**Patient Consent to Medical Weight Loss**

PLEASE READ EACH SECTION CAREFULLY. YOU MAY REQUEST A COPY OF THIS FORM FOR YOUR OWN RECORDS

## Compounded GLP-1 Weight Management Treatment Consent

### About the medications

Tirzepatide, a medication from the class of GLP-1 and GIP receptor agonists, helps with weight loss through several mechanisms. Common brand names for tirzepatide include Mounjaro and Zepbound.

* Appetite Control: Tirzepatide mimics hormones in your body that help regulate appetite. These hormones signal your brain to make you feel full sooner, reducing hunger and helping you eat less.
* Blood Sugar Regulation: It improves how your body uses insulin, which helps keep your blood sugar levels stable. This can prevent cravings and reduce overeating.
* Delayed Gastric Emptying: Tirzepatide slows down the rate at which your stomach empties food into your intestines. This helps you feel fuller for a longer time after eating, further reducing your overall food intake.

Semaglutide, a medication from the class of GLP-1 receptor agonists, helps with weight loss through several mechanisms. Common brand names for semaglutide include Ozempic and Wegovy.

* Appetite Control: Semaglutide mimics a hormone in your body called GLP-1, which helps regulate appetite. This hormone signals your brain to make you feel full sooner, reducing hunger and helping you eat less.
* Blood Sugar Regulation: It improves how your body uses insulin, which helps keep your blood sugar levels stable. This can prevent cravings and reduce overeating.
* Delayed Gastric Emptying: Semaglutide slows down the rate at which your stomach empties food into your intestines. This helps you feel fuller for a longer time after eating, further reducing your overall food intake.

Semaglutide and tirzepatide are both medications commonly used for weight loss. By addressing appetite, blood sugar, and gastric emptying, both medications effectively supports weight loss and helps you manage your weight more successfully. While similar, they have different mechanisms of action, effectiveness, and average weight loss outcomes.

##### Semaglutide:

Belongs to the class of GLP-1 receptor agonists.

Mimics the GLP-1 hormone, which increases insulin secretion, decreases glucagon release, slows gastric emptying, and reduces appetite.Clinical trials have shown that patients using semaglutide can lose an average of about 15% of their body weight over 68 weeks when combined with lifestyle interventions.

##### Tirzepatide:

Belongs to the class of dual GLP-1 and GIP receptor agonists.

Mimics both GLP-1 and GIP hormones, enhancing insulin secretion, decreasing glucagon release, slowing gastric emptying, and significantly reducing appetite. Clinical trials have demonstrated that patients using tirzepatide can lose an average of about 20% of their body weight over 72 weeks when combined with lifestyle interventions. Tirzepatide has shown to be slightly more effective in weight loss compared to semaglutide.

### Statement About Off-Label Prescribing of Compounded GLP-1s

Off-label prescribing of compounded GLP-1 receptor agonists involves using these medications for purposes or in ways not specifically approved by regulatory agencies such as the FDA. This practice can include tailoring dosages or combining ingredients to meet individual patient needs. While compounded GLP-1s may provide personalized treatment options, it is important to be aware of the potential risks and benefits.

##### Benefits

Personalized Care: Compounded medications can be customized to specific dosages and formulations that may not be available in standard commercial products.

Accessibility: May provide an option when commercially available GLP-1 medications are not accessible due to cost or supply issues.

##### Risks

Safety and Efficacy: Compounded medications do not undergo the same rigorous testing and approval process as FDA-approved drugs, leading to uncertainties regarding their safety and effectiveness.

Quality Control: There can be variability in the quality and consistency of compounded medications, as they are not produced under the same stringent manufacturing standards as FDA-approved products.

Side Effects: Similar to commercially available GLP-1 agonists, compounded versions can cause gastrointestinal issues, pancreatitis, thyroid C-cell tumors, and injection site reactions.

### Patient Informed Consent

1. I voluntarily request that New Radiance Medical and Aesthetics, LLC. to treat my medical condition (overweight or obesity) and understand that the provider is not treating or managing any other condition.
2. I understand that the provider strongly encourages me to maintain a primary care provider at all times and continue to follow up with them for regular care as they recommend.
3. I have informed my provider of any known allergies, my medical conditions, medications, allergies, social, and family history.
4. I have been informed of any alternative options, side effects, and the risks and benefits of each treatment modality.

Continued:

1. I understand the prescription will come from a compounding pharmacy, which is not FDA approved. I have been told that the manufacturing facility itself is FDA monitored along with third party testing on the medication itself. Furthermore, I understand that in certain cases that these medications will be used in off-label formats to treat and assist with weight loss.
2. Prices may vary and change. Charges will include management by the medical provider, injection supplies, and medication.
3. New Radiance Medical and Aesthetics, LLC. may change the pharmacy based on several factors (availability, shipping time, cost).
4. It has been explained to me that this medication could be harmful if taken inappropriately or without advice from the provider.
5. 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.
6. I understand symptoms may be worse after there has been a change in my medication dose or when first starting the medication.
7. I understand that treatment modalities provided by New Radiance Medical and Aesthetics LLC might not be supported by scientific/medical literature and could be seen as experimental or based off anecdotal claims. Many medical providers, including endocrinologists, surgeons, family practice doctors, etc., might see these types of treatments as not medically necessary. Ialso understand that many of the medications being utilized within the medically managedweight loss program are considered to be used “off label” and might not be FDA approved for weight loss purposes. I have reviewed the mentioned risks and have determined the benefits outweigh the possible risks associated with medically managed weight loss therapy provided by New Radiance Medical and Aesthetics LLC. I release any claim in court or any type of complaint that could result from treatment with New Radiance Medical and Aesthetics LLC and will not hold liable any provider or staff of the New Radiance Medical and Aesthetics LLC.

Common side effects include, but are not limited to:

* Gastrointestinal: Nausea, vomiting, abdominal pain, diarrhea, constipation, indigestion, belching, flatulence, gastroenteritis, acid reflux, gastritis, elevation in blood levels of lipase and/or amylase
* Neurological: Headache, dizziness
* Cardiac: Heart rate increase, low blood pressure
* Endocrine: Fatigue, hypoglycemia, hair loss
* Ophthalmic: Retinal disorder (diabetic patients)
* Skin: redness, irritation, itching, bruising, or pain at injection site
* Ineffectiveness of oral birth control medications which can result in unintended pregnancy. Patients using oral pills are advised to use a second method (such as condom) with each exposure to sperm for 4 weeks after starting and after any dose change.

Serious Reactions include, but are not limited to:

* Thyroid C-cell tumor (animal studies)
* Medullary thyroid cancer
* Hypersensitivity reaction
* Anaphylaxis
* Angioedema
* Acute kidney injury
* Chronic renal failure exacerbation
* Pancreatitis
* Cholelithiasis
* Cholecystitis
* Syncope

### Regarding Treatment Through New Radiance Medical and Aesthetics, LLC.

I understand that I have the following responsibilities:

1. I agree to obtain prescriptions for compounded GLP-1 medications only from New Radiance Medical and Aesthetics, LLC.
2. I understand New Radiance Medical and Aesthetics, LLC. only uses compounding pharmacies. We do not send to retail pharmacies or complete any preauthorizations or information for insurance companies.
3. Medical history: I will truthfully disclose my complete medical history, including: allergies, medications, medical/surgical/social/family history including any changes. This includes weight, height, blood pressure. .
4. New Radiance Medical and Aesthetics, LLC. may ask to review, with your permission, your medical history (medications, recent lab results, pertinent imaging results). You have the right to refuse but this may impact your ability to obtain prescriptions from New Radiance Medical and Aesthetics, LLC.
5. I understand that if I become pregnant or start trying for pregnancy, I must stop this medication. It is advised to not take GLP-1 medications for two months before attempting pregnancy.
6. I will be honest to the best of my ability.
7. I will tell my provider any updated health information (medication, allergies, personal medical issues/surgeries/social history, or family history changes).
8. My provider can discuss my treatment plan with any co-treating pharmacist and/or healthcare provider
9. I will always tell all providers including thos e outside of New Radiance Medical and Aesthetics, LLC. about all medications I am taking.
10. New Radiance Medical and Aesthetics, LLC.may ask for me to seek additional labs while on treatment.
11. Directions for use: I will take my medications only as prescribed according to the directions.
12. If I feel my medications are not effective, or are causing undesirable side effects, I will contact my provider for instructions.
13. I will not adjust my medications without prior instruction to do so.
14. I understand this medication must be injected in the subcutaneous tissue once weekly. I will not inject more often than every 7 days.
15. I will not share needles and dispose of needles safely.
16. The medication expires 30 days after opening and should NOT be used after that date.

##### Refills

1. All refills will require a in-person provider visit.
2. I understand, I need to schedule refill appointments 2 weeks prior to running out of medication to avoid delays in refills.
3. I understand that I may be asked to bring the medication with me to my appointments to check the quantity left or assess how I am injecting.

##### Safety

1. I understand it is important to keep my medication away from children and pets.
2. I understand I must store my medication per the pharmacy instructions (refrigerator) and discard the medication 30 days after opening.
3. I am the only one who will use my medication. I will not give or sell my medication to anyone else.

##### Discontinuation of medication

I understand that New Radiance Medical and Aesthetics, LLC. may stop prescribing my medications or decrease my dose if:

1. The medical provider deems it appropriate to start weaning my medication or transition to maintenance dosing, I will comply.
2. I am having unfavorable side effects or it’s not working to treat my medical condition
3. I am losing weight too rapidly or my body mass index approaches the mid-range of normal, even if I have not yet reached my personal goal weight
4. Certain changes occur in my medical history that would make continuing this treatment would be detrimental to my health.
5. I have been untruthful in my medical or family history
6. I do not follow through with the recommended plan of care
7. I do not follow any parts of “responsibilities” in this agreement.

I have read this form in its entirety. 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 and submittingthe weight loss medical intake, I voluntarily give my consent for treatment and agree to the risks

**Printed Patient Name** **Date** **Signature of Patient**

**Practice Representative Name** **Signature of Practice Representative**