

SEMAGLUTIDE/TIRZAPETIDE INFORMED CONSENT

Patient Name: _____

DOB: _____

Check if any of the following applies to you:

- Have a history of problems with pancreas, gallbladder or kidneys
- Have a history of diabetic retinopathy
- Have or have had depression or mental health issues
- Have known allergy to Semaglutide/Tirzepatide
- Pregnant or Breastfeeding
- Family history of thyroid cancer or Multiple Endocrine Neoplasia Syndrome Type 2 (MEN 2)
- Have or have had suicidal thought
- None of the above

MEDICATION DISCLOSURE

Semaglutide/Tirzepatide

I understand that I may be prescribed semaglutide or tirzepatide, either as:

- An FDA-approved medication under the brand name, when appropriate

OR

- A compounded formulation prepared by an FDA registered licensed compounding pharmacy

I acknowledge and understand that compounded semaglutide/tirzepatide:

- **Are NOT approved by the U.S. Food and Drug Administration (FDA)**
- Have NOT been evaluated by the FDA for safety, effectiveness, or quality
- Are NOT the same as commercially available FDA-approved medications
- May differ in formulation, concentration, inactive ingredients, and delivery method
- Our compounded medication is tested by third party Laboratory for content & sterility, documented on a CERTIFICATE OF ANALYSIS

_____ Initial

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ON LABEL & OFF LABEL USE DISCLOSURE

Semaglutide/Tirzepatide under name brands of Ozempic, Wegovy, Mounjaro, Zepbound are FDA approved medication for weight loss in patients with a BMI of 30 or higher or a BMI of 27 or higher with other medical conditions. Prescribing this medication for patients outside of these criteria is considered "off label" and not "FDA approved." Therefore, the potential risks vs. benefits may be greater. For patients not fitting the FDA approved criteria for use of this medication, you are acknowledging that:

- You have put forth a true effort to lose weight through diet and exercise over the past 6 months and have still not achieved your weight loss goals.
- Your inability to lose weight is causing significant emotional distress
- You are choosing to enter this medically managed weight loss program voluntarily and hold harmless River oaks/Bellaire Beauty & Weight Loss Center and our healthcare personnel for use of such medication.

MEDICATION INTERACTION

Tell your healthcare provider about all the medicines you take. Semaglutide/Tirzepatide may affect the way some medicines work, and some medicines may affect the way Semaglutide/Tirzepatide works. Tell your healthcare provider if you are taking other medicines to treat diabetes, including Sulfonylureas or insulin. Semaglutide/Tirzepatide slows gastric emptying which can affect absorption of medicines that need to pass through the stomach quickly such as oral birth control.

Do not share your Semaglutide/Tirzepatide injections with other people, even if the needle has been changed. You may develop a serious infection or give others a serious infection.

You will be evaluated and treated by our physician and her staff; the recommended care and treatment is subject to supervision and review by our licensed physician.

_____ Initial

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SIDE EFFECTS/COMPLICATION

The most common side effects of Semaglutide/Tirzepatide include:

Nausea, diarrhea, vomiting, constipation, abdominal pain, headache, fatigue, upset stomach, dizziness, bloating, belching, gas, and heartburn.

Some other possible side effects of Semaglutide/Tirzepatide include:

- **Possible thyroid tumors** including cancer; lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath.
- **Pancreatitis and the complications from it:** severe abdominal pain that will not go away, with or without vomiting.
- **Gallbladder problems;** pain in your upper abdomen, fever, yellowing of the skin or eyes (jaundice), or clay-colored stools.
- **Increased risk of hypoglycemia** in patients with type 2 diabetes; dizziness, light-headedness, blurred vision, anxiety, irritability/mood changes, sweating, slurred speech, hunger, confusion or drowsiness, shakiness, weakness, headache, fast heartbeat, or feeling jittery.
- **Renal failure:** due to loss of fluids (dehydration) which may cause kidney problems.
- **Allergic reactions or anaphylactic shock;** swelling of your face, lips, tongue, or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy, or very rapid heartbeat.
- **Retinopathy/Change in vision** in patients with type 2 diabetes.
- **Increased heart rate**
- **Depression or thoughts of suicide;** sudden changes in your mood, behaviors, suicidal thoughts.

Go to the Emergency room and seek medical attention right away if you are experiencing any of the above symptoms.

_____ Initial

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ACKNOWLEDGEMENT

- _____ For best results, Semaglutide/Tirzepatide should be used with a reduced calorie meal plan and increased physical activity. Semaglutide/Tirzepatide should not be used with other GLP-1 receptor agonist medicines unless approved by your primary care physician.
- _____ Semaglutide/ Tirzepatide should be stopped 8 weeks before any surgery. Please discuss with the surgical team.
- _____ Because Semaglutide/Tirzepatide delays gastric emptying, they may alter the absorption of concomitant oral medications. Such as birth control pills so it's important to have another form of contraception while on treatment. It is important to notify all healthcare providers of all prescription, over the counter, or herbal/alternative medicine and supplements that you take while using Semaglutide/Tirzepatide.
- _____ Do not use Semaglutide/Tirzepatide if you are pregnant, plan to become pregnant, breastfeed, or plan to breastfeed. Semaglutide/Tirzepatide may harm your unborn baby. You should stop using it for 2 months before you plan to become pregnant. It is not known if Semaglutide/Tirzepatide passes into breast milk.
- _____ It is not known if Semaglutide/Tirzepatide can be used safely in people with a history of pancreatitis. Your initial confirms that you do understand the possible risk of pancreatitis while on treatment.
- _____ Please acknowledge that you understand that the amount of weight loss varies from patient to patient and is largely dependent on each patient's body chemistry and commitment to their diet and exercise plan. No claims as to efficacy or specific amount of weight loss are either guaranteed, expressed, or implied. Please also understand the importance of routinely following up with River Oaks/ Bellaire Beauty and Weight loss Clinic to monitor your progress and/or to receive your medication. This is vital to the safety of the treatment program. We can terminate your treatment if you refuse to be seen by our physician in charge of your care.

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_____ Please certify that you are either under the care of a primary care provider or specialist for any health conditions that might arise from this treatment. If you do not have a primary care provider, we encourage you to seek one out. Please acknowledge that you are seeking care at River Oaks/ Bellaire Weight Loss Clinic for medically managed weight loss service only, not for primary care.

_____ I have read and fully understand this form, and I realize I should not sign this form if all items have not been satisfactorily explained to me. With my signature I acknowledge that my questions have been answered fully, I understand all the possible side effects, risks and complications listed above as well as those that are not known at this time but may arise in future because of these treatments. I fully accept the risks. I hereby release River oaks Beauty and Weight loss/Bellaire Beauty Weight Loss Center, the physician and staff from all liabilities associated with this treatment plan and would like to proceed with this treatment.

Print Name

Signature/Date

Physician

Date

Witness