or future claims.

NHS Sussex reserves the right to check practice held information at any time to support post-payment verification.

Prices will be uplifted annually in negotiation with the LMC. Practices will be notified of any changes in price.

Late or inaccurate claims

Where a practice is aware of any delay or inaccuracy in claims it should notify the primary care contracting team without undue delay.

- Submissions must be made promptly to ensure timely payment. Where submissions pertaining to activity during any given quarter are not made before the end of the

subsequent quarter,
    - payment may be significantly delayed
    - practices may be asked to give a reasonable explanation and provide supporting evidence for the claim
- Where there are claims or data submissions that cannot be submitted using the electronic submissions portal, practices should contact sxicb.sussex-lcs-claims@nhs.net or as described on the NHS Sussex intranet

Past overpayments will be recovered over a reasonable timeframe in agreement with the practice.

7. Termination

7.1 Termination

Unless otherwise notified, this Locally Commissioned Service terminates on 30th June 2026. Practices should note that it is intended to publish a revised LCS to include cohorts 2 and 3 to commence on 1st July 2026.

The service may be terminated by either NHS Sussex or the Practice through the service of three months' notice.

Where the practice serves notice, it must continue the 'follow-up and completion' part of the pathway to completion for any individual patient who has already entered that part of the pathway. No alternative provision will be made available by NHS Sussex.

NHS Sussex may require the practice to suspend the provision of the service immediately if it has reasonable grounds for believing that patient health or safety is at risk because of continuing provision of this service.

The LCS may be subject to review by NHS Sussex at any time during the term of the service. Breaches and terminations will be managed in accordance with the NHS Standard Contract.