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PERSONALIZED MEDICINE

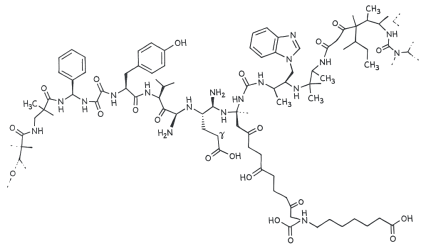
CLINICAL MONOGRAPH · METABOLIC & WEIGHT

Compounded Tirzepatide

Dual GIP/GLP-1 receptor agonist for metabolic care

Tirzepatide is a once-weekly injection used to lower blood sugar in type 2 diabetes and to help with long-term weight management [fda_label_mounjaro; fda_label_zepbound]. The brand-name versions are Mounjaro (for diabetes) and Zepbound (for weight management and, since late 2024, obstructive sleep apnea in adults with obesity). The FDA approved Mounjaro in 2022 and Zepbound in 2023.

It is the first medicine that activates two gut hormone receptors at the same time, GLP-1 and GIP. That dual action quiets appetite, slows stomach emptying, and improves how the body handles sugar. In the SURMOUNT-1 trial, adults with obesity lost between 16 and 22.5% of their body weight on tirzepatide over 72 weeks [jastreboff2022].



EVIDENCE POSTURE FDA APPROVED WELL STUDIED REVIEWED **2026-05-11**

State-licensed 503A | Pharmacist reviewed | Doctor led | Cold-chain ready | Patient choice preserved

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FOR CLINICIANS

Tirzepatide is a once-weekly subcutaneous dual GIP/GLP-1 receptor agonist FDA-approved as Mounjaro (May 2022) for adults with type 2 diabetes and as Zepbound (November 2023) for chronic weight management in adults with obesity or overweight with a weight-related comorbidity [fda_label_mounjaro; fda_label_zepbound; coskun2018]. In December 2024 the Zepbound indication was expanded to include moderate-to-severe obstructive sleep apnea in adults with obesity following SURMOUNT-OSA [malhotra2024]. Mechanism: balanced agonism at the GLP-1 receptor with imbalanced biased agonism at the GIP receptor; net effects include glucose-dependent insulin secretion, glucagon suppression, delayed gastric emptying, and central appetite suppression. Mechanistic work in obese-mouse models [samms2021] demonstrated GIP-receptor-mediated weight-independent insulin sensitization, and adipocyte studies [regmi2024] characterized long-acting GIP receptor activation as the basis for tirzepatide's metabolic phenotype [gao2023].

Phase III evidence across the SURPASS program (SURPASS-1 through SURPASS-5 plus SURPASS-J-mono, SURPASS-AP-Combo, and SURPASS-CVOT; combined N >15,000) demonstrated HbA1c reductions of 1.8, 2.6% and weight loss of 6, 13 kg, with superiority over placebo, insulin degludec, insulin glargine, dulaglutide, and once-weekly semaglutide 1 mg (SURPASS-2) [ludvik2021; dahl2022] [frias2021]. The dedicated cardiovascular outcomes trial SURPASS-CVOT [nicholls2025] reported non-inferiority of tirzepatide vs dulaglutide on three-point MACE in adults with type 2 diabetes and atherosclerotic cardiovascular disease [garvey2023; aronne2024]. The SURMOUNT program (SURMOUNT-1 through SURMOUNT-5 plus SURMOUNT-J and SURMOUNT-OSA) demonstrated 15, 22.5% mean weight loss over 72 weeks in adults with obesity, with SURMOUNT-5 [aronne2025] showing superiority over semaglutide 2.4 mg head-to-head at 72 weeks [jastreboff2022] [wadden2023]. SURMOUNT-OSA demonstrated a 25, 29 events/hour reduction in apnea-hypopnea index at 52 weeks. Safety is dominated by dose-dependent gastrointestinal adverse events; cholelithiasis risk is modestly elevated; pancreatitis is not significantly increased in pooled analysis [delprato2021; inagaki2022; nicholls2024_design]. Manufactured products carry a Boxed Warning for thyroid C-cell tumors (rodent finding, class-wide for GLP-1 receptor agonists). Compounded tirzepatide is dispensed only on documented patient-specific clinical need that the manufactured product cannot meet, not as a price-driven substitute; FAERS pharmacovigilance data on compounded GLP-1 receptor agonists [mccall2026] document a distinct adverse-event profile relative to manufactured products [fda_essentially_a_copy] [rosenstock2021].

Why Personalized Compounded Tirzepatide

Mounjaro and Zepbound use a fixed escalation: 2.5 mg, then 5, 7.5, 10, 12.5, 15 mg, four weeks per step. That schedule was calibrated to keep the average SURPASS or SURMOUNT enrollee on therapy through the worst of the GI adverse-event window. It was not calibrated for your nausea threshold, your prior GLP-1 history, your CKD stage, the metformin or insulin you titrate around, or the fact that you may sit closer to the 22.5% responder tail than to the mean. SURPASS-CVOT and the SURMOUNT program ran the average. Your prescriber runs you.

That gap is the work a compounding pharmacy does on a patient-specific 503A prescription. A doctor who knows your chart can hold at 2.5 mg for longer than four weeks when GI tolerance demands it, step up in smaller increments than the labeled 2.5 mg jumps, or land at a maintenance dose between the commercial strengths when the next labeled step provokes side effects out of proportion to the added benefit. The molecule is the same dual GIP/GLP-1 receptor agonist the FDA reviewed. The titration cadence and the maintenance strength are written for the patient on the label.

This is the older arrangement, the one that pre-dates pre-filled pens and direct-to-consumer pharmacy. A doctor wrote a prescription for a named patient, a pharmacist prepared it, and the dose matched the person. Modern state licensure, USP-track facility standards, and FAERS reporting keep that arrangement honest.

Quick Facts About Compounded Tirzepatide

Category: Dual GIP/GLP-1 receptor co-agonist

Active ingredient: Tirzepatide, a 39-amino-acid synthetic peptide with fatty-acid modification for albumin binding and once-weekly subcutaneous dosing

FDA-approved branded forms: Mounjaro (type 2 diabetes, May 2022) and Zepbound (chronic weight management, November 2023; obstructive sleep apnea expansion December 2024)

Route: Subcutaneous injection, once weekly

Evidence posture: Phase III evidence across SURPASS (type 2 diabetes) and SURMOUNT (obesity, sleep apnea) programs supports the manufactured Mounjaro and Zepbound products; compounded preparations have no separate efficacy program

FDA-approval status: Manufactured Mounjaro and Zepbound are FDA-approved. Compounded tirzepatide is not FDA-approved.

Compounded under: 503A, patient-specific prescription only, where the manufactured FDA-approved product is not clinically appropriate

Important compounding caution: Tirzepatide injection was on the FDA drug shortage list from December 2022 through October 2024. FDA's December 19, 2024 declaratory order affirmed the shortage was resolved. Compounding of essentially-a-copy preparations is now restricted to patient-specific clinical reasons (excipient sensitivity, dose individualization, route or strength not commercially available), not preference or price.

> **SPECIALS: PATIENT-SPECIFIC PRESCRIPTION ONLY**
>
> Compounded Tirzepatide described in this monograph is a 503A compounded preparation. Every dose is made on a prescription, for a named patient, by a licensed pharmacist. It is not a stocked, mass-manufactured product.
>
> - **Made to order, not off a shelf.** No batch sits in a warehouse waiting for buyers. Your prescription triggers the prep.
> - **Named-patient label.** The bottle carries one patient's name. The batch records carry one prescription.
> - **Dose, strength, and route chosen for the patient.** A prescriber decides what gets compounded, not a manufacturer who set the strength for a trial population.
> - **Licensed pharmacist on the hook.** A real person, with a license that can be pulled, signs off on every prep. State inspectors check the facility.
> - **Compounded drugs are not FDA-approved.** They should not be evaluated using branded-drug trial data alone. Availability varies by state and prescribed medication.

How This Differs from a Research-Use-Only Website

A research-use-only website ships a vial from a warehouse. There is no prescription, no pharmacist, no facility inspection, and no way to recall the product if something is wrong with it. If the vial is mislabeled, contaminated, or under-potent, there is nobody whose license is at stake.

A 503A compounding pharmacy is the other thing. The doctor writes the prescription. A licensed pharmacist, whose name is on the label, prepares the medicine in a facility the state inspects. If something goes wrong, there is a person and a license on the hook, and a documented chain of custody on every lot. That accountability is what makes it safe.

What is Compounded Tirzepatide?

Tirzepatide is a synthetic 39-amino-acid peptide engineered as a single molecule that activates both the glucose-dependent insulinotropic polypeptide (GIP) receptor and the glucagon-like peptide-1 (GLP-1) receptor. It is the first FDA-approved dual incretin receptor agonist for human use. The molecule incorporates a C20 fatty di-acid moiety that binds plasma albumin, slowing renal clearance and supporting once-weekly subcutaneous dosing.

Tirzepatide was discovered at Eli Lilly and originally designated LY3298176. The discovery and preclinical-to-clinical proof-of-concept program was reported by Coskun and colleagues in Molecular Metabolism in

2018. Clinical development proceeded through the SURPASS program for type 2 diabetes (FDA approval as Mounjaro, May 2022) and the SURMOUNT program for chronic weight management (FDA approval as Zepbound, November 2023) [coskun2018].

Both manufactured products are supplied as single-dose pre-filled pens (and, separately, single-dose vials) at strengths of 2.5, 5, 7.5, 10, 12.5, and 15 mg per 0.5 mL. The injectable solution is preservative-free and intended for subcutaneous administration in the abdomen, thigh, or upper arm [fda_label_mounjaro; fda_label_zepbound].

How Compounded Tirzepatide Works

Tirzepatide activates two related class B G-protein-coupled receptors that mediate the incretin effect: the GLP-1 receptor and the GIP receptor. Both receptors couple to Gαs and elevate intracellular cAMP, but they are expressed in different tissue patterns and contribute different physiological effects.

Through GLP-1 receptor activation, tirzepatide stimulates glucose-dependent insulin secretion from pancreatic beta cells, suppresses inappropriately elevated glucagon, slows gastric emptying, and acts on hypothalamic and brainstem circuits to reduce appetite [urva2020]. Through GIP receptor activation, tirzepatide further potentiates insulin secretion in the fed state and is hypothesized to improve insulin sensitivity and lipid handling in adipose tissue [schneck2024]. The molecule is described as 'imbalanced' or 'biased' in its receptor pharmacology, its affinity at the human GIP receptor is comparable to native GIP, while its affinity at the human GLP-1 receptor is roughly five-fold weaker than native GLP-1, and downstream signaling pathways are differentially recruited.

Net clinical effects are larger HbA1c reductions and larger weight reductions than have been observed with selective GLP-1 receptor agonists at comparable exposure [coskun2018]. The transient delay in gastric emptying observed early in dosing attenuates with continued treatment, paralleling the typical adaptation in nausea reported by patients.

Biological Role of Compounded Tirzepatide

The incretin system describes a set of gut-derived hormones, principally GIP and GLP-1, that are released in response to enteral nutrient delivery and amplify the insulin response to glucose. Beyond pancreatic islet effects, both incretins act on the central nervous system to reduce food intake, slow gastric emptying, and contribute to long-term regulation of body weight and glucose homeostasis.

Selective GLP-1 receptor agonists (exenatide, liraglutide, dulaglutide, semaglutide) had established the GLP-1 axis as a clinically tractable target through the 2000s and 2010s. The role of GIP was more contested: GIP secretion is preserved in type 2 diabetes but its insulinotropic action is blunted, and chronic GIP receptor agonism in obese rodents had previously been associated with weight gain. The Coskun et al.

discovery work proposed that simultaneous activation of both receptors recovers GIP's insulinotropic and weight-favorable effects in the context of GLP-1 receptor co-activation, and this hypothesis was substantiated by the magnitude of weight loss observed in the SURMOUNT trials, which exceeds reported effects of any selective GLP-1 receptor agonist at comparable dosing [coskun2018; jastreboff2022].

Detailed Mechanism of Compounded Tirzepatide

GIP and GLP-1 are gut-derived incretin hormones released in response to nutrient ingestion. They jointly account for most of the post-prandial insulin response in healthy adults. In type 2 diabetes, the GIP response is blunted and the GLP-1 contribution becomes relatively more important, a finding that originally argued against GIP as a therapeutic target. The Coskun et al. 2018 discovery paper demonstrated that a single molecule with balanced GLP-1 and GIP receptor activity produced glucose-lowering and weight-reduction effects in preclinical models that exceeded selective GLP-1 receptor agonism at matched exposure, motivating the SURPASS and SURMOUNT clinical programs [coskun2018].

Subsequent mechanistic work clarified the GIP-receptor contribution. Samms et al. (2021) used GIPR-knockout obese mice to show that GIPR agonism mediates weight-independent insulin sensitization by tirzepatide, validating GIPR co-agonism as a metabolic target rather than as merely an insulinotropic add-on. Regmi et al. (2024) characterized long-acting GIP receptor activation in adipocytes as a regulator of nutrient metabolism, supporting the imbalanced/biased pharmacology hypothesis at the molecular level. In adults with type 2 diabetes, Heise et al. (2022) used the SURPASS pancreatic-function substudy (vs placebo and semaglutide 1 mg) to demonstrate that tirzepatide improved both first-phase and second-phase insulin secretion and insulin sensitivity to a greater extent than semaglutide. Mather et al. (2024) extended this comparison with a meal-test protocol showing greater post-prandial β-cell function and insulin sensitivity with tirzepatide than semaglutide at matched glycemic exposure [heise2022; mather2024].

Central appetite suppression with tirzepatide is mediated primarily through GLP-1 receptors in the hypothalamic arcuate nucleus and area postrema, with additional contribution from GIP receptors expressed in the central nervous system. Peripheral effects include slowed gastric emptying (mostly attributed to the GLP-1 component, characterized by Urva et al [urva2020]. 2020) and improved insulin sensitivity in skeletal muscle and adipose tissue [samms2021, regmi2024]. Body-composition analysis in SURMOUNT-1 [look2025] confirmed that weight loss with tirzepatide is preferentially lost from fat mass with proportional preservation of lean mass compared with diet-only weight loss [fda_label_mounjaro].

Pharmacokinetically, the C20 fatty di-acid modification supports a terminal half-life of approximately 5 days, time to maximum concentration of 8, 72 hours after subcutaneous dosing, and approximately 80% subcutaneous bioavailability. Approximately 99% is bound to plasma albumin. The molecule is catabolized by proteolytic degradation; the population PK analysis (Schneck and Urva 2024) identified body weight as the only clinically relevant covariate on apparent clearance, with no clinically meaningful effects of age, sex, race, renal function, or hepatic function [schneck2024]. Immunogenicity pooled across phase 3 studies

[mullins2024] showed treatment-emergent anti-drug antibodies that did not meaningfully alter PK, efficacy, or safety. Renal and hepatic impairment do not require dose adjustment per current labeling.

Compounded Tirzepatide Research History

Tirzepatide originated at Eli Lilly as LY3298176, a fatty-acid-modified peptide designed to balance GIP and GLP-1 receptor activity in a single molecule. The discovery program, published by Coskun and colleagues in Molecular Metabolism in 2018, demonstrated weight-favorable effects in diet-induced-obese rodents and glucose-lowering in non-human primates, and reported phase 1 human data establishing the once-weekly dosing schedule. The first human phase 2 dose-finding trial [frias2018] tested LY3298176 at 1, 5, 10, and 15 mg vs placebo and dulaglutide 1.5 mg over 26 weeks in adults with type 2 diabetes and reported dose-dependent HbA1c reductions to 2.4% and weight reductions to 11.3 kg, establishing the dose range carried into phase 3 [inagaki2022].

Clinical development proceeded through the SURPASS phase III program for type 2 diabetes: SURPASS-1 (monotherapy vs placebo, Rosenstock et al [rosenstock2021]. 2021), SURPASS-2 (vs semaglutide 1 mg, Frías et al. 2021), SURPASS-3 (vs insulin degludec, Ludvik et al [ludvik2021]. 2021), SURPASS-4 (vs insulin glargine in adults with elevated cardiovascular risk, Del Prato et al [delprato2021]. 2021), and SURPASS-5 (added to titrated insulin glargine, Dahl et al [dahl2022]. 2022). Region-specific phase 3 programs added SURPASS J-mono (Japanese adults, head-to-head vs dulaglutide; Inagaki 2022) and SURPASS-AP-Combo (Asia-Pacific region, second/third-line vs insulin glargine; Gao 2023) [inagaki2022; gao2023]. FDA approval as Mounjaro followed in May 2022. The dedicated cardiovascular outcomes trial SURPASS-CVOT, prespecified to compare tirzepatide with dulaglutide on MACE in adults with type 2 diabetes and atherosclerotic cardiovascular disease, was described in its design paper [nicholls2024_design] and reported primary results in December 2025 (Nicholls et al., NEJM) demonstrating non-inferiority on three-point MACE [frias2021; nicholls2025]. Pre-specified cardiovascular meta-analyses [sattar2022] and updated meta-analyses [patoulias2022] of the phase 3 program had previously found no excess MACE signal.

The SURMOUNT program for chronic weight management produced SURMOUNT-1 (obesity without diabetes, Jastreboff et al [jastreboff2022]. 2022), SURMOUNT-2 (obesity with type 2 diabetes, Garvey et al [garvey2023]. 2023), SURMOUNT-3 (post-intensive-lifestyle adjunct, Wadden et al. 2023), SURMOUNT-4 (maintenance withdrawal, Aronne et al. 2024), and SURMOUNT-J (Japanese adults with obesity; Kadowaki 2025) [kadowaki2025]. SURMOUNT-5 [aronne2025] reported the first phase 3 head-to-head comparison of tirzepatide vs semaglutide 2.4 mg for obesity, demonstrating superior weight loss with tirzepatide over 72 weeks [wadden2023]. FDA approval as Zepbound for chronic weight management followed in November 2023, and the indication was expanded to moderate-to-severe obstructive sleep apnea in adults with obesity in December 2024 on the basis of SURMOUNT-OSA [malhotra2024] [aronne2024]. Phase 2 data for metabolic dysfunction-associated steatohepatitis (SYNERGY-NASH, Loomba et al [loomba2024]. 2024) demonstrated improvements in steatohepatitis resolution and fibrosis

at 52 weeks. Network meta-analysis evidence [karagiannis2024] integrated the SURPASS and SURMOUNT programs into the broader GLP-1 receptor agonist class and confirmed superior glycemic and weight effects of tirzepatide vs semaglutide across doses [coskun2018].

Compounded Tirzepatide Timeline

2018 • Coskun et al [coskun2018]. publish discovery and clinical proof-of-concept for LY3298176 (tirzepatide) in Molecular Metabolism

2018 • Frías et al [frias2018]. publish phase 2 dose-finding trial of LY3298176 (1, 5, 10, 15 mg) vs placebo and dulaglutide 1.5 mg in the Lancet, HbA1c reductions to 2.4% and weight reductions to 11.3 kg at 26 weeks

2020 • Urva et al [urva2020]. characterize tirzepatide's effect on gastric emptying, showing transient GLP-1-class delay that attenuates with continued dosing

2021 • Samms et al [samms2021]. (J Clin Invest) demonstrate GIPR-dependent weight-independent insulin sensitization by tirzepatide in obese mice, mechanistic foundation for the GIP-receptor contribution

2021 • SURPASS-1 (monotherapy vs placebo) published in the Lancet [rosenstock2021]

2021 • SURPASS-2 (head-to-head vs once-weekly semaglutide 1 mg) published in NEJM, first dual-agonist head-to-head superiority over a selective GLP-1 agonist [frias2021]

2021 • SURPASS-3 (vs insulin degludec) and SURPASS-4 (vs insulin glargine, elevated CV risk) published in the Lancet [ludvik2021; delprato2021]

2022 • SURPASS-5 (added to titrated insulin glargine) published in JAMA [dahl2022]

2022 • FDA approves tirzepatide as Mounjaro for adults with type 2 diabetes (May 13, 2022) [fda_label_mounjaro]

2022 • SURPASS J-mono (Inagaki et al., Lancet Diabetes Endocrinol), tirzepatide vs dulaglutide in Japanese adults with type 2 diabetes [inagaki2022]

2022 • SURPASS-3 MRI substudy (Gastaldelli et al.), tirzepatide reduces liver fat and abdominal adipose tissue more than insulin degludec [gastaldelli2022]

2022 • Heise et al [heise2022]. (Lancet Diabetes Endocrinol), tirzepatide vs semaglutide on islet function and insulin sensitivity in adults with type 2 diabetes

2022 • Heerspink et al [heerspink2022]. (Lancet Diabetes Endocrinol), SURPASS-4 post-hoc kidney outcomes analysis demonstrates favorable trajectory of eGFR and UACR vs insulin glargine

- **2022** • Sattar et al [sattar2022]. (Nature Medicine) publish prespecified cardiovascular event meta-analysis across the SURPASS program, no excess MACE signal
- **2022** • SURMOUNT-1 (obesity without diabetes) published in NEJM, up to 22.5% mean weight loss at 72 weeks [jastreboff2022]
- **2022** • FDA adds tirzepatide injection to the drug shortage list (December 15, 2022) [fda_shortage_resolution_2024]
- **2023** • SURPASS-AP-Combo (Gao et al., Nature Medicine), tirzepatide vs insulin glargine in the Asia-Pacific region [gao2023]
- **2023** • Heerspink et al [heerspink2023]. (Diabetes Care), SURPASS-4 cystatin C-based kidney function analysis confirms favorable eGFR trajectory
- **2023** • Mishra et al [mishra2023]. (J Endocr Soc) review adverse events related to tirzepatide
- **2023** • SURMOUNT-2 (obesity with type 2 diabetes) published in the Lancet [garvey2023]
- **2023** • SURMOUNT-3 (post-intensive-lifestyle adjunct) published in Nature Medicine [wadden2023]
- **2023** • FDA approves tirzepatide as Zepbound for chronic weight management in adults (November 8, 2023) [fda_label_zepbound]
- **2023** • Zeng et al [zeng2023]. (Front Endocrinol), meta-analysis of pancreatitis and gallbladder/biliary disease signals
- **2024** • Nicholls et al [nicholls2024_design]. publish SURPASS-CVOT design and baseline characteristics in Am Heart J
- **2024** • de Lemos et al [delemos2024]. (Hypertension), SURMOUNT-1 ambulatory blood pressure substudy demonstrates reduction in 24-hour SBP
- **2024** • Regmi et al [regmi2024]. (Cell Metab), long-acting GIP receptor activation regulates adipocyte nutrient metabolism
- **2024** • Mather et al [mather2024]. (J Clin Endocrinol Metab), tirzepatide vs semaglutide on β-cell function, insulin sensitivity, and glucose control during meal test
- **2024** • Mullins et al [mullins2024]. (J Clin Endocrinol Metab), pooled phase 3 immunogenicity analysis: no clinically meaningful effect on PK, efficacy, or safety
- **2024** • SURMOUNT-4 (maintenance withdrawal) published in JAMA, confirms weight regain after discontinuation [aronne2024]

2024 • SURMOUNT-OSA published in NEJM; FDA expands Zepbound indication to moderate-to-severe obstructive sleep apnea in adults with obesity (December 20, 2024) [malhotra2024]

2024 • SYNERGY-NASH phase 2 trial (Loomba et al.) published in NEJM, tirzepatide produces MASH resolution and fibrosis improvement at 52 weeks [loomba2024]

2024 • FDA declaratory order (December 19, 2024) affirms resolution of tirzepatide injection shortage; 503A compounding transition period ends February 18, 2025 [fda_shortage_resolution_2024]

2024 • Karagiannis et al [karagiannis2024]. (Diabetologia), systematic review and network meta-analysis of tirzepatide vs semaglutide for adults with type 2 diabetes

2025 • SURMOUNT-5 (Aronne et al., NEJM), first phase 3 head-to-head of tirzepatide vs semaglutide 2.4 mg for obesity: tirzepatide superior at 72 weeks [aronne2025]

2025 • SURMOUNT-J (Kadowaki et al., Lancet Diabetes Endocrinol), phase 3 in Japanese adults with obesity disease [kadowaki2025]

2025 • Look et al [look2025]. (Diabetes Obes Metab), SURMOUNT-1 body composition substudy: fat-mass-preferential weight loss with preserved lean mass

2025 • Rasouli et al [rasouli2025]. (Diabetes Ther), SURPASS post-hoc in older adults with type 2 diabetes confirms consistent efficacy and safety

2025 • Ruder (JAMA) and Liu (Am J Manag Care), practitioner-facing reviews on the safety landscape of compounded GLP-1 weight-loss drugs [ruder2025; liu2025]

2025 • SURPASS-CVOT primary results (Nicholls et al., NEJM), tirzepatide non-inferior to dulaglutide on three-point MACE in adults with type 2 diabetes and atherosclerotic cardiovascular disease [nicholls2025]

2026 • McCall et al [mccall2026]. (Expert Opin Drug Saf), FAERS pharmacovigilance analysis of compounded GLP-1 receptor agonists characterizes a distinct AE profile vs manufactured products

Clinical Contexts for Compounded Tirzepatide

Type 2 diabetes mellitus in adults FDA APPROVED

FDA-approved indication for manufactured Mounjaro.

Tirzepatide (Mounjaro) is FDA-approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes [fda_label_mounjaro; ludvik2021; delprato2021]. SURPASS-1 through SURPASS-5 demonstrated HbA1c reductions of 1.8, 2.6% from baseline depending on dose and background therapy [dahl2022]. Region-specific phase 3 evidence in Asian populations (SURPASS J-mono, Inagaki 2022; SURPASS-AP-Combo, Gao 2023) demonstrated consistent efficacy and tolerability [inagaki2022; gao2023]. SURPASS-2 demonstrated superior HbA1c and weight reduction vs once-weekly semaglutide 1 mg at 40 weeks; the network meta-analysis by Karagiannis (2024) extended this comparison across the GLP-1 receptor agonist class [karagiannis2024]. SURPASS-4 (CV-risk-elevated population) did not demonstrate excess major adverse cardiovascular events at 52 weeks; the dedicated cardiovascular outcomes trial SURPASS-CVOT [nicholls2025] reported tirzepatide non-inferior to dulaglutide on three-point MACE in adults with type 2 diabetes and atherosclerotic cardiovascular disease [rosenstock2021; frias2021]. Pre-specified meta-analyses [sattar2022] and updated meta-analyses [patoulias2022] had previously shown no excess MACE signal.

Branded product: Mounjaro (tirzepatide injection, Eli Lilly)

Chronic weight management in adults with obesity (BMI ≥30 kg/m²) FDA APPROVED

FDA-approved indication for manufactured Zepbound.

Tirzepatide (Zepbound) is FDA-approved as an adjunct to reduced-calorie diet and increased physical activity for chronic weight management in adults with BMI ≥30 kg/m² [fda_label_zepbound]. SURMOUNT-1 [jastreboff2022] reported mean weight reductions of 15.0%, 19.5%, and 20.9% with tirzepatide 5, 10, and 15 mg respectively, at 72 weeks, compared with 3.1% on placebo.

Branded product: Zepbound (tirzepatide injection, Eli Lilly)

Chronic weight management in adults with overweight (BMI ≥27 kg/m²) plus weight-related comorbidity FDA APPROVED

FDA-approved indication for manufactured Zepbound.

The Zepbound indication extends to BMI ≥27 kg/m² with at least one weight-related comorbidity (e.g., hypertension, dyslipidemia, obstructive sleep apnea, cardiovascular disease, or type 2 diabetes) [fda_label_zepbound]. SURMOUNT-2 [garvey2023] extended efficacy data into adults with type 2 diabetes, with mean weight reductions of 12.8% and 14.7% on 10 mg and 15 mg vs 3.2% on placebo at 72 weeks. The SURMOUNT-1 ambulatory blood pressure substudy (de Lemos 2024) reported a clinically meaningful reduction in 24-hour systolic blood pressure, supporting cardiovascular-risk-relevant indication breadth [delemos2024]. Body composition assessment in SURMOUNT-1 [look2025] demonstrated preferential reduction of fat mass with proportional preservation of lean mass.

Branded product: Zepbound

Moderate-to-severe obstructive sleep apnea in adults with obesity FDA APPROVED

FDA-approved indication added to Zepbound in December 2024 on the basis of SURMOUNT-OSA.

SURMOUNT-OSA [malhotra2024] reported reductions in apnea-hypopnea index of 25.3 (trial 1, not on PAP therapy) and 29.3 (trial 2, on PAP therapy) events per hour at 52 weeks with tirzepatide vs reductions of 5.3 and 5.5 events per hour with placebo. The indication was added to the Zepbound label in December 2024 [fda_label_zepbound].

Branded product: Zepbound

Metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis WELL STUDIED

Phase 2 evidence (SYNERGY-NASH); not an FDA-approved indication.

SYNERGY-NASH [loomba2024] randomized 190 adults with biopsy-confirmed MASH and stage F2 or F3 fibrosis to tirzepatide 5, 10, or 15 mg vs placebo for 52 weeks. MASH resolution without worsening of fibrosis was achieved in 44%, 56%, and 62% of tirzepatide-treated participants vs 10% on placebo. Phase 3 trials are ongoing.

Maintenance of weight reduction after initial response WELL STUDIED

Studied in a dedicated phase III withdrawal trial.

SURMOUNT-4 [aronne2024] randomized 670 adults who had achieved a target weight reduction with open-label tirzepatide (mean −20.9% at week 36) to continued tirzepatide or placebo for an additional 52 weeks. Continued tirzepatide produced a further mean −5.5% change; placebo produced +14.0% regain, supporting indefinite continued dosing for weight maintenance.

Major adverse cardiovascular events in adults with type 2 diabetes and atherosclerotic cardiovascular disease WELL STUDIED

Studied in the prespecified dedicated cardiovascular outcomes trial SURPASS-CVOT; non-inferiority demonstrated vs dulaglutide. Not a separate FDA indication for an outcome reduction claim.

SURPASS-CVOT [nicholls2025] randomized approximately 13,000 adults with type 2 diabetes and atherosclerotic cardiovascular disease to tirzepatide or dulaglutide and reported tirzepatide non-inferior to dulaglutide on the three-point MACE composite [nicholls2024_design]. Earlier pre-specified meta-analyses across the SURPASS program [sattar2022] and updated meta-analyses [patoulias2022] had reported no excess MACE signal with tirzepatide vs comparators.

Head-to-head comparison with semaglutide 2.4 mg for obesity WELL STUDIED

Studied in the SURMOUNT-5 phase 3 trial; tirzepatide superior on weight loss endpoints. Not a labeled comparative claim.

SURMOUNT-5 [aronne2025] was the first phase 3 head-to-head trial of tirzepatide vs semaglutide 2.4 mg in adults with obesity. Over 72 weeks, tirzepatide produced superior mean percent weight reduction relative to semaglutide 2.4 mg. The network meta-analysis by Karagiannis (2024) integrating earlier phase 3 evidence had previously suggested superior glycemic and weight effects of tirzepatide across the dose range [karagiannis2024].

Off-Label Uses of Compounded Tirzepatide

Metabolic dysfunction-associated steatohepatitis (MASH/NASH) WELL STUDIED

Off-label; supported by phase 2 SYNERGY-NASH evidence. Phase 3 trials ongoing.

Phase 2 SYNERGY-NASH evidence [loomba2024] demonstrated MASH resolution in 44, 62% of tirzepatide-treated adults vs 10% placebo at 52 weeks, with 1-stage or greater fibrosis improvement in 51, 55% vs 30% placebo. Use specifically for MASH remains investigational pending phase 3 data.

FDA-Approved Uses of Compounded Tirzepatide

Brand	Indication	Year	Route
Mounjaro	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	2022	Subcutaneous injection, once weekly
Zepbound	Chronic weight management in adults with obesity (BMI ≥30) or overweight (BMI ≥27) plus a weight-related comorbidity, as adjunct to	2023	

Brand	Indication	Year	Route
	reduced-calorie diet and increased physical activity; also for moderate-to-severe obstructive sleep apnea in adults with obesity (indication expanded December 2024)		Subcutaneous injection, once weekly

The FDA-approved manufactured products are Mounjaro (approved May 13, 2022 for type 2 diabetes) and Zepbound (approved November 8, 2023 for chronic weight management; indication expanded December 20, 2024 to include moderate-to-severe obstructive sleep apnea in adults with obesity) [malhotra2024]. The drug substance is identical between the two products; the indications and labels differ [fda_label_mounjaro; fda_label_zepbound].

Both labels carry a Boxed Warning regarding thyroid C-cell tumors based on rodent carcinogenicity findings, class-wide for incretin-receptor agonists. Contraindications include personal or family history of medullary thyroid carcinoma, multiple endocrine neoplasia syndrome type 2, and known serious hypersensitivity. Cardiovascular safety in adults with type 2 diabetes and elevated CV risk was studied in SURPASS-4 without a signal of excess MACE at 52 weeks; the dedicated cardiovascular outcomes trial SURPASS-CVOT is ongoing [delprato2021].

Compounded Compounded Tirzepatide (503A)

Compounded tirzepatide is dispensed under 503A only when the prescribing clinician documents a patient-specific clinical need that the manufactured Mounjaro or Zepbound product cannot meet [fda_shortage_resolution_2024]. Documented needs typically fall into three categories: (1) excipient sensitivity to a component of the manufactured pen or vial formulation; (2) dose individualization outside the manufactured strength increments (e.g., interim titration steps not commercially available); or (3) a documented manufactured-product supply interruption [fda503a, fda_essentially_a_copy].

The regulatory context is specific to tirzepatide. From December 15, 2022 through October 2, 2024, tirzepatide injection was on FDA's drug shortage list, and during that window 503A compounding was broadly permitted under section 503A(b)(1)(D) [fda_shortage_resolution_2024]. On December 19, 2024, FDA issued a declaratory order affirming the shortage was resolved, with a transition period for 503A compounders ending February 18, 2025. Outside the shortage exception, compounding of essentially-a-copy preparations is restricted; RonanRx compounds tirzepatide only when the prescriber documents that the patient cannot use the manufactured product for a clinical reason, not on the basis of preference, convenience, or price [frias2021; jastreboff2022; malhotra2024].

Compounded tirzepatide preparations are typically dispensed as preservative-containing or preservative-free sterile injectable solutions for subcutaneous administration [fda_shortage_resolution_2024]. The compounded preparation is not bioequivalent to Mounjaro or Zepbound; clinicians and patients should understand that PK/PD characteristics of a compounded preparation may differ from published

manufactured-product data, particularly when excipients, concentration, or container closure differ from the reference product. The published phase 3 evidence base for tirzepatide is generated with manufactured product and does not transfer to compounded preparations without separate stability, PK, and tolerability evaluation [aronne2025; nicholls2025].

Post-marketing pharmacovigilance literature on compounded GLP-1 receptor agonists documents distinct safety considerations [mccall2026] [rosenstock2021]. The FAERS analysis by McCall et al. (2026) reports patterns of dosing errors, sterility-related events, and unexpected adverse events with compounded GLP-1 preparations that are not predicted by the manufactured-product phase 3 data. Practitioner-facing reviews [ruder2025] [ruder2025, liu2025] catalog supply-chain risks specific to compounded GLP-1 weight-loss drugs, including concentration errors, mis-dosing, and use outside documented patient-specific clinical need.

Compounded Tirzepatide Formulations and Routes

Form	Concentration	Description
Sterile subcutaneous injection (compounded)	Custom, typically 5 mg/mL or 10 mg/mL with weekly doses of 2.5, 15 mg per injection	Sterile solution prepared under USP <797> standards for sterile compounding on a patient-specific prescription. Container closure, excipient profile, and concentration are documented per batch and matched to the patient's clinical profile.
Manufactured pre-filled pen (reference product)	2.5, 5, 7.5, 10, 12.5, or 15 mg per 0.5 mL	Mounjaro (T2DM indication) and Zepbound (chronic weight management and OSA indications) are FDA-approved manufactured pre-filled single-dose pens. Manufactured single-dose vials are also available at the same strengths.

Routes used in published literature: subcutaneous.

Compounded Tirzepatide Dosing

Route	Population	Range	Duration	Study type
Subcutaneous	Adults with type 2 diabetes (Mounjaro labeled regimen)	Start 2.5 mg once weekly for 4 weeks; increase to 5 mg once weekly. Further escalation in 2.5 mg increments after at least 4 weeks at each dose, to a maximum of 15 mg once weekly	Indefinite while clinically beneficial	FDA-approved labeled regimen

Route	Population	Range	Duration	Study type
		based on glycemic response and tolerability.		
Subcutaneous	Adults with obesity or overweight + comorbidity (Zepbound labeled regimen)	Start 2.5 mg once weekly for 4 weeks; increase to 5 mg once weekly. Further escalation in 2.5 mg increments after at least 4 weeks at each dose to a maintenance dose of 5, 10, or 15 mg once weekly based on tolerability and weight-loss response.	Indefinite while clinically beneficial; SURMOUNT-4 confirms weight regain after discontinuation	FDA-approved labeled regimen
Subcutaneous	Adults with moderate-to-severe obstructive sleep apnea and obesity	Same escalation as the Zepbound chronic weight management regimen, with maintenance at the maximum tolerated dose (10 or 15 mg in SURMOUNT-OSA)	52 weeks demonstrated in SURMOUNT-OSA; ongoing use as clinically indicated	FDA-approved labeled regimen following SURMOUNT-OSA

Doctor-prescribed and titrated. The Mounjaro and Zepbound labels share an identical 4-week-per-dose escalation schedule from 2.5 mg to a maximum of 15 mg once weekly. The 2.5 mg starting dose is intended as an initiation dose only and is not a therapeutic maintenance dose. Most gastrointestinal adverse events occur during dose escalation; slowing or pausing titration is the primary tolerability lever.

Compounded tirzepatide should mirror the manufactured-product titration unless the prescriber documents a patient-specific reason for variance [fda_label_mounjaro; fda_label_zepbound]. Higher doses than 15 mg once weekly have not been studied in phase III trials and are not supported by current evidence.

Compounded Tirzepatide Safety

Tirzepatide safety is dominated by gastrointestinal adverse events, nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain [84] [33]. In SURMOUNT-1, nausea occurred in 24.6%, 33.3%, and 31.0% of participants on tirzepatide 5, 10, and 15 mg respectively versus 9.5% on placebo; diarrhea in 18.7%, 21.2%, and 23.0% vs 7.3%. Gastrointestinal events were generally mild to moderate, concentrated in the titration period, and led to discontinuation in 4.3, 7.1% of tirzepatide-treated participants vs 2.6% on placebo. The Mishra (2023) review of phase 3 AE data and the Karagiannis (2024) network meta-analysis confirm a class-typical GI AE pattern with somewhat higher absolute event rates than reported with selective GLP-1 receptor agonists at matched glycemic exposure [32].

Class-wide GLP-1 receptor agonist labeling considerations apply. The Mounjaro and Zepbound labels carry a Boxed Warning regarding thyroid C-cell tumors based on rodent findings, the relevance of these findings to humans has not been established but the warning is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2 [16][17]. Acute pancreatitis has been reported; the systematic review by Zeng et al. (2023) of nine RCTs did not find a statistically significant increase in pancreatitis with tirzepatide vs comparators [33]. Cholelithiasis and biliary disease incidence is modestly elevated relative to placebo [15].

Cardiovascular safety is supported by SURPASS-4 (Del Prato 2021), the prespecified Sattar (2022) and Patoulias (2022) meta-analyses, and the dedicated SURPASS-CVOT trial [41] which demonstrated non-inferiority vs dulaglutide on three-point MACE [30][31]. SURPASS-4 post-hoc kidney outcomes analysis [28][28][29] reported favorable eGFR trajectory and urinary albumin-to-creatinine ratio reduction vs insulin glargine [6]. The SURMOUNT-1 ambulatory blood pressure substudy (de Lemos 2024) reported a clinically meaningful reduction in 24-hour systolic blood pressure independent of acute volume effects [34]. Immunogenicity pooled across phase 3 [35] did not alter PK, efficacy, or safety meaningfully.

Additional considerations include hypoglycemia (when used with insulin or sulfonylureas), acute kidney injury (typically in the context of volume depletion from severe GI events), hypersensitivity reactions, and diabetic retinopathy complications in patients with pre-existing retinopathy [33]. Manufactured-product safety data summarized here cannot be assumed to translate without modification to compounded preparations that differ in concentration, excipient profile, or container closure. FAERS pharmacovigilance analysis of compounded GLP-1 receptor agonists [44] documents a distinct AE profile relative to the manufactured products, and practitioner-facing reviews [45][45][46] catalog dosing-error and contamination concerns specific to the compounded supply chain.

Contraindications

Tirzepatide is contraindicated in: personal or family history of medullary thyroid carcinoma; multiple endocrine neoplasia syndrome type 2; and known serious hypersensitivity to tirzepatide or any excipient in the manufactured product. The Boxed Warning regarding thyroid C-cell tumors is class-wide for GLP-1-containing incretin therapies and is based on rodent carcinogenicity findings with selective GLP-1 receptor agonists; the relevance to humans is unknown.

Tirzepatide is not recommended in patients with a history of severe gastrointestinal disease (including severe gastroparesis), severe hypersensitivity reactions to other GLP-1 receptor agonists, and during pregnancy unless the benefit outweighs the risk. The manufactured-product labels recommend discontinuation of tirzepatide at least 2 months before a planned pregnancy due to the drug's long half-life [16][17].

Drug interactions

Tirzepatide delays gastric emptying, which can affect the absorption of orally administered medications [2]. Patients using oral hormonal contraceptives should be advised to switch to a non-oral contraceptive or add

a barrier method for 4 weeks after initiation and for 4 weeks after each dose escalation, per the Mounjaro and Zepbound labels.

When used with insulin or sulfonylureas, the risk of hypoglycemia is increased; insulin or sulfonylurea dose reduction may be appropriate. Tirzepatide is not metabolized by cytochrome P450 enzymes and is not expected to participate in CYP-mediated drug-drug interactions; the predominant DDI mechanism is the absorption-rate effect from delayed gastric emptying [16][17].

Adverse events

Across SURPASS-1 through SURPASS-5 and SURMOUNT-1 through SURMOUNT-5, the most common adverse events with tirzepatide vs placebo or active comparator were nausea (12, 33% across dose and trial), diarrhea (12, 23%), decreased appetite (6, 13%), vomiting (6, 13%), constipation (6, 12%), and dyspepsia (4, 9%) [33] [8][42]. Adverse-event-driven discontinuation ranged from approximately 4% to 7% on tirzepatide vs 1, 3% on placebo or insulin comparators [5][6][7]. The Mishra (2023) systematic review consolidated AE rates across phase 3 programs and is consistent with these ranges [9].

Serious adverse events were uncommon. Acute pancreatitis was reported in <1% of participants across the development program and was not significantly elevated vs placebo in pooled analysis [15]. Cholelithiasis and biliary disease occurred more frequently with tirzepatide than placebo [15]. Injection-site reactions were generally mild and immunogenicity pooled across phase 3 [35] did not produce neutralizing-antibody-driven loss of efficacy. In SURPASS-4 (CV-risk-elevated population), tirzepatide did not increase major adverse cardiovascular events at 52 weeks; the dedicated cardiovascular outcomes trial SURPASS-CVOT [41] subsequently reported non-inferiority on three-point MACE vs dulaglutide, and prespecified meta-analyses across SURPASS [30] [30][31] reported no excess MACE signal [33]. Kidney-function trajectory in SURPASS-4 [28] [28][29] favored tirzepatide vs insulin glargine across multiple eGFR/UACR endpoints. Pharmacovigilance signals for the compounded supply chain [44] show a distinct AE profile relative to manufactured tirzepatide that cannot be inferred from phase 3 data [34].

Monitoring Compounded Tirzepatide Therapy

Baseline assessment should include weight, blood pressure, heart rate, HbA1c (in the diabetes indication), renal function, a personal and family history focused on medullary thyroid carcinoma and MEN-2, and screening for active gallbladder disease and pancreatitis history. Pregnancy status should be confirmed in patients with reproductive potential, and contraception strategy reviewed in patients using oral hormonal contraception.

On therapy: weight and tolerability assessment at each titration step (every 4 weeks during escalation); HbA1c every 3 months in the diabetes indication; reassessment of indication-specific response after the maintenance dose is reached. Patients should be educated to recognize and report signs of pancreatitis

(severe persistent abdominal pain radiating to the back), gallbladder disease (right upper quadrant pain, jaundice), and hypersensitivity reactions [fda_label_mounjaro; fda_label_zepbound].

Compounded Tirzepatide in Special Populations

Compounded Tirzepatide Evidence Quality

Evidence supporting the manufactured Mounjaro and Zepbound products is strong: more than fifteen phase III randomized trials across the SURPASS program (type 2 diabetes; SURPASS-1 through SURPASS-5 plus SURPASS J-mono, SURPASS-AP-Combo, and SURPASS-CVOT) and SURMOUNT program (obesity, obesity with type 2 diabetes, post-lifestyle adjunct, withdrawal, head-to-head vs semaglutide 2.4 mg, Japanese adults, and obstructive sleep apnea), totaling well over 25,000 participants [fda_essentially_a_copy] [rosenstock2021; frias2021]. Effect sizes are large and reproducible across populations: HbA1c reductions of approximately 2% from baseline, weight reductions of 15, 22% at 72 weeks (and superior to semaglutide 2.4 mg head-to-head in SURMOUNT-5), and a 25, 29 events/hour AHI reduction in obstructive sleep apnea [aronne2024; aronne2025; malhotra2024]. SURPASS-2 established superiority over once-weekly semaglutide 1 mg on both HbA1c and weight endpoints, the first head-to-head superiority of a dual-incretin agonist over a selective GLP-1 receptor agonist [ludvik2021; wadden2023; kadowaki2025]. Network meta-analytic evidence [karagiannis2024] consolidated this comparison across the GLP-1 receptor agonist class [regmi2024; schneck2024]. The dedicated cardiovascular outcomes trial SURPASS-CVOT [nicholls2025] reported non-inferiority on three-point MACE vs dulaglutide [delprato2021; garvey2023]. Mechanistic and population PK evidence [coskun2018] supports a coherent dual-receptor pharmacology underpinning the clinical effect sizes [dahl2022; jastreboff2022].

Evidence specifically supporting compounded preparations is absent, there is no parallel efficacy program for compounded sterile injectable tirzepatide [samms2021; inagaki2022; gao2023]. Compounded use is therefore an extrapolation from the manufactured-product evidence base, justified case by case by patient-specific clinical factors that the manufactured product cannot accommodate. Compounded preparations may differ from Mounjaro and Zepbound in concentration, excipient profile, and container closure; PK/PD equivalence cannot be assumed. Post-marketing pharmacovigilance signals specific to the compounded supply chain [mccall2026] [mccall2026, ruder2025, liu2025] document a distinct AE profile and dosing-error risk that further argues for treating compounded tirzepatide as a separate evidence question from manufactured tirzepatide [fda_essentially_a_copy].

Major Compounded Tirzepatide Clinical Studies

Study	Design	Participants	Duration	Finding
SURPASS-1 (Rosenstock 2021, Lancet)	Phase III, randomized, double-blind, placebo-controlled, monotherapy in type 2 diabetes	478	40 weeks	HbA1c reductions of 1.87%, 1.89%, and 2.07% on tirzepatide 5, 10, and 15 mg vs +0.04% placebo; weight reductions of 7.0, 7.8, and 9.5 kg vs 0.7 kg [rosenstock2021]
SURPASS-2 (Frías 2021, NEJM)	Phase III, randomized, open-label, head-to-head vs semaglutide 1 mg once weekly, add-on to metformin	1879	40 weeks	HbA1c reductions of 2.01%, 2.24%, and 2.30% with tirzepatide 5, 10, and 15 mg vs 1.86% with semaglutide 1 mg; all three tirzepatide doses non-inferior and the 10 and 15 mg doses superior [frias2021]. Weight reductions of 7.6, 9.3, and 11.2 kg vs 5.7 kg
SURPASS-3 (Ludvik 2021, Lancet)	Phase III, randomized, open-label, vs insulin degludec, add-on to metformin ± SGLT2 inhibitor	1444	52 weeks	HbA1c reductions of 1.93%, 2.20%, and 2.37% with tirzepatide 5, 10, and 15 mg vs 1.34% with insulin degludec; superiority for all three tirzepatide doses with concurrent weight loss (vs weight gain on degludec) [ludvik2021]
SURPASS-4 (Del Prato 2021, Lancet)	Phase III, randomized, open-label, vs insulin glargine in adults with type 2 diabetes and elevated cardiovascular risk	2002	52 weeks (treatment); median 85-week follow-up for CV endpoint	HbA1c reductions of 2.43%, 2.55%, and 2.58% with tirzepatide 5, 10, and 15 mg vs 1.44% with glargine; lower hypoglycemia rate; no signal of excess major adverse cardiovascular events [delprato2021]
SURPASS-5 (Dahl 2022, JAMA)	Phase III, randomized, double-blind, placebo-	475	40 weeks	HbA1c reductions of 2.11%, 2.40%, and 2.34% with

Study	Design	Participants	Duration	Finding
	controlled, add-on to titrated insulin glargine			tirzepatide 5, 10, and 15 mg vs 0.86% with placebo; weight reductions of 5.4, 7.5, and 8.8 kg vs +1.6 kg [dahl2022]
SURMOUNT-1 (Jastreboff 2022, NEJM)	Phase III, randomized, double-blind, placebo-controlled in adults with obesity (BMI ≥30) or overweight (BMI ≥27) + comorbidity, excluding diabetes	2539	72 weeks	Mean weight reductions of 15.0%, 19.5%, and 20.9% with tirzepatide 5, 10, and 15 mg vs 3.1% placebo; 85%, 89%, and 91% achieved ≥5% weight loss vs 35% placebo [jastreboff2022]
SURMOUNT-2 (Garvey 2023, Lancet)	Phase III, randomized, double-blind, placebo-controlled in adults with obesity and type 2 diabetes	938	72 weeks	Mean weight reductions of 12.8% and 14.7% with tirzepatide 10 and 15 mg vs 3.2% placebo; clinically meaningful HbA1c reduction in parallel [garvey2023]
SURMOUNT-3 (Wadden 2023, Nature Medicine)	Phase III, randomized, double-blind, placebo-controlled adjunct to 12 weeks of intensive lifestyle intervention	579	72 weeks (after 12-week lifestyle lead-in)	Additional mean weight change of −18.4% with tirzepatide vs +2.5% with placebo; cumulative weight reduction from the start of the lifestyle lead-in approached 26% [wadden2023]
SURMOUNT-4 (Aronne 2024, JAMA)	Phase III, randomized, double-blind, placebo-controlled withdrawal trial after open-label tirzepatide lead-in	670	36-week open-label lead-in, 52-week randomized withdrawal	Continued tirzepatide produced a further −5.5% weight change from week-36 randomization; placebo produced +14.0% regain, confirms weight regain on discontinuation and supports indefinite continued therapy [aronne2024]
SURMOUNT-OSA (Malhotra 2024, NEJM)	Two phase III randomized double-blind placebo-controlled trials in adults with moderate-to-severe OSA and obesity, with (trial	469	52 weeks	AHI reductions of 25.3 events/hour (trial 1) and 29.3 events/hour (trial 2) with tirzepatide vs 5.3 and 5.5 events/hour with placebo; supported FDA expansion of

Study	Design	Participants	Duration	Finding
	2) and without (trial 1) PAP therapy			Zepbound indication to moderate-to-severe OSA in adults with obesity [malhotra2024]
SYNERGY-NASH (Loomba 2024, NEJM)	Phase II randomized double-blind placebo-controlled trial in adults with biopsy-confirmed MASH and F2 or F3 fibrosis	190	52 weeks	MASH resolution without worsening of fibrosis in 44%, 56%, and 62% on tirzepatide 5, 10, and 15 mg vs 10% placebo; 1-stage or greater fibrosis improvement in 51%, 55%, and 51% vs 30% placebo [loomba2024]
Coskun et al. (2018, Molecular Metabolism)	Discovery and clinical proof-of-concept of LY3298176 (tirzepatide), preclinical efficacy plus phase 1 human PK/PD	—	Preclinical and phase 1	Established balanced GIP/GLP-1 receptor agonism, weight-favorable effects in DIO rodents, and once-weekly human dosing profile that supported the SURPASS and SURMOUNT programs [coskun2018]
Zeng et al. (2023, Frontiers in Endocrinology)	Systematic review and meta-analysis of 9 RCTs for pancreatitis and gallbladder/biliary disease signals	—	Pooled 12, 72 weeks	No statistically significant increase in pancreatitis risk; modest increase in composite gallbladder/biliary disease (RR 1.52; 95% CI 1.17, 1.98) [zeng2023]
Frías et al. (2018, Lancet), Phase 2 dose-finding	Phase 2 randomized double-blind placebo- and active-comparator (dulaglutide 1.5 mg)-controlled dose-ranging trial of LY3298176 (tirzepatide) 1, 5, 10, and 15 mg in adults with type 2 diabetes	318	26 weeks	Dose-dependent HbA1c reductions to 2.4% and weight reductions to 11.3 kg at 15 mg; established the dose range carried into phase 3 [frias2018]
Samms et al. (2021, J Clin Invest), GIPR mechanism	Preclinical mechanistic study using GIPR-knockout and wild-type obese mice	—	—	GIPR agonism mediates weight-independent insulin sensitization by tirzepatide; validates GIPR co-agonism as

Study	Design	Participants	Duration	Finding
				a metabolic target rather than as merely an insulinotropic add-on [samms2021]
Regmi et al. (2024, Cell Metabolism), Adipocyte GIPR mechanism	Preclinical and translational mechanistic study of GIPR activation in adipocytes	—	—	Long-acting GIP receptor activation by tirzepatide regulates adipocyte nutrient metabolism and supports the imbalanced/biased agonist pharmacology hypothesis at the molecular level [regmi2024]
Heise et al. (2022, Lancet Diabetes Endocrinol), Islet function vs semaglutide	Phase 1b/2 randomized, double-blind, parallel-group study in adults with type 2 diabetes comparing tirzepatide 15 mg vs semaglutide 1 mg vs placebo	117	28 weeks	Tirzepatide produced greater improvements in first-phase and second-phase insulin secretion and insulin sensitivity than semaglutide; mechanistic substrate for the SURPASS-2 outcome difference [heise2022]
Mather et al. (2024, J Clin Endocrinol Metab), β-cell function meal-test vs semaglutide	Randomized parallel-group meal-test study of tirzepatide vs semaglutide on β-cell function, insulin sensitivity, and glucose control	—	—	Greater post-prandial β-cell function and insulin sensitivity with tirzepatide than semaglutide at matched glycemic exposure [mather2024]
Gastaldelli et al. (2022, Lancet Diabetes Endocrinol), SURPASS-3 MRI substudy	Pre-specified MRI substudy of SURPASS-3 measuring liver fat content and abdominal adipose tissue by MRI-PDFF in adults with type 2 diabetes	502	52 weeks	Tirzepatide reduced liver fat content substantially more than insulin degludec, with parallel reductions in visceral and subcutaneous adipose tissue; supports the MASH rationale that motivated SYNERGY-NASH [gastaldelli2022]
Heerspink et al. (2022, Lancet Diabetes Endocrinol),	Pre-specified post-hoc kidney-outcomes analysis of SURPASS-4 (vs insulin glargine in	1995	Median 85-week follow-up	Slower decline in eGFR and reduced urinary albumin-to-creatinine ratio with tirzepatide vs insulin glargine;

Study	Design	Participants	Duration	Finding
SURPASS-4 kidney outcomes	adults with type 2 diabetes and elevated CV risk)			favorable kidney composite outcome [heerspink2022]
Heerspink et al. (2023, Diabetes Care), SURPASS-4 cystatin C kidney function	Post-hoc analysis of SURPASS-4 using cystatin C-based eGFR as a confirmatory kidney function measure	—	52 weeks treatment	Cystatin C-based eGFR trajectory paralleled the creatinine-based analysis, supporting the favorable kidney outcomes signal [heerspink2023]
Sattar et al. (2022, Nature Medicine), Pre-specified CV meta-analysis	Pre-specified meta-analysis of major adverse cardiovascular events across the SURPASS phase 3 program	—	Pooled 40, 104 weeks	No statistically significant excess of MACE with tirzepatide vs comparators across the phase 3 program; informed the design and analytical framework for SURPASS-CVOT [sattar2022]
Patoulias et al. (2022, Am J Cardiol), Updated CV meta-analysis	Updated meta-analysis of randomized trials of tirzepatide vs placebo or active comparators for cardiovascular outcomes	—	Pooled across SURPASS trials	No excess MACE signal with tirzepatide vs comparators; complementary to the Sattar pre-specified analysis [patoulias2022]
Karagiannis et al. (2024, Diabetologia), Network meta-analysis vs semaglutide	Systematic review and frequentist network meta-analysis of subcutaneous tirzepatide vs semaglutide in adults with type 2 diabetes across the full RCT corpus	—	—	Tirzepatide superior to semaglutide on HbA1c and weight at matched dose categories; consistent with the SURPASS-2 head-to-head and the SURMOUNT-5 superiority over semaglutide 2.4 mg in obesity [karagiannis2024]
Mishra et al. (2023, J Endocr Soc), AE systematic review	Systematic review of adverse events related to tirzepatide across the phase 3 development program	—	—	Consolidated AE incidence consistent with individual trial reports; reaffirmed class-typical GI tolerability profile and absence of pancreatitis signal [mishra2023]
		600	72 weeks	

Study	Design	Participants	Duration	Finding
de Lemos et al. (2024, Hypertension), SURMOUNT-1 ambulatory BP substudy	Pre-specified ambulatory blood pressure monitoring substudy of SURMOUNT-1			Clinically meaningful reduction in 24-hour ambulatory systolic blood pressure with tirzepatide vs placebo in adults with BMI ≥27 kg/m²; supports cardiovascular-risk-relevance of the obesity indication [delemos2024]
Mullins et al. (2024, J Clin Endocrinol Metab), Pooled phase 3 immunogenicity	Pooled analysis of treatment-emergent anti-drug antibodies and their PK, efficacy, and safety correlates across phase 3 SURPASS and SURMOUNT trials	—	—	Anti-drug antibodies occurred in a minority of patients with no clinically meaningful effect on PK, HbA1c reduction, weight loss, or safety [mullins2024]
Look et al. (2025, Diabetes Obes Metab), SURMOUNT-1 body composition	Pre-specified body composition substudy of SURMOUNT-1 using DEXA imaging	160	72 weeks	Fat-mass-preferential weight reduction with proportional preservation of lean body mass; ratio of fat loss to lean loss favorable compared with reported diet-only weight loss [look2025]
Rasouli et al. (2025, Diabetes Ther), Older adults SURPASS post-hoc	Post-hoc analysis of older adults (≥65 years) with type 2 diabetes and without obesity across the SURPASS phase 3 program	—	—	Consistent HbA1c and tolerability outcomes in older adults without obesity; no signal of differential adverse events compared with the overall trial population [rasouli2025]
Inagaki et al. (2022, Lancet Diabetes Endocrinol), SURPASS J-mono	Phase 3 randomized double-blind multicentre trial of tirzepatide monotherapy vs dulaglutide in Japanese adults with type 2 diabetes	636	52 weeks	Tirzepatide produced greater HbA1c reductions and weight loss than dulaglutide 0.75 mg across all three tirzepatide doses (5, 10, 15 mg) [inagaki2022]

Study	Design	Participants	Duration	Finding
Gao et al. (2023, Nature Medicine), SURPASS-AP-Combo	Phase 3 randomized open-label trial of tirzepatide vs insulin glargine as second/third-line therapy in adults with type 2 diabetes in the Asia-Pacific region	917	40 weeks	Tirzepatide superior to insulin glargine on HbA1c reduction, weight loss, and time to glycemic target; consistent with the global SURPASS program [gao2023]
Nicholls et al. (2024, Am Heart J), SURPASS-CVOT design	Design and baseline characteristics paper for the SURPASS-CVOT trial comparing tirzepatide vs dulaglutide on MACE	13299	Event-driven (designed for 1110+ MACE events)	Established the analytic framework, non-inferiority margin, and baseline characteristics for SURPASS-CVOT [nicholls2024_design]
Nicholls et al. (2025, NEJM), SURPASS-CVOT primary results	Phase 3 randomized, double-blind, active-comparator (dulaglutide)-controlled cardiovascular outcomes trial in adults with type 2 diabetes and atherosclerotic cardiovascular disease	13299	Median follow-up approximately 4 years	Tirzepatide non-inferior to dulaglutide on three-point MACE (cardiovascular death, non-fatal MI, non-fatal stroke); secondary cardiovascular endpoints directionally favorable [nicholls2025]
Aronne et al. (2025, NEJM), SURMOUNT-5	Phase 3 randomized open-label head-to-head trial of tirzepatide vs semaglutide 2.4 mg in adults with obesity	751	72 weeks	Tirzepatide produced superior mean percent weight reduction relative to semaglutide 2.4 mg; first phase 3 head-to-head of the two products in obesity [aronne2025]
Kadowaki et al. (2025, Lancet Diabetes Endocrinol), SURMOUNT-J	Phase 3 randomized double-blind placebo-controlled trial in Japanese adults with obesity disease	—	72 weeks	Tirzepatide 10 and 15 mg produced clinically meaningful weight reduction vs placebo with consistent tolerability in a Japanese population [kadowaki2025]
McCall et al. (2026, Expert Opin Drug Saf),	Pharmacovigilance analysis of FDA Adverse Event Reporting System	—	—	Compounded preparations are associated with a distinct adverse-event profile relative

Study	Design	Participants	Duration	Finding
Compounded GLP-1 FAERS analysis	(FAERS) data for compounded GLP-1 receptor agonists including compounded tirzepatide			to FDA-approved manufactured products, including dosing errors, contamination concerns, and reports of unexpected events not predicted by phase 3 data [mccall2026]

Compounded Tirzepatide Pharmacokinetics & Pharmacodynamics

Pharmacokinetics

Tirzepatide is a 39-amino-acid synthetic peptide modified with a C20 fatty di-acid moiety that binds plasma albumin. Subcutaneous bioavailability is approximately 80%, time to maximum plasma concentration is 8, 72 hours after a single dose, and approximately 99% is bound to albumin. The terminal half-life is approximately 5 days, supporting once-weekly subcutaneous dosing with steady-state reached after approximately 4 weeks at each dose. Tirzepatide is cleared by proteolytic catabolism; cytochrome P450 metabolism is not a significant pathway.

Population pharmacokinetic analysis (Schneck and Urva 2024) integrated data from 19 trials across the SURPASS and SURMOUNT programs and identified body weight as the primary covariate on apparent clearance, with no clinically meaningful effects of age, sex, race, renal function, or hepatic function [coskun2018; schneck2024]. The manufactured product labels do not recommend dose adjustment in renal or hepatic impairment on PK grounds.

Compounded immediate-use sterile injectable preparations may differ from the manufactured pen formulation in concentration, excipient profile, container closure, and storage conditions; PK characteristics published for Mounjaro and Zepbound should not be assumed to translate without local stability and PK data [fda_label_mounjaro].

Pharmacodynamics

Pharmacodynamic effects include glucose-dependent insulin secretion, glucagon suppression, transient delay in gastric emptying that attenuates with continued dosing, and central appetite suppression [urva2020]. Insulin sensitivity in skeletal muscle and adipose tissue improves over weeks of therapy, contributing to glycemic effects beyond direct islet stimulation.

Body weight, HbA1c, and (in SURMOUNT-OSA) apnea-hypopnea index are the principal clinically measured pharmacodynamic endpoints [malhotra2024]. Effects on lipids, blood pressure, and inflammatory markers track weight loss and improvement in metabolic state [coskun2018; jastreboff2022].

Comparing Compounded Tirzepatide Formulations

The manufactured products are Mounjaro and Zepbound, both single-dose pre-filled pens (with single-dose vials also available) at strengths of 2.5, 5, 7.5, 10, 12.5, and 15 mg per 0.5 mL. Mounjaro is labeled for type 2 diabetes; Zepbound is labeled for chronic weight management and (since December 2024) moderate-to-severe obstructive sleep apnea in adults with obesity. The drug substance is identical between the two products.

Compounded sterile injectable preparations vary in concentration, excipient profile, and container closure. They are not bioequivalent to Mounjaro or Zepbound; clinicians should anticipate that local PK and tolerability may differ from manufactured-product published data and re-evaluate titration when switching [fda_label_mounjaro; fda_label_zepbound].

Compounded Tirzepatide Storage and Handling

Manufactured Mounjaro and Zepbound are stored refrigerated at 2, 8°C in the original carton to protect from light. Unopened pens may be stored at room temperature (below 30°C) for up to 21 days; once at room temperature they must not be returned to refrigeration. Compounded sterile injectable tirzepatide is stored per the pharmacy's stability data and beyond-use date assignment under USP <797>; refrigerated storage is typical for multi-dose preparations [usp_797].

Tirzepatide is a cold-chain product [fda_label_mounjaro; fda_label_zepbound]. Patients should be educated on temperature management during shipping and at home, and on recognizing temperature excursions that warrant pharmacist consultation.

Compounded Tirzepatide Compounding & Operations

503A compounding

Compounded tirzepatide is prepared under 503A on patient-specific prescriptions in state-licensed compounding pharmacies. RonanRx prepares sterile injectable preparations per USP General Chapter <797>, the official compendial standard for sterile pharmaceutical compounding, with documented active ingredient sourcing, gravimetric and analytical verification, sterility and endotoxin testing per the pharmacy's quality-management system, and full lot traceability [fda503a; usp_797; usp_795]. For any nonsterile preparative steps the corresponding USP General Chapter <795> applies; however, the finished injectable product is governed by <797> in full.

Beyond-use dating, ingredient identity verification, sterility assurance, and stability assessment follow USP <797> requirements. Each compounded batch is documented per state board of pharmacy retention rules with full traceability from API lot through dispensing.

Pharmacist review

Each prescription for compounded tirzepatide undergoes pharmacist review prior to dispensing [fda_essentially_a_copy]. The review confirms: a documented patient-specific clinical reason that the manufactured Mounjaro or Zepbound product is not appropriate (excipient sensitivity, dose individualization outside manufactured strengths, or other documented factor); absence of contraindications (personal or family history of medullary thyroid carcinoma, MEN-2, severe gastroparesis, hypersensitivity) [fda_label_mounjaro, fda_label_zepbound]; appropriate concomitant medication review including oral contraception counseling and hypoglycemia risk if combined with insulin or sulfonylurea; and a prescribed regimen consistent with FDA-label titration unless the prescriber documents a patient-specific reason.

RonanRx does not fill prescriptions that read as routine substitution of compounded for manufactured product without documented clinical rationale, consistent with FDA guidance on compounded copies of commercially available drugs, and is particularly attentive in the post-shortage regulatory context for tirzepatide [fda_essentially_a_copy; fda_shortage_resolution_2024]. Pharmacovigilance signals specific to compounded GLP-1 receptor agonists [mccall2026] [mccall2026, ruder2025, liu2025] reinforce the review threshold: dose-strength errors, sterility-related events, and AE reports not predicted by the manufactured-product phase 3 data are documented in the compounded supply chain and must be specifically excluded by the pharmacist's review.

Quality and traceability

Active pharmaceutical ingredients are sourced from FDA-registered facilities with documented certificates of analysis. Each batch is recorded with lot numbers traceable to API source, compounding date, beyond-use date, sterility test result, endotoxin test result, and dispensing pharmacist of record. Finished product lot records are retained per state board of pharmacy retention requirements.

Cold chain

Compounded sterile injectable tirzepatide is a cold-chain product. Refrigerated transport is used between the compounding pharmacy and the patient with temperature monitoring through the shipment. Patients are advised to refrigerate the product on arrival, to inspect for temperature excursions, and to contact the pharmacy if the cold-chain integrity is in question. Manufactured Mounjaro and Zepbound follow the same refrigerated-storage convention with a 21-day room-temperature allowance per labeling [fda_label_mounjaro; fda_label_zepbound].

Frequently Asked Questions About Compounded Tirzepatide

Is compounded tirzepatide the same as Mounjaro or Zepbound?

No. Mounjaro and Zepbound are the FDA-approved manufactured tirzepatide products [fda_label_mounjaro; fda_label_zepbound]. Compounded tirzepatide is pharmacy-prepared on a patient-specific prescription and is not bioequivalent to the manufactured products. Compounded drugs are not FDA-approved [fda503a].

Why did so many pharmacies compound tirzepatide in 2023 and 2024, and what changed?

Tirzepatide injection was on FDA's drug shortage list from December 15, 2022 through October 2024, which broadly permitted 503A compounding under section 503A(b)(1)(D) [fda_shortage_resolution_2024; fda_essentially_a_copy]. FDA's December 19, 2024 declaratory order affirmed the shortage was resolved, and the 503A compounding transition period ended February 18, 2025. Outside the shortage exception, compounding is now restricted to patient-specific clinical needs that the manufactured product cannot meet.

When is a compounded version appropriate?

Per FDA guidance, a compounded version of an FDA-approved drug is generally restricted unless the prescriber documents a patient-specific clinical need that the manufactured product cannot meet, for example, excipient sensitivity, dose individualization outside the manufactured strength increments, or a documented manufactured-product supply gap [fda_essentially_a_copy]. Cost or preference does not qualify under section 503A.

How much weight loss do people see on tirzepatide?

In SURMOUNT-1 (adults with obesity and no diabetes), mean weight reduction at 72 weeks was 15.0%, 19.5%, and 20.9% on tirzepatide 5, 10, and 15 mg respectively, vs 3.1% on placebo [jastreboff2022; aronne2024]. In SURMOUNT-2 (adults with obesity and type 2 diabetes), 72-week mean weight reduction was 12.8% and 14.7% on 10 mg and 15 mg vs 3.2% placebo [garvey2023]. SURMOUNT-4 confirmed that weight is regained after discontinuation, so therapy is typically continued indefinitely while clinically beneficial.

How does tirzepatide compare with semaglutide?

SURPASS-2 was the head-to-head trial: in adults with type 2 diabetes on metformin, tirzepatide 5, 10, and 15 mg produced HbA1c reductions of 2.01%, 2.24%, and 2.30% vs 1.86% with semaglutide 1 mg at 40 weeks; weight reductions were 7.6, 9.3, and 11.2 kg vs 5.7 kg [frias2021]. The 10 and 15 mg doses were

superior to semaglutide 1 mg on both endpoints. SURPASS-2 did not test semaglutide 2 mg or compare with manufactured weight-management semaglutide products.

What are the most common side effects?

Gastrointestinal: nausea, diarrhea, decreased appetite, vomiting, constipation, and dyspepsia. Most are mild to moderate and concentrated during dose escalation. Approximately 4, 7% of patients discontinued therapy for adverse events in the SURPASS and SURMOUNT programs vs 1, 3% on placebo. Cholelithiasis risk is modestly elevated; pancreatitis risk has not been significantly elevated in pooled phase III data [jastreboff2022; frias2021; zeng2023].

Who should not take tirzepatide?

Contraindicated in personal or family history of medullary thyroid carcinoma, multiple endocrine neoplasia syndrome type 2, and known serious hypersensitivity. Not recommended in severe gastroparesis or during pregnancy. Patients on oral hormonal contraception need to switch to non-oral or add a barrier method during initiation and after dose escalations [fda_label_mounjaro; fda_label_zepbound].

Does RonanRx sell compounded tirzepatide directly to patients?

No. Compounded tirzepatide requires a patient-specific prescription written by a licensed doctor for an identified patient with a documented clinical reason that the manufactured Mounjaro or Zepbound product is not appropriate, plus pharmacist review before dispensing [fda_essentially_a_copy]. RonanRx is not a direct-to-consumer storefront [fda503a].

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How to Access Compounded Tirzepatide

Compounded Compounded Tirzepatide is dispensed under 503A on a patient-specific prescription. Depending on your role, the next step looks different.

FOR PRESCRIBING CLINICIANS

Offer this medication

A pharmacist will follow up within two business days. We'll cover state availability, supported formulations, and what integration looks like for your clinic.

ronanrx.com/request-partnership-call

PATIENT WITH A DOCTOR

Receive your prescription

If your doctor has prescribed Compounded Tirzepatide, sign up so we can prepare and ship your medication. The signup wizard collects intake and connects you to the prescribing workflow.

ronanrx.com/patients

PATIENT WITHOUT A DOCTOR

Find a partner clinic

RonanRx prescribes through partner clinics — we don't initiate prescriptions on this site. Read how the referral process works and how to find a partner clinic in your state.

ronanrx.com/find-clinic

Other compounds RonanRx makes

This monograph is one of many in the RonanRx formulary. Every compound below is prepared under 503A on a patient-specific prescription. Browse the full catalog at ronanrx.com/medications and ronanrx.com/peptides, or scan the codes at right for each index.

Medications

Peptides

MEDICATIONS (40)

Alpha-Lipoic Acid (ALA) — Antioxidant & mitochondrial
Coenzyme Q10 (CoQ10) — Antioxidant & mitochondrial
Glutathione — Antioxidant & mitochondrial
NAD+ / NMN — Antioxidant & mitochondrial
Compounded Topical Anesthetics (BLT, LET) — Dermatology
Topical Minoxidil — Dermatology
Topical Tretinoin — Dermatology
Compounded Magnesium — Energy & nutritional
Cyanocobalamin — Energy & nutritional
High-Dose Vitamin D — Energy & nutritional
Hydroxocobalamin — Energy & nutritional
Iron (Compounded) — Energy & nutritional
L-Carnitine — Energy & nutritional
Methylcobalamin (B12) — Energy & nutritional
Methylfolate — Energy & nutritional
Anastrozole — Hormone optimization
Clomiphene & Enclomiphene — Hormone optimization
DHEA — Hormone optimization
Estradiol — Hormone optimization
Estriol — Hormone optimization
Human Chorionic Gonadotropin (HCG) — Hormone optimization
Pregnenolone — Hormone optimization
Progesterone — Hormone optimization
Testosterone — Hormone optimization
Compounded Metformin — Metabolic & weight
Compounded Semaglutide — Metabolic & weight
Compounded Tirzepatide — Metabolic & weight
Lipotropic Injection (MIC, MICC) — Metabolic & weight
Low-Dose Naltrexone (LDN) — Metabolic & weight
Naltrexone-Bupropion Combination — Metabolic & weight
Topiramate — Metabolic & weight
Bremelanotide / PT-141 — Sexual health
Compounded Sildenafil — Sexual health
Compounded Tadalafil — Sexual health
Trimix Injection — Sexual health
Compounded Gabapentin — Sleep & recovery
Compounded Melatonin — Sleep & recovery
Compounded T3 (Liothyronine) — Thyroid
Compounded T3/T4 Combinations — Thyroid
Compounded T4 (Levothyroxine) — Thyroid

PEPTIDES (21)

Sermorelin — Available now

Tesamorelin — Available now

AOD-9604 — Growth-hormone axis (under FDA review)

CJC-1295 — Growth-hormone axis (under FDA review)

GHRP-2 / GHRP-6 — Growth-hormone axis (under FDA review)

Hexarelin — Growth-hormone axis (under FDA review)

Ipamorelin — Growth-hormone axis (under FDA review)

MK-677 / Ibutamoren — Growth-hormone axis (under FDA review)

5-Amino 1MQ — Metabolic & longevity (under FDA review)

Epitalon / Epithalon — Metabolic & longevity (under FDA review)

MOTS-C — Metabolic & longevity (under FDA review)

Thymosin Alpha-1 / Thymalin — Metabolic & longevity (under FDA review)

DSIP, Delta Sleep-Inducing Peptide — Neuro & cognitive (under FDA review)

Selank — Neuro & cognitive (under FDA review)

Semax — Neuro & cognitive (under FDA review)

Vasoactive Intestinal Peptide (VIP) — Neuro & cognitive (under FDA review)

BPC-157 — Tissue repair (under FDA review)

KPV — Tissue repair (under FDA review)

LL-37 — Tissue repair (under FDA review)

Pentadeca Arginate (PDA) — Tissue repair (under FDA review)

TB-500 / Thymosin Beta-4 — Tissue repair (under FDA review)