

INFORMED CONSENT FOR TIRZEPATIDE/MOUNJARO TREATMENT

Patient Name: _____

Date of Birth: _____

I, the undersigned, hereby give my consent to receive treatment with tirzepatide, a medication prescribed for the management of type 2 diabetes and/or chronic weight management in adults with obesity or overweight.

1. Purpose and Benefits of tirzepatide Treatment

I understand that tirzepatide has been approved by the FDA for one indications. Tirzepatide was first approved by the FDA in May 2022 as Mounjaro, a once-weekly injectable medication for the treatment of adults with type 2 diabetes.

Any other use is considered OFF LABEL use.

2. Administration of tirzepatide

Tirzepatide is administered via subcutaneous injection using a prefilled pen. The specific dose and pen options may vary based on the formulation of tirzepatide prescribed.

3. Contraindications and Limitations of Use

I acknowledge the following contraindications and limitations of tirzepatide use:

Contraindications:

- Personal or family history of medullary thyroid carcinoma
- Multiple endocrine neoplasia type 2
- Prior serious hypersensitivity reaction to tirzepatide or any of its components

Limitations of Use:

- tirzepatide should not be used in combination with other tirzepatide-containing products or any other GLP-1 receptor agonist.
- Safety and efficacy of tirzepatide in combination with other weight loss medications or products have not been established.
- tirzepatide has not been studied in patients with a history of pancreatitis.

4. Warnings and Adverse Events

I understand that tirzepatide treatment may have certain warnings and potential adverse events, including but not limited to:

- Risk of thyroid C-cell tumors: Regular thyroid examinations and calcitonin measurements may be required.
- Acute pancreatitis: Signs and symptoms of acute pancreatitis should be monitored, and tirzepatide should be discontinued if this condition occurs.

- Acute gallbladder disease: Rapid weight loss with tirzepatide may increase the risk of acute gallbladder disease, and patients should be monitored for related symptoms.
- Hypoglycemia: tirzepatide can cause low blood sugar levels, especially when used with other hypoglycemic medications. Diabetic patients should be aware of this risk, and blood glucose levels should be monitored.
- Acute kidney injury: tirzepatide may lead to acute kidney injury or worsening renal failure in some cases, particularly in patients experiencing adverse gastrointestinal reactions such as nausea, vomiting, diarrhea, or abdominal pain.
- Hypersensitivity reactions: Anaphylaxis or angioedema may occur, especially in patients with a history of hypersensitivity to GLP-1 receptor agonists.
- Diabetic retinopathy complications: Temporary worsening of diabetic retinopathy has been associated with rapid improvement in glucose control.

According to clinical studies, gastrointestinal adverse events are the most common and tend to be mild to moderate, decreasing over time.

The most common adverse events reported in more than 5% of the patients treated with tirzepatide include nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia and abdominal pain.

5. Follow-up Appointments

I understand that regular follow-up appointments and laboratory tests are necessary to monitor the effectiveness and safety of tirzepatide treatment. These appointments may include assessments of body mass index, vital signs, glucose levels, lipid profile, renal function, liver function, and thyroid function.

6. Right to Withdraw Consent

I understand that I have the right to withdraw my consent for tirzepatide treatment at any time.

7. Questions and Concerns

I have had the opportunity to ask questions about tirzepatide treatment, and my healthcare provider has addressed my concerns to my satisfaction. I understand that I can contact my healthcare provider if I have any further questions or concerns.

By signing below, I acknowledge that I have read and understood the information provided in this informed consent document, and I voluntarily agree to proceed with tirzepatide treatment under the supervision of my healthcare provider.

Patient Signature: _____

Date: _____

Healthcare Provider Signature: _____

Date: _____