

Use of Tirzepatide (Mounjaro®)

TARGET AUDIENCE	Primary and Secondary care
PATIENT GROUP	Adults with Type 2 Diabetes Mellitus

Clinical Protocol

Indications for use:

SMC restriction:

- In addition to other oral anti-diabetic medicines as an option when glucagon-like peptide-1 (GLP-1) receptor agonists would be considered.
- Use of Tirzepatide as monotherapy is not recommended when metformin is considered inappropriate due to intolerance or contraindications.

Eligibility criteria:

- Inclusion Criteria: Third line treatment for people with Type 2 DM, alongside GLP1RA for those with a BMI of >35. Patients with established cardiovascular disease should be treated with a GLP1RA with proven CVD benefit.
- Exclusion criteria – see “Precautions, contraindications & adverse events”
- Treatment should be withdrawn if there is no clinical benefit either in terms of weight loss (under 5%) and/or glycaemic control (HbA1c reduction under 5mmol/mol) at 6 months.

Pre-Treatment Evaluation/Investigations:

- Hba1c, routine biochemistry, weight.

Treatment Requirements

- Initiation should be based on advice from acute or community-based specialist Diabetes Services albeit this could be provided asynchronously and does not require direct review.
- Initially 2.5 mg once weekly for 4 weeks, then increased to 5 mg once weekly for at least 4 weeks. Can be increased if necessary up to a maximum dose of 15 mg once weekly, with the dose increased in steps of 2.5 mg at intervals of at least 4 weeks.
- Dose escalation should be stopped at the lowest effective dose.
- Self-administered, although some patients may need assistance from a family member or carer to help administer the injection.

How to take Mounjaro® injections:

- Injected under the skin (subcutaneously) of the abdomen, thigh, or upper arm.
- Inject no more than once per week, at any time of the day.
- Do not mix insulin and Mounjaro® together in the same injection.
- You may give an injection of Mounjaro® and insulin in the same body area, but not right next to each other.
- Rotate the injection site with each weekly injection. Do not use the same site for each injection.

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.
- Discontinue treatment at least one month before a planned pregnancy.
- Use in caution in patients with renal and hepatic disease..
- Tirzepatide 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.

Investigations prior to subsequent treatment:

- Routine diabetes monitoring, including review of drug efficacy.

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 should be reviewed during and following the titration period by their diabetes team to ensure they are responding to treatment. Treatment should be withdrawn if this is not the case.

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			3
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