Restore Mental Health
Informed Consent for Compounded Weight-Loss Medication
Medical Weight Management Program

Patient Name: _____ DOB: _____

Today's Date: _____ Provider: _____

Medication prescribed: ___ Compounded semaglutide **___** Compounded tirzepatide
Concentration: _____ **Prescribed dose/volume:** _____
Frequency: _____

Important Information About Compounded Medication

☐ I understand that a compounded drug is not FDA-approved. The FDA does not review an individual compounded drug for safety, effectiveness, or quality before it is marketed.

☐ I understand that compounded medication is not the same as an FDA-approved generic drug and should not be represented as an FDA-approved product.

☐ My clinician has discussed why a compounded medication is being considered for my individual medical needs and the reasonable alternatives available to me.

☐ I understand that compounded injectable products may be supplied in different concentrations or containers. I will use only the exact medication, concentration, syringe, dose, and instructions provided for my prescription.

☐ I will not change my dose, inject more frequently, accelerate dose increases, share medication, share needles/syringes, or use another person's medication.

☐ I understand that dosing errors with compounded injectable GLP-1 medications have been reported, including errors involving milligrams, milliliters, and syringe 'units.' If I am uncertain how much to draw up or inject, I will not guess; I will contact the prescribing practice or dispensing pharmacy before administering the dose.

☐ I will inspect the medication and packaging as instructed and contact the pharmacy/practice if the product arrives damaged, appears different than expected, has questionable labeling, or has been stored outside the required conditions.

☐ I will follow the pharmacy label and storage/discard instructions. I will use a new sterile needle and syringe for each injection and dispose of sharps safely.

GLP-1 / GIP Medication Risks and Precautions

If my compounded prescription contains semaglutide or tirzepatide, I understand that risks associated with the active medication class may include, but are not limited to nausea, vomiting, diarrhea, constipation, abdominal discomfort, decreased appetite, dehydration, kidney problems related to dehydration, gallbladder disease, pancreatitis, serious allergic reactions, and low blood sugar particularly when used with certain diabetes medicines. Severe gastrointestinal reactions can occur.

☐ I have told my clinician whether I or a family member has had medullary thyroid carcinoma (MTC) or whether I have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). I understand FDA-approved semaglutide/tirzepatide weight-management products carry a boxed warning concerning thyroid C-cell tumors observed in rodents and are contraindicated with a personal/family history of MTC or MEN 2.

☐ I have disclosed pregnancy, plans for pregnancy, breastfeeding, diabetes medications, and all other relevant health conditions and medicines.

☐ I understand that the compounded formulation may differ from an FDA-approved product in formulation, concentration, container, inactive ingredients, and instructions. I will rely on my specific prescription label and clinician/pharmacy instructions rather than dosing information found online or supplied with a different product.

Consent

By signing below, I acknowledge that the compounded medication has not been FDA-approved, that I have received an explanation of material risks, benefits, alternatives, and dosing instructions applicable to my treatment, and that my questions have been answered. I voluntarily consent to treatment with the compounded medication prescribed for me.

Printed Name: _____

Signature: _____