

Drug Shortages and Management – Updates Fall 2023

Drug shortages can adversely affect drug therapy, compromise or delay medical procedures, and result in medication errors. This often results in inadequate patient care, high institutional costs, and patient complaints.

The FDA defines a drug shortage as a period of time when the demand or projected demand for the drug within the US exceeds the supply of the drug. Manufacturing quality issues are a major reason for most drug shortages. However, additional factors such as production delays at the manufacturer, increased demand, and delays in receiving raw materials from suppliers are also contributing to these global shortages.

We have been tracking two important shortages that first disrupted the pharmacy industry in late 2022/early 2023. Manufacturers had hoped to resolve the shortages by mid-year 2023, but shortages are on-going. The first group includes several medications used in managing ADD/ADHD and the other group is made of the popular Diabetes/weight loss medications in the GLP1 drug class. Below is a summary:

	ADD/ADHD Agents	GLP-1 Receptor Agonists
Drugs in Shortage	Immediate release formulation of amphetamine mixed salts (generic Adderall) Lisdexamfetamine (newly launched generic Vyvanse) Methylphenidate extended release (generic Concerta)	1) Mounjaro ^Y (Tirzepatide) 2) Ozempic ^Y and Wegovy* (Semaglutide) 3) Trulicity ^Y (Dulaglutide) 4) Victoza ^Y and Saxenda* (Liraglutide)
What is it used for?	1) Treatment of ADD/ADHD 2) Treatment of a sleep disorder called narcolepsy	1) Type 2 Diabetes ^Y 2) Obesity* ^Y
Why is it in short supply?	These products are controlled by the DEA due to their potential for abuse, so the amount of raw ingredients available is limited. The number of prescriptions for ADD/ADHD has been increasing over the past 2 years and the DEA announced they will not allow an increase in production of these ingredients which has resulted in manufacturing delays. The generic Vyvanse is still mostly in production as it has only just launched September 2023.	An increase in popularity and media attention around weight loss has led to a rise in demand and supply chain problems
Are there any alternatives that aren't in shortage?	Pharmacies may have brand and/or generic Adderall/Vyvanse/Concerta on hand, but the supply of different products or strengths varies. Periodic delays may occur until the supply is fully restored. Other medicines similar to Adderall/Vyvanse/Concerta are available and are not experiencing shortages at this time. These include dextroamphetamine (generic Dexedrine), dexamethylphenidate (generic Focalin), and methylphenidate (generic Ritalin). There are also some non-controlled alternatives such as guanfacine (Intuniv), clonidine (Catapres), and atomoxetine (Strattera).	<u>Other GLP1 Medications:</u> 1) Byetta ^Y and Bydureon ^Y (Exenatide) 2) Adlyxin ^Y (Lixisenatide) 3) Rybelsus ^Y (Semaglutide)
When is the expected resolution?	No release date at this time. Several manufacturers anticipate releasing supplies as they become available; mid-October 2023 listed as target date for some products/strengths/dosages.	Ozempic & Mounjaro shortages expected to end by late 2023; no resupply date for Wegovy or Trulicity. Generic Victoza (liraglutide) expected mid-2024.

*Only approved for Obesity

^Y Only approved for Diabetes

Frequently Asked Questions:

What can someone do if the pharmacy is out of their medication?

- Check if other pharmacies have a supply of the medication to fill it.
- Talk to their provider to see if they can go without the medication while the pharmacy tries to order the medication or ask if the doctor can prescribe an alternative.
- Check benefit guide documents for out of network coverage and process for submitting paper claims.

If a drug cannot be filled at an in-network pharmacy due to shortage, can the plan offer that the drug be filled at an out-of-network pharmacy?

- A member has two options if their in-network pharmacy is unable to fill the prescription:
 - 1) The PBM can provide one off overrides for shortage issues. However, these overrides can take some time to process and would not be ideal for members who need the medication immediately.
 - 2) If the member can find a drug at an out of network pharmacy, the member can pay out of pocket for the medication and submit for a paper reimbursement. You'll just have to make sure that the member is reimbursed at 100% less copay and not the "contracted" rate since the contracted rate essentially reimburses them as a pharmacy.

Are targeted letters to members planned?

- Since drug shortages tend to be sporadic and stock levels can vary from pharmacy to pharmacy, it is not feasible or beneficial to create a targeted communication to members.

Do you recommend ordering refills early? How early can they be filled?

- We do recommend ordering refills when the patient is running low on their medication to ensure the pharmacy has time to order the medication if they don't currently have it in stock.
- The member should contact the pharmacy to see the earliest date that they can fill their prescription. How early they can fill the prescription depends on the medication due to restrictions surrounding controlled substances.

Will the timing of refills or limitations be changed?

- To change the timing of refills or limitations would require changes to a clients plan design. These changes require a number of steps and signatures, and the shortages will likely be resolved prior to the changes being implemented.

Resources:

- <https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages>
- <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>
- <https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-shortage-adderall>
- <https://www.ashp.org/drug-shortages>
- <https://prescriptionhope.com/blog-pharmacy-is-out-of-your-medication/>
- <https://www.novonordisk-us.com/supply-update.html>