

ACMA WEBINAR SESSION

The Weight Loss Craze: Navigating Approvals & Patient Demands



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Date: Feb 21st, 2024
Time: 1PM EST



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**TIME
BEST
INVENTIONS
2023**

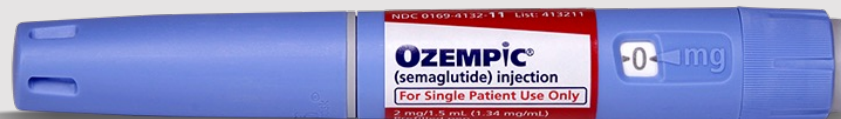
Semaglutides listed in TIME's Best Inventions of 2023



Pharmaceutical Sensation
Novo Nordisk Semaglutides



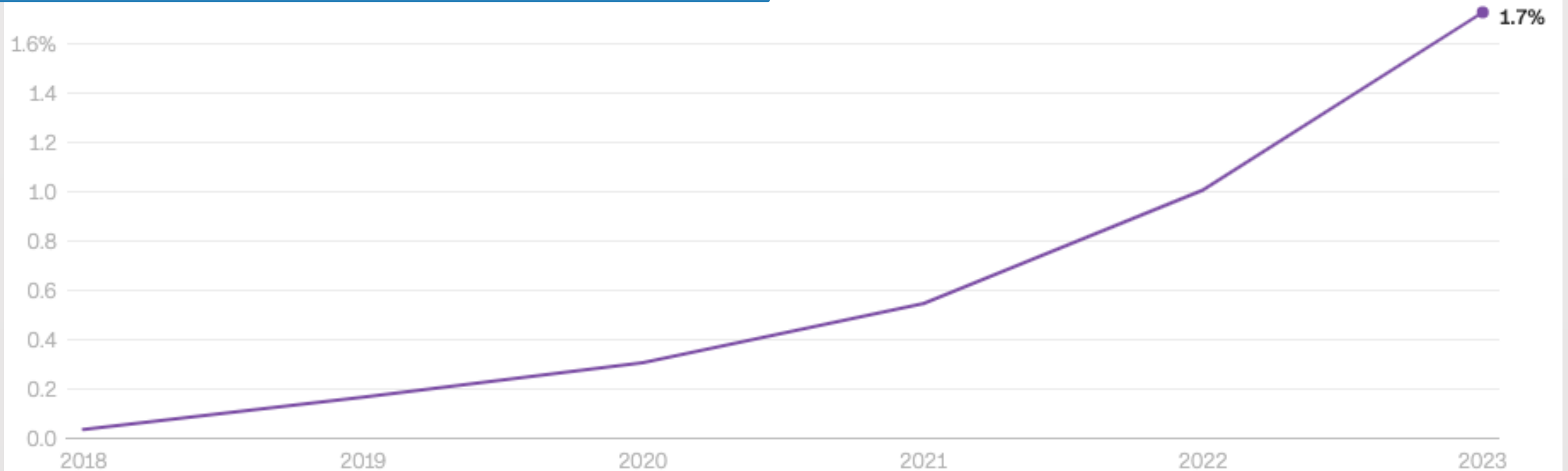
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The Semaglutide Surge

Semaglutide prescriptions increased 40-fold over the past 5 years

Share of all patients with a health care visit who were prescribed semaglutide

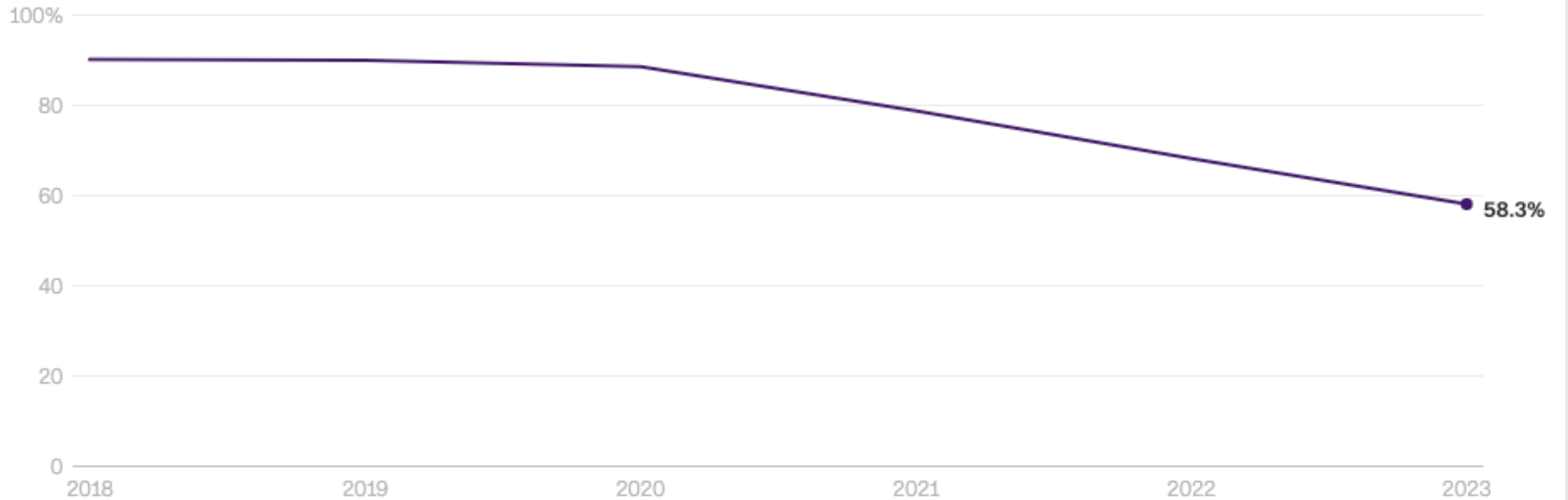


Note: The US Food and Drug Administration has approved three semaglutide treatments: injectables Ozempic and Wegovy, and the Rybelsus tablet. Data as of September 21, 2023.

Source: Epic Research

The Semaglutide Surge # Semaglutide patients with Type 2 diabetes decreased by > 30%

Share of patients prescribed semaglutide who have Type 2 diabetes



Note: Data as of September 21, 2023.

Source: Epic Research

GLP-1 Receptor Agonists (RAs)

- **How does it work?** biosynthetic form of the GLP-1 hormone
 - Slows rate of gastric emptying
 - Directly increases satiety – suppresses appetite in brain
 - Stimulates insulin release in pancreas & suppresses glucagon secretion

- **What are GLP-1 agonists?**

- Semaglutide (Ozempic, Wegovy)
- Tirzepatide (Mounjaro, Zepbound)
- Liraglutide (Saxenda)

Adv Ther (2022) 39:2452–2467
<https://doi.org/10.1007/s12325-022-02153-x>

REVIEW


Efficacy of GLP-1 RA Approved for Weight Management in Patients With or Without Diabetes: A Narrative Review

- Mean weight loss difference between GLP-1 RAs* and Placebo:
 - With diabetes = 4 - 6.2%
 - Without diabetes = 6.1 - 17%

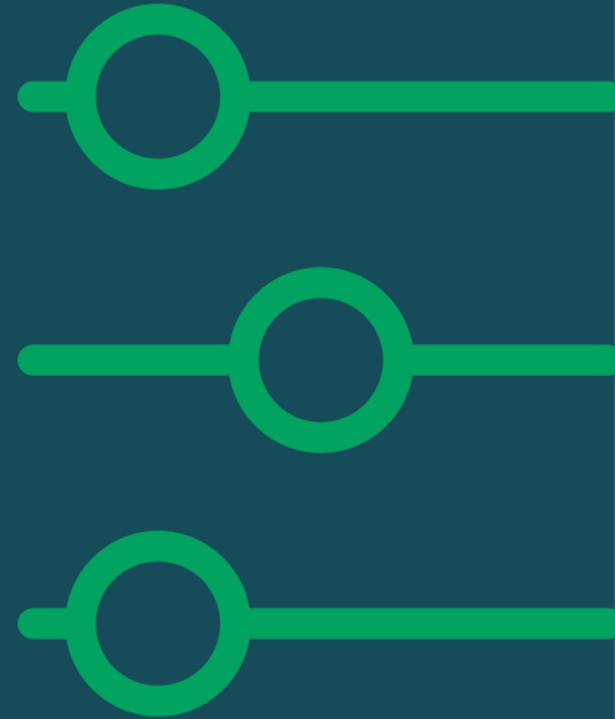
*% weight loss varies based on specific product

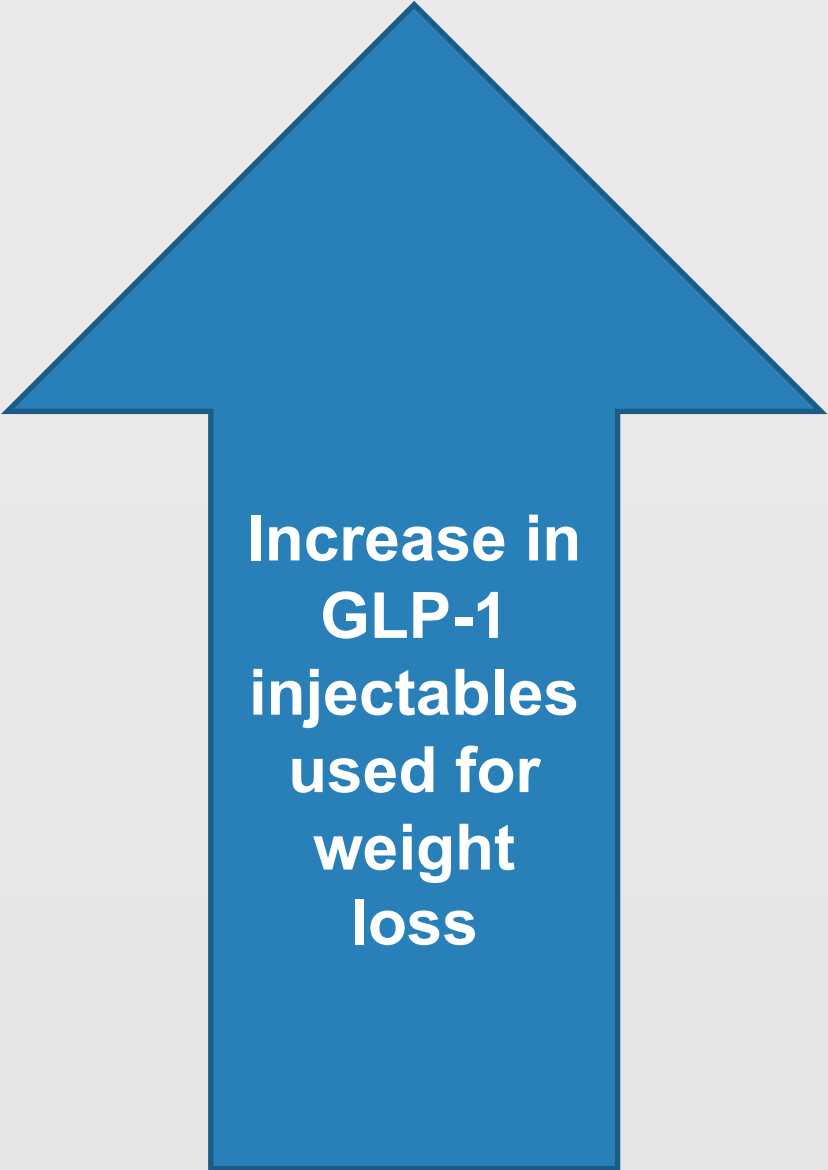
Jensterle M, et al. *Adv Ther.* 2022. 39:247-2467

Popular GLP-1 Agonists Used for Weight Loss in the U.S.

	Brand Drug	Generic	Manufacturer	Weight Loss Approval Status (Feb 2024)
	Ozempic	Semaglutide	Novo Nordisk	NOT FDA-approved for weight loss
	Mounjaro	Tirzepatide	Eli Lilly	NOT FDA-approved for weight loss
	Wegovy	Semaglutide	Novo Nordisk	FDA-approved for weight loss
	Saxenda	Liraglutide	Novo Nordisk	FDA-approved for weight loss
	Zepbound	Tirzepatide	Eli Lilly	FDA-approved for weight loss

What challenges is the healthcare system facing with this class of drug?

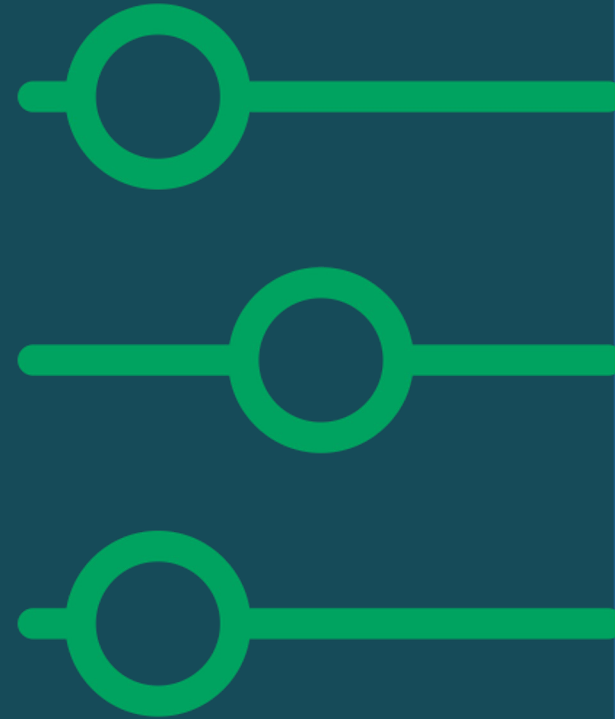




**Increase in
GLP-1
injectables
used for
weight
loss**

- Increased Demand
- Product Shortages
- Unsatisfactory, Unsafe Alternatives
- Barriers to Access

Which factors must be taken into consideration when exploring compounding options for GLP-1 RAs?



Compounding GLP-1 RA Considerations

- FDA Short List
- Salt forms
- Counterfeit meds
- Sterile vs Non-Sterile conditions

Current and Resolved Drug Shortages and Discontinuations Reported to FDA

[Report a Drug Shortage](#) | [Contact Us](#) | [FAQ](#) | [Background Info](#) | [Get Email Alerts](#) | [Download Current Drug Shortages](#)

Search by Generic Name or Active Ingredient:

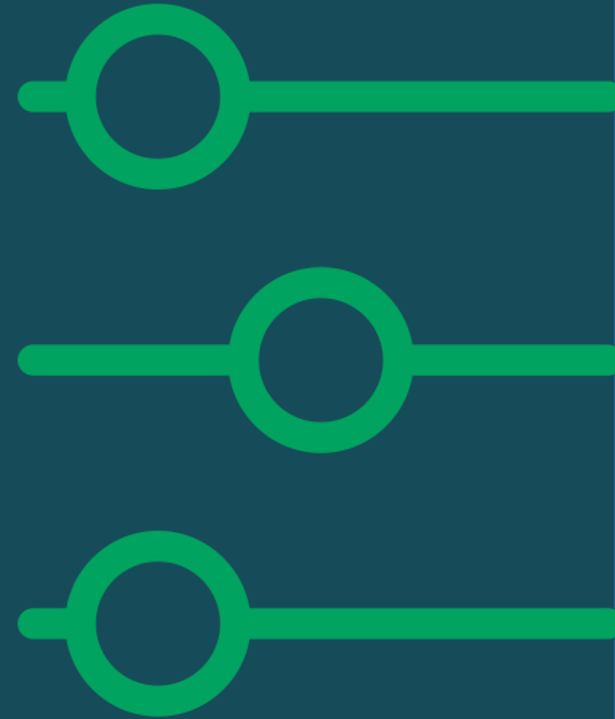
[Start Over](#)

Results for: semaglutide

- [Semaglutide Injection](#) (Currently in Shortage)

<https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

Which barriers exist for patients' access to these medications?





PRIOR AUTHORIZATIONS



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What is Prior Authorization?

- A utilization management process used by payers, or health plans, to assist in determination of coverage



How do payers determine need?

- Payers, also known as health plans or insurance companies, create policies to determine what they will cover
 - Up-to-date Clinical Guidelines
 - Treatment algorithms
 - Clinical studies
 - New Research
 - Cost-effectiveness analysis
 - Health Economics & Outcomes Research

Why is Prior Authorization an issue?



Restricts Care

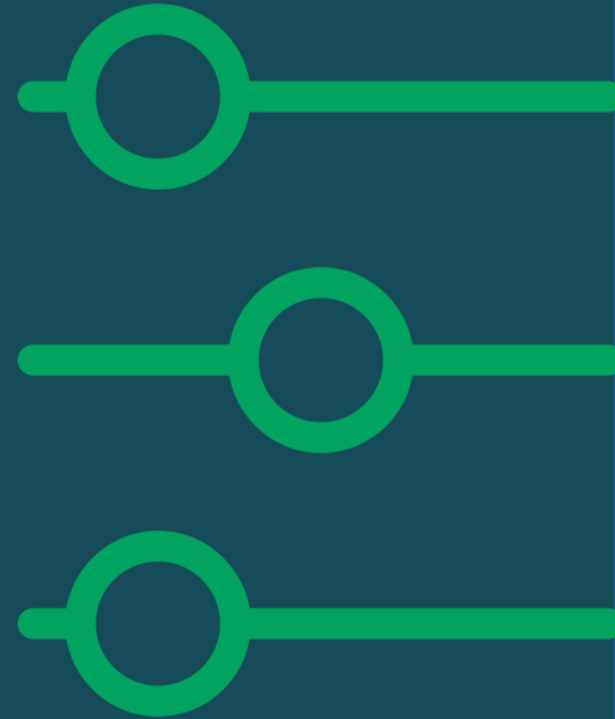


Administrative burden



Time consuming

What PA criteria is required or can be used for patients to access these medications?



SAMPLE COVERAGE REQUEST LETTER

- ▶ *The example below is for reference only. When drafting a coverage request letter, it should be written on your health care provider's letterhead. This form should **NOT** be used as the coverage request letter.*

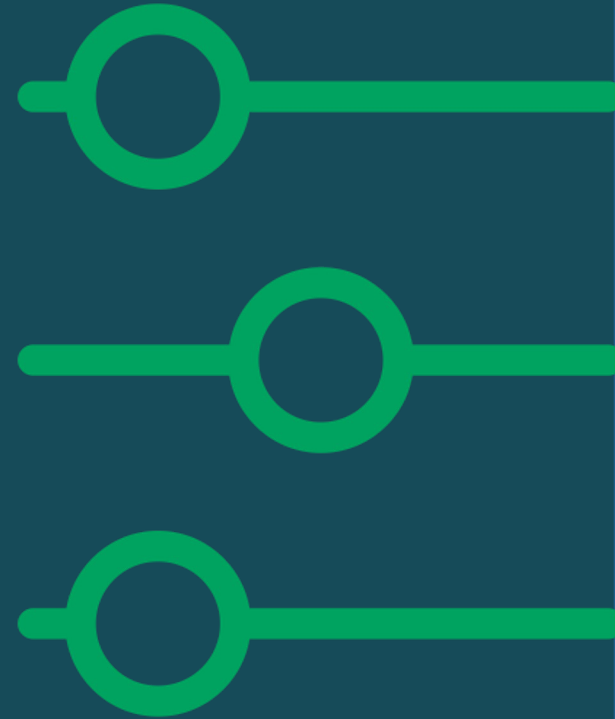
To Whom It May Concern:

I am writing this letter on behalf of my patient, *Patient's Name*, to express a concern. My patient is in need of prescription weight loss medication that is currently not covered by your insurance plan.

It is well recognized that obesity is a chronic illness associated with many related diseases, such as dyslipidemia and hypertension. Obesity deserves the same treatment and attention as any other chronic illness. Please contact your health plan or pharmacy benefit manager to pursue coverage for either this individual employee or for the company at large.

Sincerely,
Health Care Provider's Signature
Health Care Provider's Name

Are there any other
ways to get these
medications?



Direct-to-Consumer Healthcare Programs

- **Goal:** improve patient access to medications in the U.S.
- **How does it work?**
 - Patient "visits" an independent telehealth provider
 - HCP provides a prescription electronically
 - Medication is dispensed through 3rd-party pharmacy
 - Medication is delivered directly to patient's home

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Questions?



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priorauthtraining.org