

# Interim commissioning guidance

Implementation of the NICE Technology Appraisal TA1026 and the NICE funding variation for tirzepatide (Mounjaro®) for the management of obesity.

This interim commissioning guidance provides a framework for commissioners to implement the NICE Technology Appraisal (NICE TA1026) and NICE Funding Variation for tirzepatide (Mounjaro®) for the management of weight during its first three years of delivery within the NHS. The document details eligible patient cohorts, prioritisation strategy and phased implementation of tirzepatide (Mounjaro®) 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.

#### **National Context**

Obesity is a growing public health concern in England, with 29% of adults living with obesity (BMI  $\geq$ 30 kg/m<sup>2</sup>), and 64% living with overweight or obesity.<sup>1</sup> The prevalence of obesity continues to rise, driven by a multiple factors such as diet, sedentary lifestyles, socioeconomic inequalities and genetic predispositions. Obesity significantly increases the risk of developing several chronic conditions, including type 2 diabetes, cardiovascular disease, certain cancers, and musculoskeletal disorders,<sup>2</sup> as well as being associated with reduced quality of life and increased mortality rates.

<sup>&</sup>lt;sup>1</sup> NHS England. (2024). *Health Survey for England, 2022 Part 2.* Available at: <u>https://digital.nhs.uk/data-and-information/publications/statistical/health-survey-for-england/2022-part-2</u>

<sup>&</sup>lt;sup>2</sup> Fruh, S. (2017). Obesity: Risk factors, complications, and strategies for sustainable long-term weight management. *Journal of the American Association for Nurse Practitioners*. 29: 3-14. Available at: 10.1002/2327-6924.12510

The rising prevalence of obesity imposes a significant economic burden on the NHS and the wider economy, costing the NHS approximately £11.4 billion annually<sup>3</sup>, with this figure projected to increase with rising obesity rates and related comorbidities. Further, the wider societal impact of obesity-related ill health costs such as lost productivity, unemployment, and social care amounts to an estimated £74.3 billion per year.<sup>3</sup>

Obesity is associated with reduced workforce participation and social mobility, lower earnings and barriers to career progression thus compounding socioeconomic inequalities.<sup>4</sup> The increasing strain on NHS primary care, specialist services, and hospital admissions<sup>5</sup> underscores the need for more cost effective, scalable and innovative treatments and management approaches. 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.

Despite public health initiatives and lifestyle interventions to address the rising prevalence of obesity and associated comorbidities, progress has been slow.<sup>6</sup> 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.<sup>7</sup>

However, any period of weight reduction, for people living with overweight or obesity brings meaningful health benefits, including improved metabolic health, reduced cardiovascular risk, and enhanced quality of life.<sup>6</sup> 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.

https://www.gov.uk/government/publications/life-sciences-healthcare-goals/obesity-healthcare-goals/ <sup>4</sup> Office for Health Improvement and Disparities. (2025) Public health profiles. Available at: https://fingertips.phe.org.uk/.

<sup>&</sup>lt;sup>3</sup> Office for Life Sciences, Department of Health & Social Care, and Department for Science, Innovation and Technology. (2024). *Obesity Healthcare Goals.* Available at:

<sup>&</sup>lt;sup>5</sup> Statistics on Obesity, Physical Activity and Diet, England 2021, Available at: <u>Statistics on Obesity</u>, <u>Physical Activity and Diet</u>, <u>England 2021 - NHS England Digital</u>

<sup>&</sup>lt;sup>6</sup> NHS England. (2024). *Health Survey for England, 2022 Part 2.* Available at: <u>https://digital.nhs.uk/data-and-information/publications/statistical/health-survey-for-england/2022-part-2</u>

<sup>&</sup>lt;sup>7</sup> Fruh, S. (2017). Obesity: Risk factors, complications, and strategies for sustainable long-term weight management. *Journal of the American Association for Nurse Practitioners*. 29: 3-14. Available at: <u>10.1002/2327-6924.12510</u>

# Pharmacotherapy for weight management

Pharmacotherapy represents a transformative addition to the obesity management landscape. 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.

While the efficacy of Glucagon-like peptide-1 (GLP-1) receptor agonists and the novel Gastric inhibitory polypeptide/Glucagon-like peptide-1 (GIP/GLP-1) receptor agonist, tirzepatide (Mounjaro®), for weight management are well documented in clinical trials and forms the basis for current NICE recommendations, there are important considerations which need to be taken into account in real world implementation in the NHS in England. Due to tirzepatide's (Mounjaro®) status as a <u>Black Triangle</u> medication, it is crucial to explore its practical application beyond controlled trial settings, ensuring that outcomes align with real-world patient experiences.

A key consideration is access and delivery within primary care as a new setting of care. Given the novel nature of weight management pharmacotherapies in this context, implementation must be carefully aligned with system capacity, workforce readiness, and resource availability to ensure equitable and sustainable access for eligible patients.

Further, given the impact on NHS resources, eligibility will need to be phased in across the entire eligible patient population. This means that a protocol for prioritising who gets initial access to treatment is needed.

# Driving sustainable and cost effective weight management in the NHS

By implementing tirzepatide (Mounjaro®), the NHS in England will make a significant step toward transforming weight management. Successful implementation will require robust clinical pathways, comprehensive patient and healthcare professional education, and ongoing monitoring to maximise benefits and address potential risks.

The NHS in England intends to embed weight management pharmacotherapy as one element of a broader, holistic strategy to address obesity through complementary expansion in access to lifestyle and behavioural support alongside other interventions, such as very low calorie diets and bariatric surgery. This will ensure resources are used effectively, empowering individuals to achieve meaningful, lasting health improvements while maintaining cost effective, equitable access to care across the system.

# Overview of the requirements of the NICE TA for tirzepatide (Mounjaro®)

#### Patient Eligibility Criteria

Patient eligibility criteria is set out below, as per the <u>NICE TA1026</u> and the <u>NICE</u> <u>Funding Variation</u>.

- Overview of the NICE Technology Appraisal for tirzepatide (Mounjaro®) outlines the recommended cohort eligible for tirzepatide (Mounjaro®) which is clinically and cost effective for the management of obesity, as per the <u>NICE TA1026</u> recommendation.
- Overview of the NICE Funding Variation for tirzepatide (Mounjaro®) outlines the priority cohort as per the <u>NICE Funding Variation</u>, for primary care settings, that are eligible under the phased access within the NHS.

# Overview of the NICE Technology Appraisal for tirzepatide (Mounjaro®)

Tirzepatide (Mounjaro®) is a novel dual GIP/GLP-1 receptor agonist recommended by <u>NICE TA1026</u> for managing obesity alongside a reduced calorie diet and increased physical activity in adults, only if they have:

- an initial body mass index (BMI) of at least 35 kg/m<sup>2\*</sup>; and
- at least 1 weight-related comorbidity.

\*Use a lower BMI threshold (usually reduced by 2.5 kg/m<sup>2</sup>) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds.

Tirzepatide (Mounjaro®) is recommended by NICE for use in primary care settings and specialist weight management services.

# **Overview of the NICE funding variation for tirzepatide (Mounjaro®)**

According to the eligible cohort outlined by NICE, ICBs would be required to meet the cost for funding access to tirzepatide (Mounjaro®) for an estimated 3.4 million people from 24 March 2025 (90 days from publication of the <u>NICE TA1026</u>).

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 the following amendments, as outlined in <u>Section 4 "Implementation"</u> of <u>NICE TA1026</u>.

#### Eligible patient cohort phasing and related setting of care

The <u>NICE Funding Variation</u> outlines a 90 day funding mandate in specialist weight management services for the full eligible population and a 180 day funding mandate in primary care settings in line with the prioritised patient cohorts set out by NHS England.

Implementation in NHS specialist weight management services

From 24 March 2025 (90 days after NICE final guidance publication), ICBs are required to meet the costs of funding access to tirzepatide (Mounjaro®) for the management of obesity in NHS specialist weight management services for any person who meets the eligibility criteria in the <u>NICE TA1026</u> and where the treatment is approved by a prescribing clinician.

• Implementation in NHS Primary Care Settings

ICBs are required to meet the costs of funding access to tirzepatide (Mounjaro®) for the treatment of obesity in primary care settings from 23 June 2025 (180 days after final guidance publication), alongside other available treatment options, to patient cohorts on a phased basis. Tirzepatide (Mounjaro®) will be made available to prioritised cohorts in primary care settings during an initial phased implementation period, which reflects the available capacity in primary care. The initial implementation period will be used to evaluate and make the necessary arrangements to safely and efficiently scale a variety of implementation service models in primary care.

# NICE funding variation eligible population

The <u>NICE Funding Variation</u> 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 (Mounjaro®).

The total eligible population, as outlined in the NICE TA <u>("Recommendations"</u>), should have access within the maximum period of 12 years, based on cohort prioritisation led by clinical need. This section outlines the cohorting approach for the initial 3 years of implementation, from 2025 – 2028. Under the cohorting approach patient eligibility will increase in stages to ~220,000 patients after the first three years.

NICE asked NHS England to work with relevant clinical experts to consider both referral prioritisation in NHS specialist weight management services and which patient cohorts should receive access in NHS primary care based services. In collaboration with representatives from partner organisations, NHS England developed an approach, referred to as the "cohorting approach" to identify the initial cohorts for access in primary care based services. NHS England engaged with ICBs, patient and public voices, healthcare professionals, charities and relevant organisations and Royal Colleges in line with its responsibilities under Section <u>13Q</u> of the National Health Service Act related to public involvement.

#### a. Implementation in NHS specialist weight management services

Patient eligibility for tirzepatide (Mounjaro®) in specialist weight management services is as per the full eligible cohort as outlined in the <u>NICE TA1026</u>, where treatment is considered appropriate by a prescribing clinician.

ICBs have the option to align access to specialist weight management services with the proposed cohorting approach that will apply in primary care (see "Implementation in primary care Settings") in order to ensure appropriate prioritisation of resources in line with population need.

#### b. Implementation in Primary Care Settings

Patient eligibility and the associated funding mandate within primary care is in line with the prioritised patient cohorts set out by NHS England.

The approach to implementation within primary care as a novel care setting for tirzepatide (Mounjaro®) in the management of obesity, 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 1 for the phasing proposal for the initial 3 years of tirzepatide (Mounjaro®) implementation.

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

Funding Variation	Estimated	Cohorts	Cohort Access Groups	
Year*	Cohort Duration		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	<ul> <li>≥4 'qualifying' comorbidities</li> <li>hypertension, dyslipidaemia,</li> <li>obstructive sleep apnoea,</li> <li>cardiovascular disease,</li> <li>type 2 diabetes mellitus</li> </ul>	≬35 — 39.9
Year 2/3 (2026 and 2027/28)	026 and 15 Cohort 0bstructive sleet months III cardiovascula		3 'qualifying comorbidities hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, type 2 diabetes mellitus	≥ 40

\*Funding Variation year refers to the financial year.

\*\* Use a lower BMI threshold (usually reduced by 2.5 kg/m<sup>2</sup>) for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds

# **Qualifying comorbidities definitions**

The clinical definitions for comorbidities were initially based on randomised clinical trial cohort definitions, ensuring alignment with evidence based research. NHS England has further refined these in collaboration with clinical experts and by reference to clinical guidelines and real world practice, incorporating existing NICE standards and relevant Quality and Outcomes Framework (QOF) indicators to ensure consistency and applicability in routine care (Table 2).

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) $\geq$ 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 $\geq$ 1.7 mmol/L	
Obstructive Sleep Apnoea (OSA)	Established diagnosis of OSA (sleep clinic confirmatio 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 *	

Table 2. Qualifying Comorbidities and Definitions for initial assessment.

\*People with type 2 diabetes can be prescribed tirzepatide (Mounjaro®) for obesity or for glycaemic management in type 2 diabetes if they meet the criteria set out in the recommendations in either:

a) NICE's technology appraisal guidance on tirzepatide (Mounjaro®) for managing overweight and obesity (<u>NICE TA1026</u>); or

#### b) Tirzepatide (Mounjaro®) for treating type 2 diabetes (NICE TA924).

Tirzepatide (Mounjaro®) for treating type 2 diabetes (NICE TA924) is subject to different eligibility criteria. There are clinical complexities for this cohort of patients including medication interactions and NICE recommendations should be reviewed when providing local guidelines.

# Financial and allocations for implementation

Funding has been allocated in 2025/26 for the implementation of the <u>NICE Funding</u> <u>Variation</u> for weight loss drugs, for the management of obesity 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 on the basis of obesity prevalence rates at ICB level. This ensures resources are directed towards populations with higher obesity rates, addressing health inequalities and enabling ICBs to scale services effectively.

The allocation is fixed and will not be adjusted to take account of actual take up in year. It will not be ring fenced.

ICBs may consider the implementation of a pre-approval process for prescribing tirzepatide (Mounjaro®) and <u>semaglutide (Wegovy®)</u> for management of obesity in specialist weight management services, using the NHS BlueTeq system. This will capture key information and may provide a clear and established framework to support ICBs to manage medicine reimbursement exclusively within specialist weight management services.

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**

<u>NICE TA1026</u> recommends primary care as a new care setting and point of access for tirzepatide (Mounjaro®).

To implement the <u>NICE Funding Variation</u> in primary care, NHS England has collaborated with ICBs to conceptualise four implementation models for the safe and effective delivery of tirzepatide (Mounjaro®) for weight management in primary care, as follows:

- Community / Local based delivery model
- General Practice delivery model
- Specialist weight management services provision of community outreach delivery model
- Specialist weight management services Community & General Practice sharedcare model

These models are indicative and intended to inform local planning. ICBs have flexibility to select the model(s) which best meets their population's needs, with the aim of growing and scaling these models over an initial three year period in the primary care setting.

A defined approach to access pharmacotherapy for the management of obesity is required in all ICBs, ensuring patients meet the necessary clinical criteria before considering pharmacological treatment in consultation with the patient, accessed via the most appropriate care setting.

Local delivery models for access to tirzepatide (Mounjaro®) and other licensed weight loss drugs, need to complement integration strategies and emerging weight management pathways to ensure seamless, equitable and effective patient care whilst addressing the multifaceted nature of obesity management.

The removal of tiered systems in the 2025 NICE 'Overweight and Obesity Management' guideline (NG246) signals a shift towards reconsidering access routes and care models for obesity management beyond the stepwise tiered system.

# Compliance with online prescribing guidelines

Where ICBs utilise an online prescribing pathway for system delivery in either primary care or specialist weight management services for tirzepatide (Mounjaro®) and alternative <u>NICE-recommended weight management medicines (NG246)</u>, commissioners must ensure compliance with the <u>General Pharmaceutical Council</u> (<u>GPhC</u>) guidance on safe prescribing practices by all contracted service providers.

The updated <u>GPhC guidelines</u> stress that for high risk medicines, such as tirzepatide (Mounjaro®), prescribing decisions cannot be based solely on the information provided in an online questionnaire. Prescribers are required to independently verify the information given by the patient through timely communication, accessing the patient's clinical records, or contacting the patient's GP or another regular prescriber. This approach is considered essential to prevent the potential misuse of the system and ensure patients are prescribed medicines that are clinically appropriate for their individual health needs.

# Wraparound care provision and access

The <u>NICE TA1026</u> and the associated Medicines and Healthcare Products Regulatory Agency (MHRA) <u>product license approval</u> emphasise wraparound care as an essential adjunct for tirzepatide (Mounjaro®), for the management of obesity, which must be prescribed alongside a reduced calorie diet and increased physical activity.

The <u>NICE TA1026</u> effectively mandates provision of wraparound care alongside the prescribing of tirzepatide (Mounjaro®) for all patients receiving tirzepatide (Mounjaro®), regardless of their setting of care.

For the delivery of the <u>NICE Funding Variation</u> 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.

#### • Provision in specialist weight management services

Where patients are prescribed tirzepatide (Mounjaro®) in a specialist weight management service, through a multidisciplinary team that offers a combination of nutritional, psychological and medical intervention, based on the individual patient's needs, further provision of wraparound care is not necessary.

• Provision in primary care

Where patients are prescribed tirzepatide (Mounjaro®), in primary care additional wraparound care will need to be provided.

The <u>NICE TA1026</u> does not specify the exact content of wraparound care in this setting related to tirzepatide (Mounjaro®). Through a review of NICE published guidelines and quality standards for related services, the lifestyle intervention provision in related SURMOUNT clinical trials<sup>8</sup>, and in consultation with relevant professional and patient groups, an informed approach to the development of an effective wraparound care service, to be delivered for primary care, has been taken by NHS England.

Given the expected patient numbers to be treated over the early phase of implementation, a dedicated wraparound care service exclusively for tirzepatide (Mounjaro®) is unlikely to be viable in the short term. To support consistent access to a support offer across all ICBs, NHS England intends to utilise existing service infrastructure, specifically, leveraging appropriate established provider networks to provide a short term option. This approach will allow for rapid mobilisation of services through existing contracts, ensuring efficient and equitable care delivery.

NHS England intends to make centrally funded wraparound care services available to all ICB from 23rd June 2025, which will be accessible from primary care settings. This will be exclusively for use by the identified priority cohort, for each ICB. The access and associated service pathway will be confirmed with all ICBs in May 2025.

Where patient care is initiated and managed within primary care settings, ICBs can opt to use the NHS England provision of wraparound care or may choose to independently provide wraparound care. In the latter instance, commissioners are required to ensure wraparound care is made available to this cohort of patients which incorporates appropriate nutritional and dietetic advice, physical activity guidance and behavioural change components, over a minimum time frame of 9 months from the point of prescribing.

<sup>&</sup>lt;sup>8</sup> Jastreboff, AM, Tirzepatide Once Weekly for the Treatment of Obesity, New England Journal of Medicine, 2022, Available at: <u>https://www.nejm.org/doi/full/10.1056/NEJMoa2206038</u>,

Frandsen, CS, SURMOUNT-2: new advances for treating obese type 2 diabetes with tirzepatide, The Lancet, Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)01292-8/abstract Wadden TA, *et al* Tirzepatide after intensive lifestyle intervention in adults with overweight or obesity: the SURMOUNT-3 phase 3 trial. Nat Med. 2023 Accessible at https://pubmed.ncbi.nlm.nih.gov/37840095/ Aronne LJ, *et al;* SURMOUNT-4 Investigators. Continued Treatment With Tirzepatide for Maintenance of Weight Reduction in Adults With Obesity: The SURMOUNT-4 Randomized Clinical Trial. JAMA. 2024. Available at: https://pubmed.ncbi.nlm.nih.gov/38078870/

# **Patient management**

ICB patient management protocols, clinical guidance and clinical governance policies should be delivered in line with the <u>NICE TA1026</u> and the <u>NICE "Practical guide to using</u> <u>medicines to manage overweight and obesity"</u>.

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 of tirzepatide (Mounjaro®), 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 deprescribing, as well as potential adverse effects, including psychological impacts.

In line with NICE guideline <u>NG246</u>, the correct and suitable equipment and facilities for managing people living with overweight should be made available in all settings of care.

## Initiating prescribing and titration guidance

Local commissioners should ensure prescribing of tirzepatide (Mounjaro®) aligns with the eligibility criteria outlined by the <u>NICE TA1026</u>, as well as the licensed indication and dosage schedule available in the <u>NICE prescribing information</u> for tirzepatide (Mounjaro®), the <u>summary of product characteristics</u> and the <u>British National Formulary (BNF)</u>.

NICE has developed <u>tirzepatide: local formulary information</u> to support the adoption of tirzepatide (Mounjaro®) into local formularies.

The prescribing of tirzepatide (Mounjaro®) should be in accordance with robust local system clinical governance, with clinical and expert advice guiding the process.

Commissioners should ensure the initial assessment for tirzepatide (Mounjaro®) prescribing in primary care is performed by an appropriately trained healthcare professional and it is recommended this assessment should include as a minimum:

• Eligibility assessment, to include: BMI assessment and comorbidity complexity according to <u>NICE TA1026</u> and <u>NICE Funding Variation</u> for tirzepatide (Mounjaro®); medical history, including comorbidities and concomitant

medication; suitability for treatment, including contra-indications and cautions, psychological assessment; and relevant assessments depending on clinical circumstances.

• Review of concomitant medicines and polypharmacy (see <u>NICE "Practical guide</u> to using medicines to manage overweight and obesity").

Further information on the initial assessment can be found in the <u>NICE "Practical guide</u> to using medicines to manage overweight and obesity", and the <u>NICE "Initial</u> <u>assessment checklist"</u> for a list of actions or assessments that may be needed.

The appropriately trained healthcare professional undertaking the initial assessment should discuss the factors related to the choice of medicines, or alternative treatments/services available to the patient, when deciding on the appropriate treatment, as outlined in the NICE "Practical guide to using medicines to manage overweight and obesity".

The <u>Edmonton Obesity Staging System (EOSS)</u> may be used to provide an individual subjective assessment of the severity of obesity related health, to include a holistic assessment of the presence and severity of obesity related comorbidities, mobility and functioning and psychological symptoms and wellbeing.

In line with the <u>GPhC guidance</u> on prescribing weight loss medications, prescribers should carefully consider the patient's overall wellbeing, particularly when eating disorders, body dysmorphia, or mental health status are factors in the request and consideration for treatment. Onward referral to dedicated services may be made where appropriate, in line with local guidelines and existing NICE guidance (NG222).

Due to the current <u>Black Triangle</u> status of tirzepatide (Mounjaro®), commissioners and prescribers are required to exercise extra caution and adhere to rigorous protocols to ensure the drug is appropriate and safe for each patient; prioritising comprehensive clinical evaluation and ongoing monitoring throughout the course of treatment.

ICBs may wish to consider the implementation of a prior approval system for the prescribing of semaglutide (Wegovy®) and tirzepatide (Mounjaro®) in specialist weight management services to support with cost management and resource planning. For example, BlueTeq. Implementation of a prior approval system would also allow data collection ensuring specialist weight management service providers prescribe in line with locally defined referral criteria.

# **Patient monitoring**

Further information on the follow up and monitoring required for tirzepatide (Mounjaro®) can be found in the <u>NICE "Practical guide to using medicines to manage overweight and obesity"</u>. Also see the <u>NICE "Follow up and monitoring checklist"</u> detailing actions or assessments that may be needed during dose titration and once on a stable dose.

#### • Reviewing and stopping prescribing

Unlike other <u>NICE-recommended weight management medicines</u>, which currently have a maximum prescription duration of 2 years, tirzepatide (Mounjaro®) does not have a set "stopping rule" or maximum treatment period, allowing for indefinite prescribing.

The decision to continue short or long term prescribing should be made on a case by case basis by an appropriately trained healthcare professional, in consultation with the patient.

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 if clinical benefits, including weight loss, are not seen.

It is the responsibility of ICB commissioners and clinical leads to stay informed and up to date with the latest guidelines and prescribing recommendations for weight management treatments, including tirzepatide (Mounjaro®).

Commissioners should ensure local clinical governance frameworks are aligned with updated guidelines and the delivery of services reflects the most current standards of care. This includes regularly reviewing and adapting policies and procedures to ensure safe, effective prescribing and optimal patient outcomes, whilst also fostering a culture of continuous improvement and evidence based practice within the healthcare system.

# Incidence and adverse event reporting

Tirzepatide (Mounjaro®) is classified as a <u>Black Triangle</u> medication by MHRA, meaning it is subject to additional safety monitoring. Healthcare professionals, the public, and pharmaceutical companies must report all suspected adverse drug reactions via the <u>Yellow Card Scheme</u>, accessible through the <u>website</u>, app, telephone, or clinical IT systems, as well as standard patient safety reporting mechanisms.

SNOMED CT codes are available to record and report adverse events related to all weight loss medications. Known tirzepatide (Mounjaro®) side effects and cautions are detailed in the <u>BNF</u>.

Table 3. SNOMED CT Code guide for adverse reactions: Located under the Parent ID of 62014003 Adverse reaction caused by drug (disorder)

No.	SNOMED CT Code	Code Type	SNOMED CT ID (SCTID)
1	Adverse reaction to GLP-1	Disorder	2385961000000109
2	Adverse reaction to GIP *	Disorder	2385971000000102
3	Adverse reaction to tirzepatide	Disorder	2385981000000100
4	Adverse reaction to semaglutide	Disorder	2385991000000103
5	Adverse reaction to liraglutide	Disorder	238600100000104

\*Due to the terminology currently used in the SNOMED CT browser, tirzepatide has the parent code 'Glucose dependent insulinotropic peptide (substance) SCTID: 416401008'

## Local population needs

Local Systems should continue to consider weight management services for specific populations disproportionately affected by excess weight and groups which experience significant barriers to equitable access of services. Commissioners should review current models of care and develop multidisciplinary team approaches to support vulnerable people to be able to access treatment and care.

#### • Ethnicity

There is an increased risk of health conditions at lower BMI thresholds in certain populations. The BMI applied to assess eligibility for tirzepatide (Mounjaro®)

must be adjusted by 2.5 kg/m<sup>2</sup> 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.

#### • 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 cardiometabolic disease and will potentially benefit from weight management support and/or treatment through weight loss therapies, including tirzepatide (Mounjaro®). 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.

The <u>BNF</u> entry advises '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 (Mounjaro®) treatment and after dose increases'. Appropriate advice on hydration should be offered alongside the importance of exercise.

For people living with severe mental health conditions, a learning disability, or who are autistic, 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. It is important to include carers in the conversation, explaining which side effects to look out for and providing advice on the disposal of sharps.

The BNF advises on <u>important safety information</u> and additional monitoring needs related to potential drug/drug interactions which may increase blood levels of antipsychotic therapies and consideration of potential impairment of intestinal peristalsis antipsychotic therapies.

#### • Children and young people

The development or continuation of clear transition pathways for prescribing and monitoring of all weight management pharmacotherapies for <u>young people</u>

moving into adult services from Complications from Excess Weight (CEW) clinics and paediatric services is recommended.

#### • Detained persons

Local arrangements aligned with the <u>'NHS Health and Justice Framework for</u> <u>Integration 2022–2025: Improving lives – reducing inequality</u>' are recommended to embed consistent, equitable pathways through a whole systems approach to care.

## Housebound

ICBs and local authorities should ensure appropriate delivery and support of equitable access<sup>9</sup> to tirzepatide (Mounarjo®) for patients who are housebound.<sup>10</sup>

Equitable access may include considering the use of a community based multidisciplinary team approach, to include social prescribing, community dietetics, and other appropriate services, where available.

# Implementation activity in settings of care

A GPIT template will be published in June 2025 to provide a structured approach for capturing essential data within current GP IT systems (EMIS, TPP and SystmOne). This integrated patient review template will ensure consistent capture of both clinical and administrative data across healthcare providers, improving data quality and reliability. It will include fields for key metrics such as patient demographics, treatment eligibility, contraindications, medication history, side effects, and treatment outcomes.

The template's standardised data fields will enhance data accuracy by minimising variability in entries, leading to more reliable patient records. With clear, consistent fields guiding clinicians through each entry. The completeness of these records will improve and provide a comprehensive view of each patient's needs and treatment progress. The template will also include step by step guidance on assessment criteria, contra-indications and follow up requirements, ensuring alignment with evidence based guidelines and appropriate patient care throughout their treatment journey.

<sup>&</sup>lt;sup>9</sup> Equitable access may include considering the use of a community-based multidisciplinary team approach, to include social prescribing, community dietetics, and other appropriate services, where available, as well as the systems' <u>neighbourhood health and care model</u> for the local population. <sup>10</sup> A patient is deemed to be housebound when they are unable to leave their home or require significant assistance to leave their home environment due to illness, frailty, surgery, and/or mental health.

SNOMED CT codes have been published within the <u>SNOMED CT browser</u> in the March 2025 release for use across all care settings. These are held under the parent code "NHS obesity medication pathway". Two regime/therapy codes distinguish between the tracking and monitoring of prescribing and monitoring and wraparound care: "NHS obesity medication pathway (regime/therapy)", and "NHS obesity medication wraparound support pathway (regime/therapy)".

These codes are integrated into GP IT systems and are also available for use in secondary care settings. This allows for consistent coding of activity related to the delivery of the <u>NICE Funding Variation</u> for tirzepatide (Mounarjo®) across key steps in the patient journey. This includes initial assessment, referral to wraparound care, prescription monitoring and treatment completion, providing a standardised approach for tracking patient management and reporting activity.

Table 4. SNOMED CT Code guide for NHS obesity medication pathway: Located under the Parent ID of NHS obesity medication pathway.

No.	Terminology Name	Code Type	SNOMED CT ID (SCTID)
1	Referral to National Health Service obesity medication wraparound support pathway (procedure).	Procedure	238620100000107
2	Unsuitable for National Health Service obesity medication pathway (finding).	Finding	2386221000000103
3	Review of anti-obesity drug therapy (regime/therapy).	Regime/therapy	2386251000000108
4	National Health Service obesity medication pathway started (situation).	Situation	2386231000000101
5	National Health Service obesity medication pathway declined (situation).	Situation	2386241000000105

# System reporting of implementation and access

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 (Mounjaro®) in primary care settings and the management of patients.

Data collection timeframes:

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

ICB level aggregate data allows NHS England to observe the delivery of the <u>NICE</u> <u>Funding Variation</u> for tirzepatide (Mounjaro®), understand access and identify trends and prescribing practices. Collated information generated from this aggregated data will help shape reporting requests from the Department of Health and Social Care (DHSC) and support informed decision making on future financial allocations.

#### **Review of Implementation and Access**

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

An independent evaluation of the implementation of tirzepatide (Mounjaro®) has also been commissioned by the National Institute for Health and Care Research (NIHR), through its Health Services Delivery Research (HSDR) Programme.

The evaluation will generate comprehensive data across delivery models to evaluate feasibility, acceptability, safety, effectiveness, and cost effectiveness of new models for providing weight loss drugs across socio-demographic groups.

To achieve the aims of the evaluation, the appointed research partner will engage with healthcare professionals, patients and providers, across ICBs, to understand the impact of delivery models to accessing tirzepatide (Mounjaro®).