Healthier Together
Improving health and care in Bristol, North Somerset and South Gloucestershire

NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

FAQs to support the delivery of Tirzepatide (Mounjaro) for Weight Management in Primary Care

FAQ topics

Bloods and initial screening

1. What baseline bloods need to be taken before starting tirzepatide?

Blood tests that are usually required prior to initiation are: FBC, U&Es, LFTs, TSH, Bone profile, Lipid profile, Vitamin B12, Folate, Vitamin D, HbA1c

This cohort of patients will have at least 4 weight related co-morbidities, so it is highly likely that they have had most of these blood tests within the last year. If these have been done within the last year there is no need to repeat apart from HbA1c if the initial result was high (above target).

Bloods at initiation will need to be considered on an individual patient basis:

- Despite having obesity, people might be malnourished so FBC, B12, folate, bone profile, and vitamin D are useful.
- This patient cohort are at higher risk of CVD (cardiovascular disease) so a lipid profile is important.
- They are at higher risk of diabetes, pre-diabetes, and NAFLD (Non-alcoholic fatty liver disease)
- Hypothyroidism predisposes to increase in weight so TSH (Thyroid Stimulating Hormone) is reasonable

2. Are you looking for any specific blood test apart from standards (U&E, LFT, FBC, Hba1c, TSH) from weight management specialist view? Also, could you guide if patient is found low in B12 post Mounjaro initiation, is oral supplementation sufficient or they need to be offered B12 injections?

We usually suggest B12, Folate, Vit D, Calcium profile and Lipid profile in specialist weight management services, alongside those standard biochemistry you mention.

With regards to B12 replacement, if the B12 is <145ng/L (low), if no other new cause/contributing factor has been identified - then oral B12 replacement can be tried first, with a switch to IM B12 replacement if oral this does not yield a clinical response. If the B12 is in the indeterminate range (145 - 180ng/L) then ideally the patient should exhibit symptoms too before trialling replacement - if not, then consider watchful wait. Oral supplementation is a reasonable initiation, if suitable for the individual patient and there's no other reason(s) to be on injections. Please refer to the BNSSG Vitamin B12 guidelines.

3. We don't routinely do those bloods for patients with diabetes pre-starting. Is there a reason why we don't, and should we be?

The additional bloods provide benefit for patients with obesity to consider other weight related co-morbidities not yet defined. These could be considered for patients you initiate primarily for T2DM if considered appropriate to the individual patient.

4. Can a panel for the bloods be added to ICE?

There is a panel for bloods on ICE found under the diagnosis tab and listed as weight management.

5. Should we be screening for eating disorders as part of the initiation process?

In the Surmount 1 and 2 trials for Tirzepatide (basis of evidence for NICE TA1026) patients with eating disorders were excluded so there isn't evidence for its use in this population as to whether it works or not. There isn't any guidance to say that there is a need to screen for an eating disorder. However, if this arises during consultation, then it is worth knowing more about it and referring them to appropriate services, for example SWEDA (SWEDA, England, UK). NBT SWMS usually screen for eating disorders before bariatric surgery.

Criteria and contraindications

1. Why is NAFLD not one of the qualifying comorbidities?

NHSE's response to this was that it was highly likely that Cohort 1 would pick up this patient group, so they didn't make it a qualifying criterion.

2. Is cholecystectomy/previous cholecystitis a contraindication?

No, this is not a contraindication. However, it is worth warning the patient with existing asymptomatic gallstone disease that it could be exacerbated. We would suggest if there were significant patient concern or clinical uncertainty to get this treated first and be cautious starting Tirzepatide in individuals living with active choledocholithiasis or biliary obstruction.

3. Is there an eGFR cut off for use?

No dosage adjustment is required for patients with renal impairment including end stage renal disease (ESRD). Experience with the use of tirzepatide in patients with severe impairment and ESRD is limited. In people with eGFR<15ml/min it is recommended to use with caution. See Summary of Product Characteristics (SPC).

4. Would history of bariatric surgery be contraindicated? Can patients with a history of bariatric surgery who have gained weight be contraindicated?

The clinical data in this population is limited but not contraindicated.
We will provide guidance on eligibility for patients who have previously had bariatric surgery in due course.

Prescribing/Titration

1. How do you make the decision to titrate up or down?

If a person is tolerating the medication well, it is recommended to titrate gradually every 4 weeks up to the maximum dose (15mg once a week). If the person doesn't achieve 5% weight loss at 6 months, consider stopping.

2. Does the pen come with needles? Do we need to prescribe?

No. Needles and sharps bins need to be prescribed. Prescribe in line with BNSSG Pen Needle Guidance.

3. How many doses can be missed before we must consider re-titration, and what is the guidance around this?

The SPC states: If a dose is missed, it should be administered as soon as possible within 4 days after the missed dose. If more than 4 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.

There isn't any guidance on number of missed doses. Tirzepatide is cleared in 4 weeks so would advise titrating again at this point. Patients can miss a dose and safely continue their usual weekly dose. For patients in between this period, in general it would depend on how the patient has tolerated the doses so far, the side-effects and the dose they are taking (a lower dose would be tolerated better than a higher dose).

4. Would the maintenance dose long-term be the maximum tolerated dose?

Yes

Local Enhanced Service offer to Practices

1. What is the difference between WAC and BSOP?

NICE mandates wraparound care (WAC) with tirzepatide prescribing to provide patients with diet, behavioural and physical activity support to improve weight loss. This is provided through the Behavioural Support for Obesity Prescribing (BSOP) programme delivered by Living Well Taking Control.

2. If a practice doesn't sign up to the LES can they make a referral for the WAC (wraparound care)?

NHSE have commissioned the WAC for patients who are being prescribed tirzepatide for weight management in line with the NHSE Funding Variation cohort 1 only.
Referral to BSOP requires prescribers to declare that the patient is being prescribed tirzepatide under the NHSE Funding Variation on the BSOP referral form.
Therefore, if a Practice has not signed up to the LES and is not prescribing tirzepatide under the NHSE Funding Variation referral to WAC will not be supported.

3. If a practice does not sign up to the LES, who will provide the service to the patients registered at that practice?

We will consider equity of access and how to manage this through the BNSSG Weight Management Working Group.

4. Will we be provided with a search tool to try to identify our eligible patients before we decide to sign up to the LES?

Yes, the ICB Medicines Optimisation team will prepare a search tool and send to all Practices. This will also ensure that Practices are looking for the same population parameters.

5. Are practices still paid for patients who stop their treatment part way through the titration or later due to side effects?

We propose that Practices will be paid quarterly if they sign up to the LES therefore Practices will be paid up to and including the quarter in which a patient stops treatment.

Wrap Around Care/BSOP/Dietetic support and other

1. How is dietetic input going to be managed in primary care?

This will be provided by the NHSE commissioned wraparound care (WAC) provider, Living Well Taking Control. Dietetic support through health coaches is part of the package of care offer to patients through the BSOP programme.

There are some useful patient-facing websites that may be helpful to signpost patients to:

- British Nutrition Foundation - Homepage
- Eating with diabetes | Guide to diabetes | Diabetes UK
- Heart Matters Magazine – British Heart Foundation

2. What is the difference between BSOP (Behavioural Support for Obesity Prescribing) provided by NDPP (NHS Diabetes Prevention Programme) and NBT SWMS and Oviva?

In BNSSG we will have:

NBT who provide a **face-to-face Specialist Weight Management Service** providing increased physical activity, dietetic and psychological support through a multidisciplinary team.

Oviva is a **digital Specialist Weight Management Service** providing increased physical activity, dietetic and psychological support.

Living Well Taking Control will provide a **Behavioural Support for Obesity Prescribing** (BSOP) programme delivered through health coaches specialised in dietetic and exercise support and will be upskilled to support behavioural change. Living Well Taking Control's BSOP programme does not have clinical psychologists. BSOP referral is only for Practices who prescribe tirzepatide for patients meeting the NHSE Funding Variation eligibility criteria for cohort 1. The programme will offer patients a choice of:

1. Face to face group sessions in community settings
2. Digital face to face group sessions via an online platform
3. Digital only self-directed support through structured modules

If a patient is clinically more complex or a more individualised approach is needed, you may wish to consider referral to a SWMS for tirzepatide prescribing and support.

3. If primary care is starting tirzepatide for weight loss which service should the patient be referred to?

Tirzepatide prescribed by primary care to patients meeting the eligibility criteria for cohort 1 of the NHSE Funding Variation should refer patients to the **Behavioural Support for Obesity Prescribing** (BSOP) programme delivered by **Living Well Taking Control** for wraparound care (WAC).

If a patient is clinically more complex or a more individualised approach is needed you may wish to consider referral to a SWMS for tirzepatide prescribing and support.

4. Does the WAC model allow for non-English speakers?

The BSOP programme delivered by Living Well Taking Control has health coaches who speak various languages and are able to support patients whose first language is not English.

5. If a patient is not engaging with WAC/BSOP, should we stop Tirzepatide?

NICE mandates WAC with tirzepatide prescribing so compliance with WAC/BSOP programme should be discussed clearly and agreed with the patient on initiation of tirzepatide and engagement checked at follow-up and review. It would be helpful to advise patients to make sure they ask the BSOP team questions about the programme offers if they don't understand.

Living Well Taking Control will let Practices know if patients are not engaging and do try to support engagement. If a patient isn't engaging, they contact to patient 3 times via telephone, email and or text message and send a final invitation letter. If they then don't hear from the patient they discharge them from the service and the prescriber will be notified of this. At the point of BSOP triage patients have the opportunity to decide with pathways works for them.

Patients who persistently do not engage with WAC and have not shown any dietetic, behavioural or increased physical activity modifications whilst receiving tirzepatide should be reviewed with a view to stopping treatment.

6. Is the nutrition and dietetic input appropriate for our ethnic diversity?

Living Well Taking Control who are providing the Behavioural Support for Obesity Prescribing (BSOP) wraparound care have confirmed that they have coaches who speak various languages and are able to support patients whose first language is not English.

They also confirm that they follow NHS guidelines for nutrition; however, where there are specific cultural needs or dietary requirements, they can adapt their nutritional content accordingly. They also offer relevant signposting and resources to ensure culturally appropriate support.

7. Many of my patient group are digitally excluded, require single sex spaces and may not venture out of their local community.

We have further detail from Living Well Taking Control's BSOP programme offer of:

- Digital 1-1 services
- Tailored Remote Delivery – with a telephone dial in option for those that do not have access to an internet connection or do not feel confident with accessing via a Teams platform.
- Face to Face Delivery – Delivered at Local Venues close to General Practice or the Patient's Home Address

For the specific patients listed above, Digital 1-1 or remote single-sex groups would be the most appropriate options. These can be offered; however, single-sex groups may involve a slightly longer waiting period to allow time for enough patients to run the programme.

Other

1. **Should a private prescriber be providing to a patient with T1DM as our team could not see it as licensed?**

T1DM is not a licensed indication for use and people with T1DM were excluded from the SURMOUNT 1 and 2 trials.
The NHSE cohort 1 criteria do not include T1DM as a qualifying weight related comorbidity so they need to meet the other criteria to be eligible. If they meet the NHSE cohort 1 criteria then it is worth considering treatment but explaining to the person that the current evidence is limited for T1DM.

2. **What do we do if patients are already accessing tirzepatide privately and meet the criteria - can we start on the dose that they have got to privately, or do we have to start at the lowest dose?**

If you are confident in the recording of weight prior to initiation and the original BMI was accurate (private providers can allow self-reported weights which is not always accurate) and they met the NHSE Cohort 1 comorbidity eligibility criteria at that time, then it is pragmatic to continue their treatment even if the patient's BMI has dropped below 40. They will still need to be referred to the WAC BSOP programme delivered by Living Well Taking Control.

If the patient is stable and has had the appropriate monitoring and you are confident with the dose they are taking privately, then it makes sense to continue the same dose rather than going to back to baseline.

3. **If they have met their HbA1c target on tirzepatide for T2DM under the NICE TA924 eligibility can we up titrate dose further for weight loss?**

In most cases 5 mg/week will be sufficient for good glycaemic control in patients with T2DM. Doses higher than 5mg/week may be considered after careful assessment if there has been a beneficial metabolic response to the 5 mg dose i.e. reduction of HbA1c of at least 11 mmol/mol **and** weight loss of at least 3% in first 6 months **and** further weight loss may benefit other obesity-related complications. This will be on a case-by-case basis. Note that if higher doses are appropriate don't substitute by doubling up a lower dose. This was within our previous tirzepatide prescribing guidance (no longer available as it was felt that it was not needed with the increase in clinical experience).

4. **If they have reached or exceeded their HbA1c target, should we continue tirzepatide?**

In those who have T2DM and proven metabolic response (defined as HbA1c improvement **and** weight loss >3%) consider ongoing prescribing, even where HbA1c target has been achieved or exceeded and continues to be achieved. Normalisation of HbA1c does not remove their eligibility for Tirzepatide under the Type 2 Diabetes NICE TA924.

5. If patients are achieving more than 5% weight loss, what would the intended duration of treatment be - until their BMI is within normal range?

NICE have not stipulated a time limit on treatment, or lower BMI cut-off. However, all patients will have a plateau of their weight loss, so depending on their starting BMI, it is important for patients to appreciate that there will be a limit, that will be highly individual to the patient.

6. Why is there no lower BMI cut off? Is this because patients tend to plateau in their weight before it becomes worryingly low? And if they don't plateau and continue to lose presumably, we stop prescribing?

There is usually a plateau before reaching any worrying cut-offs (i.e. BMI <18). This is why monitoring for response is important to see how they go. What is even more important though is rather than discontinuing, considering tapering back to a maintenance dose, trials from SURMOUNT-4 indicate they will relapse if we remove the drug entirely. It worth noting that people initiated in primary care will have a very high starting point so unlikely to reach worryingly low BMIs.

7. HCP - need to have clinical competence to prescribe in this area. Does this mean it can't be an HCA to then request Rx from a prescriber having completed the training and competent in consultations?

NHSE commissioning guidance states the initial assessment and decision to continue are conducted by an **appropriately trained healthcare professional** although this is not defined**.** We have taken a pragmatic approach and recommend that this is defined as**:**

a. Completion of SWMS-led webinar (recorded) **and**
b. Clinical competence to prescribe in this area

It is at the Practice's discretion to decide on the internal processes for safe repeat prescribing noting that patients will require additional support through the titration period to monitor side-effects/adverse drug reactions before reaching a maximum tolerated dose.

8. Could you clarify around using this drug in patients with previous suicidal ideation?

Suicidality was more strongly mentioned with regards to Semaglutide (Wegovy) initiation. However, the Medicines and Healthcare Review Agency (MHRA) undertook a thorough review and concluded in September 24 that the 'available evidence did not establish a causal relationship between GLP-1s and suicidal behaviour, suicidal ideation, self-injury and depression'. Although Tirzepatide was not included in this review it would be reasonable to assume that it is likely to be relevant to Tirzepatide too; it is not listed as a contraindication in the summary of product characteristics. It is worth noting that people with active suicidal ideation, previous suicidal attempts, or unstable mental health were excluded from the SURMOUNT-1 and 2 trials.

Note that Tirzepatide (Mounjaro) is classified as a Black Triangle medicine by the MHRA so is subject to additional safety monitoring. Any potential or actual adverse effects should be reported through the MHRA Yellow card reporting scheme.

9. If a patient cannot exercise due to a mobility issue, would treatment need to be altered in any way? E.g. would there be an adjustment for predicted higher risk of lean mass loss?

There is a lack of data in this population, but we suggest that there would be no need to adjust the treatment if the person has mobility issues. Please encourage the person to do as much physical activity as feasible and this does include chair exercises – you can preserve lean muscle mass and avoid deconditioning this way which is important. If they lose weight, they are more likely to be able to do more exercise.

10. We understand that the recent delivery plans for the implementation only includes the first year of treatment. Would you be able to estimate what the monitoring requirements will be after 1 year of treatment? And would there be any payment for that monitoring after 1 year of treatment?

This is still unknown at this point, we will communicate to practices when we know more about this.

11. What is the percentage of patient population under the weight management service who are obese but do not have metabolic disorder like diabetes?

Around 30% of people attending the NBT tier-3 obesity service have T2DM.

Version Control	
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Footnote: FAQs from Tirzapetide webinar held 11 June 25, some minor typographical corrections have been made for readability. Further questions have been added and we will continue to update these FAQs as colleagues in primary care begin to offer this new service.	