



Did You Know...

Earlier this year, the FDA determined compounding pharmacies will no longer be able to compound semaglutide or tirzepatide.

Background

Federal law (Federal Drug & Cosmetic Act) prohibits compounding commercially available medications like semaglutide (Ozempic®/Wegovy®) and tirzepatide (Mounjaro®/Zepbound®) unless one of two specific conditions are met. See below.

Two exceptions allow compounding for commercially available products:

1. *Significant Medical Need* – If an FDA-approved version does not meet a patient's medical needs (e.g., an ingredient allergy or a required unique dosage form). The difference must be documented and have clinical rationale.
2. *Drug Shortages* – If the FDA lists a medication as “currently in shortage,” temporary compounding may be permitted.

Due to supply shortages (2022–2025), the FDA temporarily allowed the compounding of semaglutide and tirzepatide. In February 2025, the FDA announced that semaglutide and tirzepatide shortages were resolved, ending the compounding allowances. **By April 22, 2025, all compounding of semaglutide and tirzepatide was to cease at 503A and 503B pharmacies.**

What this means for providers, patients, and pharmacies...

After these deadlines, compounding semaglutide and tirzepatide is no longer permitted unless for a documented medical necessity as listed above. Providers should educate patients about shortage resolutions and the need to transition back to FDA-approved products. Due to safety, quality and effectiveness concerns, the American Diabetes Association does not recommend the use of non-FDA approved compounded GLP-1 receptor agonist products. If cost or coverage is a concern, providers can help patients explore the manufacturer savings programs listed below. **As a reminder the Duke Commercial Plans (Duke Basic, Duke Select, Duke BCBS, and DukeUSA) do not cover GLP-1 receptor agonists for weight loss. Appeals for use of Saxenda, Wegovy, or Zepbound for comorbid conditions will not grant coverage as these medications are excluded under the weight loss category (this includes use of these agents for sleep apnea and cardiovascular risk reduction). Mounjaro, Ozempic, Trulicity, Rybelsus, etc are covered under the Duke Plans for those with Type 2 Diabetes.** The cash paying options below may benefit those without coverage.



Elly Lilly Savings Programs

- *Mounjaro Savings Card*: Eligible commercially insured covered patients may pay as little as \$25 for a 1-month or 3-month prescription of Mounjaro. The maximum savings are \$150 per 1-month prescription, \$300 per 2-month prescription, or

\$450 per 3-month prescription fill. A 1-month supply is defined as 28 days and 4 pens. For more information and to obtain the savings card, visit <https://mounjaro.lilly.com/savings-resources> to confirm eligibility and download the card.

- *LillyDirect for Zepbound*: Cash pricing for patients who do not have coverage. No prior authorization or insurance coverage is required. Patients must have a valid prescription. Medication is available in VIALS ONLY and is mailed from LillyDirect Self Pay Pharmacy Solutions. Availability: 2.5mg vial: \$349/month, 5mg vial: 499/month, 7.5mg and 10mg vials:

\$499/month when refilled within 45 days through the Zepbound Self Pay Journey Program; prices increase to \$599 and

\$699 respectively if refilled outside this window. For more information visit <https://lillydirect.lilly.com/pharmacy/zepbound> and attached pdf for prescribing information.

Novo Nordisk Savings Programs

- *Ozempic Savings Card*: Eligible commercially or privately insured covered patients may pay as little as \$25 for a 1-, 2-, or 3- month prescription of Ozempic. The maximum savings are \$100 per 1-month prescription, \$200 per 2-month prescription, and \$300 per 3-month prescription. A month is defined as 28 days. For more information and to request the savings offer, visit <https://www.novocare.com/diabetes/products/ozempic/savings-offer.html> and complete the required information.
- *Wegovy through NovoCare*: Novo Nordisk offers a cash price for Wegovy at \$499/month for all strengths. No prior authorization or insurance coverage is required. Medication is available in PEN FORM and is mailed from NovoCare Pharmacy. Patients must have a valid prescription. For additional information about how to send Rx to NovoCare Pharmacy visit <https://www.novocare.com/obesity/products/wegovy/get-product.html>

Additional Resources

- <https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize#%3A%7E%3Atext%3D%2C2022%20due%20to%20increased%20demand>
- <https://www.njconsumeraffairs.gov/phar/Documents/Semaglutide-Compounding-Statement-04282023.pdf#%3A%7E%3Atext%3DWhen%20Is%20Compounding%20of%20Semaglutide%2Cthe%20above%20site%20and%20its>
- https://diabetesjournals.org/care/article/48/Supplement_1/S181/157569/9-Pharmacologic-Approaches-to-Glycemic-Treatment