NICE's recommendation on tirzepatide (Mounjaro®) for the management of obesity.

Frequently asked questions for patients

1. What is changing in the treatment of obesity?

The National Institute of Health and Care Excellence (NICE) has recommended a treatment called tirzepatide (Mounjaro®) to help manage obesity. This treatment is to be used alongside healthy eating and physical activity advice.

This medication can be offered to people who are eligible in both specialist weight management services and primary care settings. Previously, similar medications like semaglutide (Wegovy®) and liraglutide (Saxenda®) were only recommended by NICE for prescription in specialist weight management services (which are usually hospital based services). The inclusion of tirzepatide (Mounjaro®) as a treatment option in primary care marks an opportunity to expand access and offer new treatments for people living with obesity.

Introducing this new treatment to an estimated 3.4 million eligible patients requires the NHS in England to develop a completely new service for weight management and train the varied healthcare professional workforce needed to deliver tirzepatide (Mounjaro®) in primary care. A staged approach will help manage the impact on existing healthcare services, ensuring tirzepatide (Mounjaro®) is prescribed safely and that patients receive appropriate support.

In the staged roll out, tirzepatide (Mounjaro[®]) will initially be offered to individuals facing the most significant health risks related to their weight. People will start to become eligible for tirzepatide (Mounjaro[®]) through primary care services from June 2025.

2. When can people start accessing tirzepatide (Mounjaro®)?

From Monday, 23 June, people living with obesity will be able to begin accessing tirzepatide (Mounjaro®) for weight loss purposes in primary care settings.

This does not mean prescriptions will be provided immediately. It means primary care settings can begin discussions with patients about whether tirzepatide is the right option to improve their health through weight loss.

Access is prioritised for those with the greatest clinical need, it's for people living with obesity, in poor health with multiple obesity related conditions; as they would benefit most from the treatment.

3. How does tirzepatide (Mounjaro®) work?

The weight loss medicine tirzepatide also known as Mounjaro [®] is a GLP-1/GIP agonist. Other medications such as semaglutide (Wegovy [®]), liraglutide (Saxenda [®]), are known as GLP-1 agonists. They mimic gut hormones released by the body after eating, telling the brain you are full, they also slow down the time it takes the stomach to empty and help control blood sugar levels.

Until now most of these medicines have been used in the NHS to treat diabetes, to help control blood sugar levels helping improve diabetes and other health conditions.

Tirzepatide (Mounjaro[®]) can only be prescribed by a healthcare professional alongside programmes that support people to lose weight and live healthier lives, by making changes to

their diet and physical activity. Tirzepatide (Mounjaro®) is an injection, that you inject yourself once a week.

More information can be found here: GLP-1 medicines for weight loss and diabetes: what you need to know [LINK GLP-1 medicines for weight loss and diabetes: what you need to know - GOV.UK]

4. Who can access tirzepatide (Mounjaro®) in primary care?

The following groups of patients will be eligible for access to tirzepatide (Mounjaro[®]) in primary care in the first three years, starting from June 2025. There will be a phased approach to rollout in primary care, and initially tirzepatide (Mounjaro[®]) will only be available on the NHS to those with the highest clinical need.

This approach will ensure the service is delivered safely and that the NHS in England is able to plan for an increase in numbers of people eligible for assessment for tirzepatide (Mounjaro[®]), whilst building skills and knowledge within the workforce. National Institute for Health and Care Excellence (NICE) will complete a review at 3 years about who else will be able to access the medication and then more information will be provided about the next groups of people.

Access to the medication will be prioritised to ensure patients with the greatest clinical need can access the medication. The approach was developed based on discussions with clinical experts and engagement with key organisations. The following weight related health conditions are considered, as a way of prioritising groups of people with the greatest clinical need:

- type 2 diabetes mellitus
- high blood pressure
- heart disease
- obstructive sleep apnoea (when your breathing stops and starts while you sleep)
- abnormal blood fats (dyslipidaemia)

Cohort 1 – will start in June 2025.

• At least **four** of the five health conditions listed above plus a **BMI of 40** (BMI to be adjusted for ethnicity*) or more.

Cohort 2 – in addition to the patients in Cohort 1 access to the medicine will also be offered to patients meeting the following criteria for year two.

• At least **four** of the five health conditions listed above plus a **BMI of 35 – 39.9** (BMI to be adjusted for ethnicity*).

Cohort 3 – in addition to patients in Cohorts 1 and 2, access to the medicine will also be offered to patients meeting the following criteria for year three.

• At least **three** of the five health conditions and a **BMI of 40** (BMI to be adjusted for ethnicity*) or more.

*Due to an increased risk of heath conditions at lower BMI thresholds in these populations, the BMI applied to assess eligibility for tirzepatide (Mounjaro®) must be 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.

5. What other options do I have for weight loss support via the NHS?

Tirzepatide (Mounjaro[®]) will not be suitable for everyone and not everyone who meets the eligibility criteria will want to use it to support their weight loss. There are other options available including weight loss programmes that use tried and tested methods such as lifestyle changes and nutrition and physical activity advice. Please speak to a healthcare professional about what the best option is, that is offered locally to you.

There are other options available, depending on the health-related conditions you have and your BMI. The NHS Digital Weight Management Programme is available for those with diabetes, high blood pressure or both, with a BMI greater than 30. The BMI threshold is lowered to 27.5 for those from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds. NHS staff do not need high blood pressure or type 2 diabetes to access the programme.

The NHS Type 2 Diabetes Path to Remission Programme is available if you are aged 18-65, have a diagnosis of type 2 diabetes within the last 6 years and have a BMI over 27 kg/m2 (where individuals are from White ethnic groups) or over 25 kg/m2 (where individuals are from Black, Asian and other ethnic groups).

Adults are eligible to access the NHS Diabetes Prevention Programme if they have had a blood test in the last year that shows they are at risk of diabetes or if you were diagnosed with diabetes in pregnancy (gestational diabetes).

6. What can I expect to happen if I am eligible for tirzepatide (Mounjaro®)?

New patient services are being developed to support access to tirzepatide through primary care and this will include the following steps:

Initial assessment and discussion about the best treatment option

• There will be an assessment which will include discussions around the different options for weight management. The clinician will carry out checks to make sure you are eligible, this includes BMI, medical assessment, medication history and psychological assessment. The risks and benefits of starting the medication will be discussed, so you have the information to make the right choice for you. If you are eligible, you do not need to decide immediately if you want to start tirzepatide (Mounjaro[®]). More information can be found in this tirzepatide (Mounjaro[®]) decision aid produced by NICE.

• If you choose to start tirzepatide (Mounjaro[®]), you will need up to date blood tests, to check kidney, liver and thyroid function. If these are within an acceptable range an appointment will be made with a healthcare professional to train you how to self-inject.

Dose adjustment and initial monitoring

• The prescribing healthcare professional is responsible for ensuring that patients are supported with taking the medicine, adjusting the dose and managing side effects. This is a new medicine, so it is important to monitor safety, help patients take the medication and follow dietary and physical activity advice.

Maintenance

• Ongoing prescribing of the medicine, review of progress and wraparound care provided for the first 9 months.

7. What are side effects of the medication?

Like all medications, tirzepatide (Mounjaro®) can cause side effects and healthcare professionals should discuss the side-effects with you. The medication will come with a Patient Information Leaflet which lists common side effects including:

- feeling sick
- indigestion (heartburn)
- constipation
- diarrhoea.

There can be some more serious side effects, such as low blood sugar, gallstones and inflammation of the pancreas (pancreatitis).

Tirzepatide (Mounjaro[®]) is a new medication, so any side effects should be reported through the **Yellow Card Scheme**, which is the government system used for recording side effects with medicines in the UK.

8. Will I be supported whilst taking the medication?

Patients taking tirzepatide (Mounjaro[®]) on the NHS for obesity management will be supported by the healthcare professional who is prescribing the medication, this may be in primary care or specialist weight management services. Healthcare professionals will focus on prescribing the medication, manage side-effects, monitoring the other long-term health problems, and management of potential medicine interactions.

Patients will also be given access to a lifestyle support programme that focuses on diet and nutrition advice when taking the medication and physical activity advice. Through the programme, people will be encouraged to make sustainable habits that encourage long-term improvements in metabolic health, physical wellbeing and lifestyle. This lifestyle support programme will be available for the first 9 months of being prescribed the medication.

Patients cannot be prescribed tirzepatide (Mounjaro®) if they do not wish to undertake the wraparound care support. This is because the NICE recommendations state tirzepatide (Mounjaro®) must be prescribed alongside diet and physical activity advice.

9. How long can or should I take it for?

NICE guidance recommends if you do not lose enough weight (5%) after 6 months of being on the highest dose you can manage, tirzepatide (Mounjaro[®]) should be stopped. This is because the medication is not working as well as it should be for you.

Currently there is no specified time limit for being prescribed tirzepatide (Mounjaro[®]). The decision to continue or stop tirzepatide (Mounjaro[®]) should be discussed with an appropriate healthcare professional.

10. Can I take it if I'm pregnant or trying to get pregnant?

Tirzepatide (Mounjaro[®]) should not be taken during pregnancy or just before trying to get pregnant. This is because there is not enough safety data to know whether taking the medicine can cause harm to the baby.

There is specific information about how these medications affect contraceptive methods, like the pill. The Faculty for Sexual and Reproductive Health has produced this information leaflet for patients to read: Patient-information-GLP-1-agonists-and-contraception.[LINK <u>Patient-information-GLP-1-agonists-and-contraception.]</u>

11. Is it okay to take tirzepatide (Mounjaro®) with the other medications that I take?

Tirzepatide (Mounjaro[®]) can affect the absorption of other medications being taken. In some cases, this may affect how well and/or how fast those medications work; or it may make no difference. For this reason it is particularly important that patients receive follow up care and advice from a healthcare professional. This medication is still relatively new, and the healthcare community are learning about how tirzepatide (Mounjaro[®]) interacts with other medications, for example, Hormone Replacement (HRT).

Before starting the medicine, a healthcare professional will check which other medications you are taking to see if there may be any medicine interactions and to see if they are compatible when taken together. While taking the medicine, some people may find that their long-term health conditions (like high blood pressure) improve, and they might need less medication. Your healthcare professional will talk to you about this, any monitoring that might need to happen and make any necessary changes to your treatment.

It is important to be honest with the healthcare professional if you are eligible for the medication. Let them know about any medical conditions, other medicines you are taking, the dose and if you buy any medication over the counter. This information will need to be considered before you are prescribed tirzepatide (Mounjaro®).

12. What if I am already using tirzepatide (Mounjaro®)?

Patients can continue taking tirzepatide (Mounjaro®) if they are prescribed it by the NHS to manage their diabetes. If you have any questions, contact a suitable healthcare professional.

If patients are using tirzepatide (Mounjaro[®]) bought privately, they may be able to access the medication through an NHS prescription if they meet the NHS qualifying criteria outlined above.

It is important your GP is aware you are taking tirzepatide (Mounjaro[®]), if it hasn't been prescribed by the NHS, as it may impact on your health and any other treatments you are having or may need.

13. I am currently on a waiting list for NHS specialist weight management services. Can I transfer to another list to access this medicine?

A healthcare professional will determine if it is appropriate for you to receive tirzepatide (Mounjaro®) as part of your care in a different care setting (for example, through primary care).

14. Will there be a cost to the patient for being prescribed tirzepatide (Mounjaro®)?

Normal prescription charges will apply unless you are entitled to free NHS prescriptions (for example, because you have a medical exemption certificate).