THE URGENT CARE

Weight Management (Tirzepatide) Prescription Drug Management Consent

This document is intended to serve as a confirmation of informed consent for compounded **Tirzepatide,** *which is a prescription weight management medication.*

Patient Informed Consent

1. I voluntarily request that The Urgent Care Clinic treats my medical condition.
2. I have informed my provider of any known allergies, my medical conditions, medications, social/family history.
3. I have been informed of this treatment and considered the risks and benefits.
4. I understand how it is to be administered, and agree to use only the prescribed dosage.
5. I understand the prescription will come from an FDA-approved compounding pharmacy.
6. I understand that this medication cost may increase based upon supply and demand.
7. It has been explained to me that this medication could be harmful if taken inappropriately or without advice from the provider.
8. I understand this medication may cause adverse side effects (see below). I understand this list is not complete and it describes the most common side effects, and that death is also a possibility of taking this medication. I understand symptoms may be worse after there has been a change in my medication dose or when first started the medication.
   this medication could be harmful if taken inappropriately or without advice from the provider.

What is Tirzepatide Weight Management Treatment:
Tirzepatide weight management injections are *used for weight loss along with a diet and exercise plan*.
These injections are delivered beneath the surface of the skin (subcutaneously) for chronic weight management in adults with obesity (BMI >30) or who are overweight (BMI >26) with at least one weight-related condition, including high blood pressure, diabetes type 2, and/or high cholesterol. Tirzepatide mimics both GIP and GLP-1 receptor agonist hormones, which trigger insulin creation, sensation of fullness, and appetite reduction.

Treatment benefits will vary by individual but may include:

1) reduced appetite,
2) feeling a sense of fullness for longer durations after eating (delayed gastric emptying),
3) and increased fat-burning mechanisms which may result in weight loss.

Additional treatment benefits associated with these weight loss injections may include:

1) improved A1C and blood sugar levels by increasing insulin (a hormone that lowers blood sugar levels) and inhibiting glucagon (a hormone that raises blood sugar);
2) improved blood pressure;
3) reduced risk of major adverse cardiovascular events.

I understand the **Purpose and Benefits** of Tirzepatide treatment:
Initials:_____

What To Expect During Treatment: Your treatment provider will review your health and medication history to ensure you are a good candidate for weight loss injections. You will be counseled on nutrition and exercise recommendations to be used along with Tirzepatide injections for chronic weight management, including reducing calories and increasing physical activity. You will be taught how to perform these injections at home just below the surface of the skin (subcutaneously) and will be prescribed a dosage that is adjusted for your individual needs, in accordance with your treatment plan. There is no downtime associated with this treatment. You may feel minor discomfort during the injection, similar to an insulin injection. Common side effects include: nausea, vomiting, diarrhea, indigestion, abdominal pain, constipation, fatigue, and dizziness. Multiple injections will be needed over the course of months to achieve desired results.

Dosing adjustments will be made by your treatment provider based on your body's response and any side effects you're experiencing. Treatment Regimen: Typical treatment regimen includes an initial series of weekly injections, including monthly follow-ups. You will return to the office for follow-up visits and dose adjustments once per month until you've reached your weight loss goals. Maintenance: Once you have achieved your weight loss goal, you may be weaned down to lower dosing Tirzepatide at specified intervals and/or given a maintenance protocol. Maintenance injections may be necessary to maintain desired results.

I understand the **treatment goal is weight loss**. I understand that repeated injections will be necessary in order to achieve desired results and that I will need to return to the office weekly for injections, as well as maintain regular follow-ups with my treatment provider. Initials:_____

Contraindications / Precautions: Tirzepatide causes thyroid C-cell tumors in rats. It is unknown whether Tirzepatide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined. Tirzepatide is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors. Patients with Hepatic Impairment: No dosage adjustment of tirzepatide is suggested for patients with hepatic impairment. Patients with Renal Impairment: Tirzepatide is associated with gastrointestinal ADRs, including nausea, vomiting, and diarrhea leading to dehydration, which can cause acute kidney injury. Use with caution in patients prone to dehydration.

Adverse Reactions/Side Effects: Based on available data, most users do not experience significant adverse drug reactions. The primary adverse effects reported are gastrointestinal, but other side effects have also been infrequently reported. Decreased appetite is frequently reported, though this is a potential contributory etiology of intentional weight loss. Below are the adverse drug reactions reported by System Organ Class (SOC).

Common side effects include, but are not limited to:

1. **Gastrointestinal**: Many people report having a lowered appetite. Up to 10% of patients may experience nausea and diarrhea, and there may also be sporadic reports of vomiting and acid reflux. Additionally, some individuals have reported having constipation.12 Other oral drugs have a harder time being absorbed when stomach emptying is delayed. This is especially important for people who already have delayed stomach emptying because it can make their symptoms worse. It is significant to highlight that oral hormonal contraceptives no longer work as well as they once did, so patients should be urged to use non-oral contraceptive methods instead. 12
2. **Neurological:** Headache, dizziness
3. **Cardiac:** Heart rate increase, Hypotension
4. **Endocrine**: Fatigue, hypoglycemia (diabetic patients), alopecia
5. **Ophthalmic**: Retinal disorder (diabetic patients)
6. **Skin**: redness or pain at the injection site
7. **Serious Reactions** include, but are not limited to
8. **Thyroid C-cell tumor (animal studies)**
9. **Medullary thyroid cancer**
10. **Hypersensitivity reaction**
11. **Anaphylaxis**
12. **Angioedema**
13. **Acute kidney injury**
14. **Chronic renal failure exacerbation**
15. **Pancreatitis**
16. **Cholelithiasis**
17. **Cholecystitis**
18. **Syncope**

This list is not exhaustive of all possible risks associated with Tirzepatide/Pyridoxine weight management treatment, as there are both known- and unknown- side effects and risks associated with any medication or treatment.

*I have read and understand **possible risks, reactions, side effects, and complications**:*

Initials:_____

Pregnancy and Tirzepatide

The amount of information on ***tirzepatide use during pregnancy is insufficient*** to evaluate the drug's potential relation to congenital problems and poor maternal or fetal outcomes. An increased risk to the mother and fetus is linked to poorly managed pregnancy diabetes. Additionally, increased rates of skeletal, visceral, and exterior abnormalities have been noted in research on animal reproduction. Therefore, tirzepatide exposure during pregnancy can pose dangers to the fetus. As a result, tirzepatide should only be used during pregnancy if the benefit outweighs the danger to the fetus. Tirozepatide should only be provided to women of childbearing age after being fully evaluated for possible teratogenic effects. Before recommending tirzepatide, doctors should also talk about starting a contraceptive regimen. Additionally, while using tirzepatide medication, the effectiveness of oral hormonal contraception decreases. For at least four weeks following the start of tirzepatide therapy, barrier contraception should be used or switching to a non-oral method of contraception may need shared decision-making.

I have read and understand **Pregnancy and Tirzepatide**.

Initials:_____

Patient Responsibilities:

1. I agree to obtain prescriptions for compounded Tirzepatide or similar product
2. Medical history: I will disclose to the clinic my complete medical history, including: allergies, medications, medical/surgical/social/family history.
    a. I understand that if I become pregnant or start trying for pregnancy, I must stop this medication and advise my prescribing provider.

b. If I am of childbearing age I acknowledge this medication has not been studied in pregnant humans & the risk to the fetus is unknown. Contraceptive use is advised.
c. If I plan to become pregnant I will stop Tirzepatide 2 months prior to pregnancy.
d. I will be honest to the best of my ability the medical history needs to know.
e. I will tell my provider any updated health information (medication, allergies, personal medical issues/surgeries/social history, or family history changes).
f. My provider can discuss my treatment plan with any co-treating pharmacist and/or healthcare provider
g. I will always tell other providers about all medications I am taking.
h. We may ask for additional labs while on treatment to ensure its safety.

I have read and understand the **Responsibilities** to treatment:
Initials:_____

Directions for use: I will take my medications only as prescribed according to the directions.

1. If I feel my medications are not effective or are causing undesirable side effects, I will contact my provider for instructions.
2. I will not adjust my medications without prior instruction to do so.
3. I understand that the medication must be kept refrigerated.
4. I understand this medication must be self-injected in the subcutaneous tissue once weekly. I will not inject any less than 7 days unless directed by my provider.
5. I will not share needles and dispose of needles safely.
6. If I'm having trouble with the administration of the medication, I will seek help from my provider.
7. The medication expires after date listed on the bottle. I will refer to the Beyond Usage Date (BUD).

I have read and understand the **Directions for use** to treatment:
Initials:_____

Safety Protocol:

1. I understand it is important to keep my medication away from children (<18 years old)
2. Store Tirzepatide safely in the refrigerator
3. I am the only one who will use my medication. I will not give or sell my medication to anyone else. `

I have read and understand the **Safety** protocol for treatment
Initials:_____

Discontinuation medication Protocol: I understand that my provider may stop prescribing my medications if:

1. I am having unfavorable side effects or it's not working to treat my medical condition
2. I have been untruthful in my medical or family history
3. I do not follow through with the recommended plan of care.
4. I do not follow any parts of "Part B: responsibilities" in this agreement.

I have read and understand the **Discontinuation medication protocol**
Initials:_____

Contraindications protocol/ May NOT be SUITABLE for you:
Please tell your treatment provider if you have any other medical conditions, including the following, as Tirzepatide injections may not be suitable for you:

1) plan to become ***pregnant*** (you should stop Tirzepatide 2 months prior to pregnancy)
2) have, or have had, problems with your ***pancreas or kidneys***
3) have ***type 1 diabetes, type 2 diabetes***, or a history of diabetic retinopathy
4) are taking certain medications, including ***sulfonylureas or insulin***
5) have, or have had, ***depression, mental health issues, and/or suicidal thoughts***

I have read and understand the **Contraindications to treatment protocol** and affirm that I do not have any of the aforementioned conditions and have disclosed pertinent medical history to my treatment provider
Initials:_____

Possible Medication Interactions and/or Reduced Effectiveness

Prescription and OTC Medication, Herbal and Nutritional Supplements, and Minerals:
I understand that certain herbal products, medications, and supplements may affect the way Tirzepatide works, resulting in reduced efficacy of treatment and/or additional side effects. Tirzepatide slows stomach emptying and can affect the absorption of oral medications medicines, which may affect the way certain medications work or the effectiveness of medications. ***For example, one may want to add a barrier method if using oral contraceptives for further protection from unintended pregnancy when using oral contraceptives as tirzepatide may make oral birth control less effective.***

I have read and understand the **possibility of interactions** with treatment
Initials:_____

Liability Release Related to Adverse Effects: I assume full liability for any adverse effects that may result from the non-negligent administration of the proposed treatment. I waive any claim in law or equity for a redress of any grievance that I may have concerning- or resulting from- the treatment, except as that claim pertains to the negligent administration of this procedure.
I agree to assume full liability for any adverse effects of treatment
Initials:_____

Pregnancy Waiver: I deny the possibility of being pregnant at this time. I understand that Tirzepatide may harm an unborn baby and the safety of the use of Tirzepatide during pregnancy and breastfeeding has not been studied. If I am unsure of pregnancy, I will request a pregnancy test before my treatment. I further acknowledge that I should stop using Tirzepatide at least 2 months prior to becoming pregnant.
I deny the possibility of being **pregnant** at this time and acknowledge risk of harm to an unborn child while taking Tirzepatide
Initials:_____

No Guarantee of Results: In some situations, it may not be possible to achieve desired weight loss results. It is also possible that Tirzepatide/Pyridoxine injections may fail to produce any weight reduction. Should complications occur, additional or other-treatments may be necessary. Tirzepatide/Pyridoxine injections are not a permanent solution for weight management, and must be maintained with lifestyle and diet modifications; you may also require maintenance injections to maintain desired weight. As a weight management treatment, it is recommended to allow at least 90 days of treatment to achieve results. Duration of results is unknown and not guaranteed.
I have read and understand results are **not guaranteed**
Initials:_____

Alternative Treatments: Alternative forms of non-surgical and surgical treatment consist of: No treatment whatsoever, diet and lifestyle modifications, increased physical activity, other pharmaceutical weight management therapies, and bariatric surgery. Every procedure will involve a certain amount of risk. An individual's choice to undergo a procedure is based on the comparison of the risk to the potential benefit. Although most patients do not experience adverse complications, you should discuss your concerns and potential risks with your treatment provider in order to make an informed decision.
It has been explained to me that alternative treatments are available
Initials:_____

Financial Responsibility: By signing below, I acknowledge that I understand the regular charge applies to all treatments. I understand- and agree- that all services rendered to me are charged directly to me and that I am personally responsible for payment. I acknowledge that most insurance do not cover the cost of weight loss injection treatment, and therefore, I am required to pay for services and medication out of pocket. In the event that I am not satisfied with my results, I agree not to seek a refund for Tirzepatide treatment services rendered, as I am fully aware that there is no implied or explicit guarantee of results, as stated in the acknowledgment above. *I further agree in the event of non-payment and/or reversal of payment via a credit card dispute that I initiate, I will bear the cost of collection fees, and/or court fees, and/or any reasonable legal fees resulting from such instance*
Initials:_____

Treatment Liability Waiver: I acknowledge that elective supplementation therapies, including, but not limited to Tirzepatide/Niacinamide Weight Management Treatment, may be considered medically unnecessary. It may or may not mitigate, alleviate, or cure the condition for which it has been prescribed. This treatment has been recommended to me in the belief that it is of potential benefit and its use will quite probably improve the condition for which I am under treatment for. Based on the risks and potential benefits of this proposed treatment, I have elected to receive this proposed treatment from providers and staff at The Urgent Care Clinic. I understand that I may suspend or terminate my treatment at any time by informing my medical provider. I assume full liability for any adverse effects that may result from the non-negligent administration of the proposed treatment. I waive any claim in law or equity for redress of any grievance that I may have concerning or resulting from the procedure, except as that claim pertains to negligent administration of this procedure. The risks involved and the possibilities of complications have been explained to me. I fully understand and confirm that the nature and purpose of the aforementioned treatment to be provided may be considered unproven by scientific testing and peer-reviewed publications and therefore may be considered medically unnecessary or not currently indicated. I have read this form in its entirety. It has been explained to me. I have had the opportunity to ask questions and have all my questions answered. I fully understand the above information and have no further questions. By signing this form, I voluntarily give my consent for treatment and agree to the risks. Therefore, in consideration for any treatment received, I agree to unconditionally defend, hold harmless, and release from any and all liability the company and the individual that provided my treatment, the insured, and any additional insured's, as well as any officers, directors, or employees of the above companies for any condition or result, known or unknown, that may arise as a consequence of any treatment that I receive. I understand and agree that any legal action of any kind related to any treatment I receive will be limited to binding arbitration using a single arbitrator agreed to by both parties.

By signing below, I acknowledge and agree: I have carefully read the information in this document and understand that I may be giving up some important legal rights by signing.

Patient Signature *Date*

Staff Signature *Staff Printed Name* *Date*