DRAFT FOR CLINICAL APPROVAL

Proposed Tirzepatide Weight-Management Protocol

Adults | Subcutaneous tirzepatide | Telehealth and in-clinic workflow

> This is a proposed operational protocol—not a standing order. It requires review and written approval by Phoenix Clinical Services' authorized prescriber/collaborating physician and must be reconciled with Tennessee law, current product labeling, the dispensing pharmacy's formulation, and each patient's clinical needs.

1. Purpose and scope

To provide a consistent process for evaluating, prescribing, educating, and monitoring adults receiving subcutaneous tirzepatide for chronic weight management. This pathway does not cover pediatric treatment or independently establish an obstructive-sleep-apnea treatment plan. OSA treatment requires a confirmed diagnosis and coordination with the patient's sleep-care plan when applicable.

2. Eligibility

Consider treatment when all of the following are met:

- Age 18 years or older.
- BMI at least 30 kg/m², or BMI at least 27 kg/m² with at least one weight-related condition (for example hypertension, dyslipidemia, type 2 diabetes, obstructive sleep apnea, or cardiovascular disease).
- Patient is willing to participate in nutrition, physical-activity, follow-up, and safety monitoring.
- No contraindication and no clinically unacceptable risk after medication reconciliation and history review.
- For telehealth, identity, current location, emergency contact, pharmacy, reliable communication, and ability to understand/perform the prescribed injection are verified.

3. Exclusions and reasons to defer

Label contraindications

- Personal or family history of medullary thyroid carcinoma (MTC).
- Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Known serious hypersensitivity to tirzepatide or formulation excipients.

Do not initiate or continue under this weight-management pathway

- Pregnancy; discontinue when pregnancy is recognized.
- Concurrent use of another tirzepatide-containing product or a GLP-1 receptor agonist unless the prior drug is being stopped under a documented transition plan.

Defer, obtain additional records, or use specialist input when appropriate

- Severe gastroparesis or severe active gastrointestinal disease; active/recent pancreatitis; symptomatic gallbladder disease; recurrent dehydration; unstable renal disease.
- Uncontrolled diabetes, recurrent severe hypoglycemia, insulin or sulfonylurea use without a glucose-monitoring and dose-adjustment plan, or active diabetic retinopathy requiring coordination.
- Pregnancy planning, lactation when risks/benefits are unresolved, or an inadequate contraception plan. Oral hormonal contraception requires additional counseling because efficacy may be reduced after initiation and dose escalation.
- Active eating disorder, significant untreated psychiatric instability, suspected medication misuse, inability to understand dosing, or inability to obtain safe follow-up.
- Upcoming procedure requiring general anesthesia or deep sedation when the procedural team has not provided a peri-procedure plan.

4. Baseline evaluation

History and medication review

- Weight history, prior lifestyle and medication attempts, goals, dietary pattern, activity, sleep, alcohol use, and symptoms suggesting secondary causes of weight gain.
- Complete medication and supplement reconciliation, including diabetes drugs, other weight-loss drugs, oral drugs with a narrow therapeutic index, hormonal contraception, and all GLP-1/GIP medicines.
- MTC/MEN 2, allergy, pancreatitis, gallbladder disease, gastrointestinal motility disease, renal disease, diabetic retinopathy, hypoglycemia, cardiovascular disease, OSA/PAP use, and planned procedures.
- Pregnancy status, pregnancy plans, contraception method, and lactation status when applicable.

Measurements

- Height, weight, BMI, blood pressure, resting heart rate, and—when useful for longitudinal care—waist circumference.

Baseline testing—individualize to history and comorbidities

- A1c or fasting glucose; renal function/electrolytes; hepatic panel. Consider fasting lipid profile.
- Pregnancy test when pregnancy is possible and status is uncertain.
- TSH only when clinically indicated. Routine calcitonin testing or thyroid ultrasound has uncertain value for early MTC detection and is not required solely because tirzepatide is prescribed.
- Additional testing or specialist records as indicated by symptoms, OSA status, medication use, or chronic disease.

5. Shared decision-making and documentation

- Discuss expected benefits, realistic variability in response, chronic-treatment expectations, common adverse effects, serious warnings, alternatives, cost, and what may happen if treatment is stopped.
- Provide and document patient education, medication-specific instructions, injection teaching, missed-dose guidance, pregnancy/contraception counseling, procedure/anesthesia warning, and emergency precautions.

- Advise patients using oral hormonal contraceptives to switch to a non-oral method or add a barrier method for 4 weeks after initiation and for 4 weeks after every dose escalation.
- Document the product/presentation, dispensing pharmacy, concentration, container, prescribed dose in mg, calculated volume in mL, syringe type/marking when applicable, and independent verification.
- If compounded medication is used, document the patient-specific clinical reason an FDA-approved product does not meet the patient's need and comply with applicable federal and state compounding requirements. Do not describe a compounded product as FDA-approved, generic, or identical to Zepbound/Mounjaro.

6. Proposed dosing pathway

> **Medication-safety rule:** Prescribe in milligrams. Do not create a universal 'units' schedule. Convert mg to mL and syringe markings only for a verified, product- and pharmacy-specific concentration and syringe. Require re-verification whenever the presentation, concentration, vial, or syringe changes.

Stage	Timing	Dose SC weekly	Clinical direction
Start	Weeks 1-4	**2.5 mg**	Initiation only; not a maintenance dose.
Maintain / escalate	Week 5+	**5 mg**	First weight-management maintenance option.
Escalate	After ≥4 weeks	**7.5 mg**	Intermediate escalation step if additional response is needed and tolerated.
Maintain / escalate	After ≥4 weeks	**10 mg**	Weight-management maintenance option.
Escalate	After ≥4 weeks	**12.5 mg**	Intermediate escalation step if additional response is needed and tolerated.
Maintain	After ≥4 weeks	**15 mg**	Weight-management maintenance option and maximum weekly dose.

Increase only in 2.5 mg increments after at least 4 weeks at the current dose. If a dose is not tolerated, delay escalation, remain at a tolerated maintenance dose, reduce the dose, or discontinue based on severity and clinical judgment. Do not escalate during significant nausea, vomiting, diarrhea, constipation, abdominal pain, dehydration, or poor oral intake.

For weight management, 5 mg, 10 mg, and 15 mg are the labeled maintenance doses. The 7.5 mg and 12.5 mg doses are escalation steps. For FDA-approved treatment of moderate-to-severe OSA in adults with obesity, labeled maintenance is 10 mg or 15 mg weekly.

7. Follow-up and monitoring

Suggested cadence

- Follow up approximately every 4 weeks during dose escalation, after a dose change, or sooner for adverse effects.

- Once stable, follow up every 8-12 weeks or at a clinically appropriate interval; comply with payer, pharmacy, telehealth, and clinic-policy requirements.

At each follow-up

- Confirm product/presentation, pharmacy, concentration, dose in mg, measured volume/syringe marking when applicable, injection day, adherence, storage, and injection technique.
- Record weight/BMI trend, blood pressure and resting pulse when available, waist trend when used, nutrition, hydration, activity, and treatment goals.
- Assess nausea, vomiting, diarrhea, constipation, abdominal pain, reflux, dehydration, gallbladder symptoms, pancreatitis symptoms, allergy, injection reactions, vision change, and upcoming procedures.
- For diabetes, review glucose/A1c and coordinate reductions in insulin or sulfonylurea when clinically indicated to reduce hypoglycemia risk.
- Confirm the contraception plan for patients using oral hormonal contraceptives after initiation and every dose escalation.
- Repeat renal function/electrolytes promptly when vomiting, diarrhea, poor intake, or dehydration could cause kidney injury. Repeat metabolic labs according to comorbidities and clinical change.
- Document benefit, tolerability, patient preference, and the rationale to continue, hold, escalate, reduce, or stop.

8. Missed-dose and restart pathway

- Missed dose within 4 days (96 hours): administer as soon as possible, then resume the regular weekly schedule.
- More than 4 days since the missed dose: skip it and administer the next dose on the regularly scheduled day.
- The injection day may be changed if at least 72 hours separate two doses.
- Two or more consecutive doses missed: clinician review before restarting; consider a lower restart dose and re-escalation to reduce gastrointestinal adverse effects.
- Never double a dose or administer two doses less than 72 hours apart.

9. Hold, stop, or escalate care

Trigger	Proposed action
Suspected pancreatitis	Stop tirzepatide and initiate urgent evaluation/management. Restart only if the diagnosis is excluded and the prescriber documents the rationale.
Severe allergy	Stop permanently; emergency treatment as indicated.
Pregnancy	Stop when pregnancy is recognized; counsel and coordinate obstetric care.
Persistent severe GI symptoms or dehydration	Hold dose; assess volume status, renal function, electrolytes, obstruction/gastroparesis, and need for urgent care.
Gallbladder symptoms	Prompt clinical evaluation and appropriate imaging/labs.

Trigger	Proposed action
New vision change in diabetes	Prompt ophthalmic/diabetes evaluation; reassess treatment plan.
Dosing discrepancy or product change	Do not administer. Reconcile presentation, prescription, concentration, volume, syringe, and pharmacy instructions before resuming.

10. Vial-and-syringe medication-safety controls

- Identify the exact presentation: FDA-approved single-dose pen/vial, FDA-approved multidose single-patient vial or KwikPen, or compounded medication. Do not transfer directions between presentations.
- Use a single standardized pharmacy concentration whenever feasible; never assume the concentration remains unchanged between orders.
- Prescription and chart must show dose in mg and volume in mL. If syringe units are used, record the syringe type and independently verify the conversion.
- Match syringe capacity to the intended volume. Avoid a syringe substantially larger than the prescribed volume.
- Provide teach-back before the first dose and after any presentation, concentration, vial, syringe, or dose change. Patient demonstrates the exact syringe marking using current written instructions.
- Require a patient-facing label or dosing card listing medication; concentration (mg/mL); dose (mg); volume (mL); syringe marking/type; injection day; storage; discard/beyond-use date; and clinic/pharmacy contacts.
- If calculation or labeling is unclear, stop the process and contact the dispensing pharmacy. Do not rely on an internet calculator or a prior vial's directions.
- Maintain a documented adverse-event and medication-error pathway, including FDA MedWatch reporting when appropriate.

11. Continuation and periodic reassessment

At least every 3 months after reaching a stable dose, reassess weight trajectory, cardiometabolic benefit, side effects, adherence, cost/access, patient goals, and whether continued treatment provides meaningful clinical benefit. If response is inadequate despite adherence and an adequate trial at a tolerated maintenance dose, reassess diagnosis, contributing medications/conditions, lifestyle plan, and alternative treatments. Avoid automatic escalation solely because a target weight has not been reached.

12. Minimum chart elements

- Eligibility and indication; baseline weight/BMI and relevant comorbidities.
- Contraindication/risk screen, pregnancy/contraception assessment when applicable, medication reconciliation, and relevant baseline labs.
- Shared decision-making, informed consent/education, alternatives, oral-contraceptive counseling, and emergency precautions.
- Exact product, presentation, pharmacy, formulation, concentration, dose in mg, volume in mL, syringe marking/type if applicable, and independent verification.
- Follow-up findings, adverse effects, weight/vital trends, diabetes monitoring when applicable, and treatment decision/rationale.

Approval record

Clinical lead	_____
Collaborating/approving physician	_____
Effective date	_____
Review date/version	_____

Sources and important references

This material summarizes selected information and does not replace the full prescribing information, Medication Guide, product-specific Instructions for Use, pharmacy label, or individualized medical advice.

- Zepbound (tirzepatide) Prescribing Information, revised February 2026: https://pi.lilly.com/us/zepbound-uspi.pdf
- Zepbound vial Instructions for Use: https://pi.lilly.com/us/zepbound-vial-us-ifu.pdf
- FDA: Concerns with unapproved GLP-1 drugs used for weight loss (updated June 2026): https://www.fda.gov/drugs/drug-alerts-and-statements/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss
- FDA MedWatch adverse-event reporting: https://www.fda.gov/medwatch