

TIRZEPATIDE (MOUNJARO®) AS AN ADJUNCT TO LIFESTYLE MEASURES IN WEIGHT MANAGEMENT

TARGET AUDIENCE	Primary and Secondary care
PATIENT GROUP	Patients engaging with a Lanarkshire Weight Management Service (LWMS) intervention

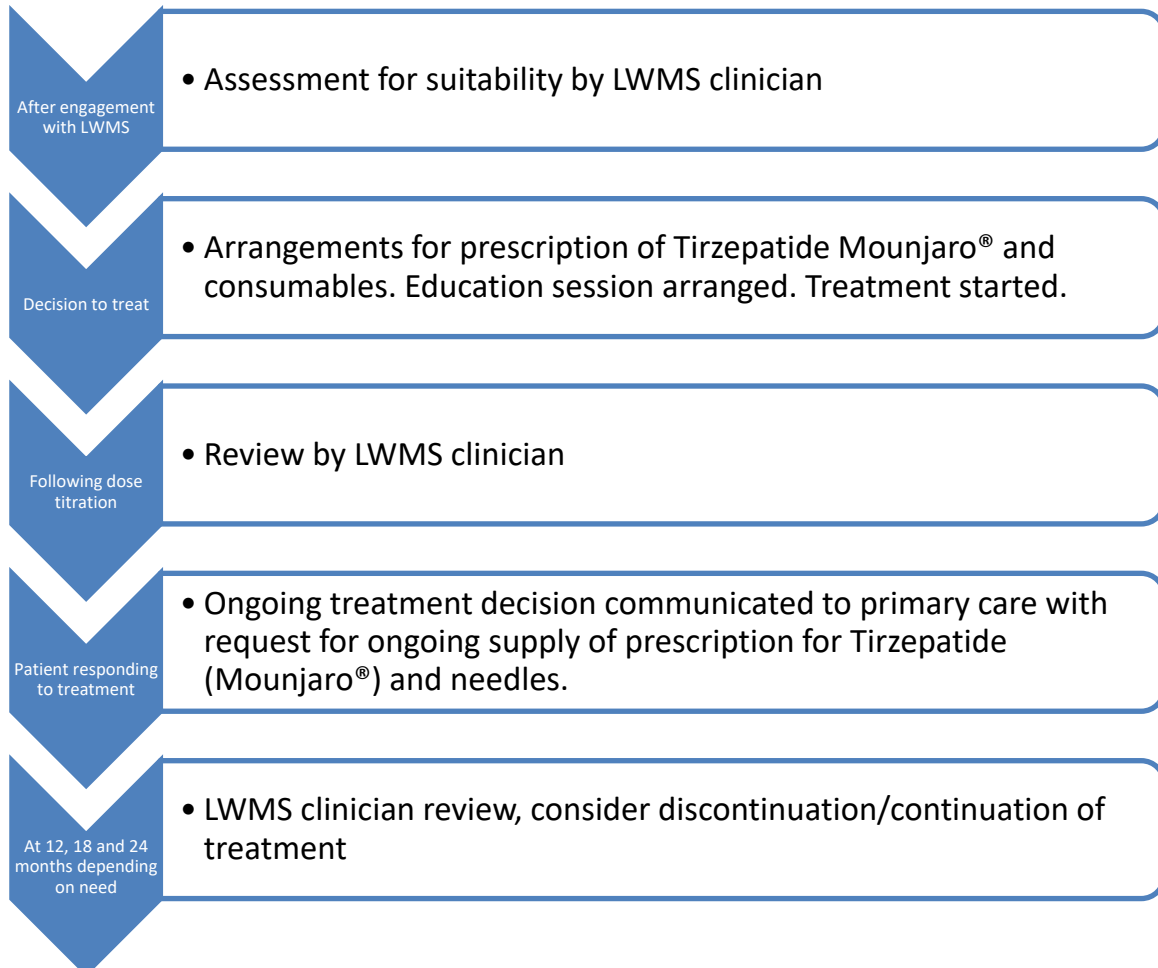
Clinical Protocol

Indications for use:

The SMC has accepted the use of Tirzepatide (Mounjaro®) for restricted use in NHS Scotland for those with a BMI of $\geq 30 \text{ kg/m}^2$ in the presence of at least one weight-related co-morbidity.

An NHS Scotland consensus statement was published in September 2024. It stated that the first phase of implementation of the SMC guidance should be those with a BMI of $\geq 38 \text{ kg/m}^2$ in the presence of at least one weight-related co-morbidity.

REFERRAL FOR WEIGHT MANAGEMENT ACCEPTED BY LWMS AND INTERVENTION COMMENCED ⁽²⁾



Patient Pathway (see summary previously)

Referral Accepted by LWMS and Intervention Commenced

Patients will be referred to the LWMS for support with weight management. They will be accepted if they have complex weight management needs in keeping with the LWMS referral criteria⁽²⁾ and a decision made as to which intervention is appropriate. Patients with less complex needs will be referred on to community led Weight Management services. *It is important to note that patients should not be referred to the LWMS for pharmacotherapy specifically. The appropriateness of this treatment will be decided by the LWMS clinical team as below, and in line with SMC/national guidance.*

After engagement with LWMS Intervention - Clinician review of patients

Each intervention has an active phase of around 12-16 weeks followed by a maintenance phase with monthly LWMS input for the following 9 months. Once the patient has engaged with their intervention, they will be reviewed by the LWMS clinicians either in clinic, or following discussion at the LWMS MDT.

Decision to Treat

- Baseline screening will be performed – height, weight, U&E, LFTs, HbA1c, lipids.
- A decision will be made regarding eligibility based on the inclusion and exclusion criteria (see Appendix A – Eligibility Criteria).
- The LWMS clinician will counsel the patient regarding Tirzepatide (Mounjaro®) and its use.

Decision to Treat - Arrangements for prescription of Tirzepatide (Mounjaro®), consumables and education session made.

Following a decision to commence treatment with Tirzepatide (Mounjaro®)

- The LWMS clinician will correspond with the patient and their primary care provider with details of: dosing schedule and where to pick up prescription, advice regarding needle disposal, points of contact (the LWMS clinician team).
- The LWMS prescriber will send a prescription for Tirzepatide (Mounjaro®) to the hospital pharmacy. This will be for the 6-month titration phase.

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- The LWMS clinician will write to the primary care provider requesting a prescription for adequate needles for this period (Insupen pen needles which are available on the local formulary).
- As Tirzepatide (Mounjaro®) is administered by weekly subcutaneous injection. The LWMS team will arrange an education appointment with the patient.

Following the 6 Month Titration Phase (with ongoing maintenance phase of LWMS intervention running concurrently) – Review by LWMS specialist nurse/team

- Following dose titration, a review appointment will be conducted by the LWMS team. They will record the patient’s weight, and a decision will be made about ongoing treatment.

Response to treatment - Ongoing treatment decision communicated to primary care with request for ongoing supply prescription of Tirzepatide (Mounjaro®) (with ongoing maintenance phase of LWMS intervention running concurrently)

- If the patient is not responding to treatment an assessment will be made as to the appropriateness of a further prescription. If the patient is responding the LWMS clinician will send a recommendation to the primary care prescriber asking for their prescription for Tirzepatide (Mounjaro®) and needles to be continued in primary care for a further 6 months.

One Year - LWMS team, consider discontinuation/further year of treatment

- A review appointment with the LWMS team will be arranged a year after commencement of treatment and a decision made about continuation. This will be communicated to the primary care prescriber. Options will be:
 - If treatment has either not been effective or not tolerated it will be discontinued
 - If weight-loss has plateaued, dose reduction will be advised to the lowest effective dose and ongoing follow up will remain with the LWMS. Prescribing of Tirzepatide (Mounjaro®) will be taken over by the LWMS for the duration of titration and the primary care prescriber kept informed. Further review will be arranged at 2 years.
 - If weight-loss is ongoing and the prescription is stable, prescribing will remain with primary care, and follow up will continue under the LWMS.
- This part of the protocol will remain under review as evidence emerges.

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Eligibility Criteria

Inclusion criteria:

- Age 18-75
- Meet criteria for the Tier 3 LWMS service and are/have engaged with a behaviour change intervention
- No contraindications to Tirzepatide (Mounjaro®)

Exclusion criteria:

- Contraindications to Tirzepatide (Mounjaro®) – see below
- Previous treatment with intolerable side effects.

Withdrawal criteria:

- Intolerable side effects
- Development of contra-indications
- Non-response
- Disengagement with LWMS behaviour change intervention

Pre-Treatment Evaluation/Investigations

Weight, height, BMI, Hba1c, lipids, U&E

Treatment Requirements

- Dose titration: Initially 2.5 mg once weekly for 4 weeks, then increased to 5 mg once weekly for at least 4 weeks, then increased if necessary up to 15 mg once weekly, dose to be increased in steps of 2.5 mg at intervals of at least 4 weeks. Assess benefit of continuing treatment if at least 5% of initial body weight has not been lost after 6 months at highest tolerated dose.
- Patients will be taught to self-administer drug at home. Tirzepatide (Mounjaro®) is injected subcutaneously into the skin of the abdomen, thigh or upper arm. Dosing is weekly. Site should be rotated with each dose.

Precautions, contraindications and adverse effects:

- Contraindicated in medullary thyroid cancer, multiple endocrine neoplasia
- Avoid in pregnancy
- Use with caution in women who are breast-feeding
- Female patients who are using an oral contraceptive should add a barrier method or switch to a non-oral contraceptive for the first 4 weeks of treatment and for 4 weeks after each subsequent dose increase

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- Discontinue treatment at least one month before a planned pregnancy
- Use in caution in patients with renal and hepatic disease
- Tirzepatide (Mounjaro®) delays gastric emptying which potentially can slow down absorption of other medication, monitor those on medications with a narrow therapeutic index
- The most common side effects include nausea, diarrhoea, decreased appetite, vomiting, constipation, indigestion, burping, dizziness, gastrointestinal discomfort, hypersensitivity, hypotension, lethargy
- Rarer side effects include gall bladder disorders, pancreatitis – patients should be advised of symptoms

Dose modifications:

- There are no specific dose modifications in renal or hepatic disease, but it should be used with caution.

Audit/Evaluation of Response to Treatment:

- All patients will be reviewed during and following the titration period by the LWMS team to ensure they are responding to treatment. Treatment should be withdrawn if this is not the case.

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Responsible Person (if different from lead author)	

CONSULTATION AND DISTRIBUTION RECORD	
Contributing Author / Authors	

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<p>Consultation Process / Stakeholders:</p>	<p>LWMS clinicians and management team Acute and primary care medical directors Acute clinical DMT and EDG GP subcommittee</p>
<p>Distribution</p>	<p>As above: LWMS clinicians and management team Acute and primary care medical directors Acute clinical DMT and EDG GP subcommittee</p>

CHANGE RECORD

Date	Lead Author	Change	Version
30.1.2024	I Howat		1
			2
			3
			4

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