

# From Evidence to Insight: Integrating Obesity Drug Therapies in Underwriting

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# Disclaimer



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# Questions

# Agenda

## 01 ▶ The Obesity Epidemic

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## 02 ▶ Obesity Medication Overview

- What are they?
  - When are they indicated?
  - What are the risks and benefits?
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## 03 ▶ Approach to Underwriting

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## 04 ▶ Case Studies

# Today's Focus



## **Obesity is recognized as a chronic disease state requiring treatment and prevention efforts**

This presentation covers the clinical management and underwriting of obesity

- i.e., we will not cover short term weight loss interventions

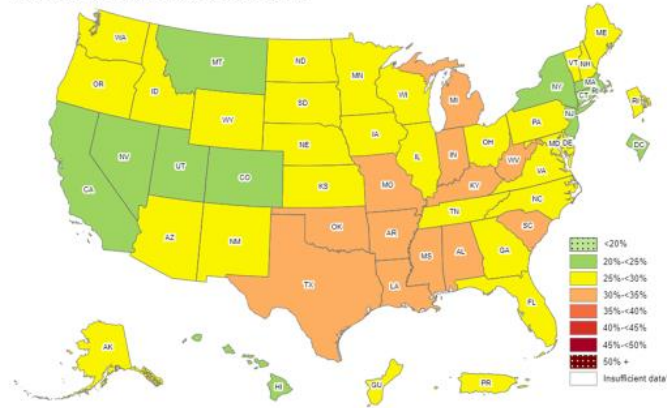
Focus on newer weight loss medications

# The Obesity Epidemic

## Prevalence<sup>1</sup> of Self-Reported Obesity Among U.S. Adults by State and Territory, BRFSS

2011

<sup>1</sup> Prevalence estimates reflect BRFSS methodological changes started in 2011. These estimates should not be compared to prevalence estimates before 2011.

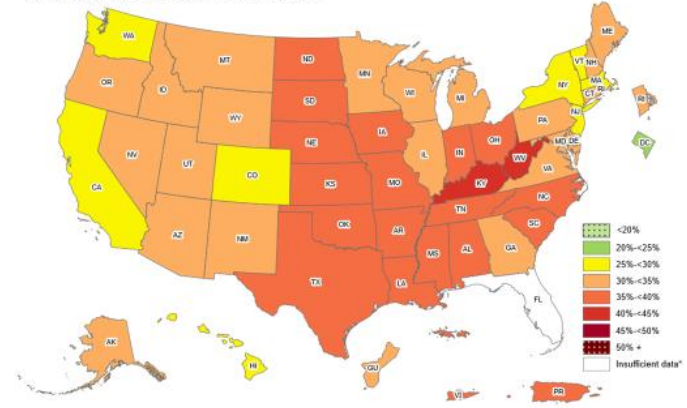


\*Sample size <50, the relative standard error (dividing the standard error by the prevalence)  $\geq 30\%$ , or no data in a specific year.



2021

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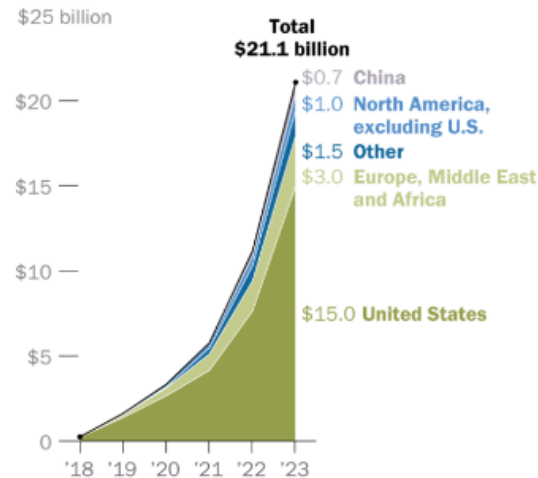




# Weight loss drug sales have ALSO significantly increased

## Weight-loss drug sales reach 5-year high

Combined annual sales for Ozempic, Rybelsus and Wegovy, in billions of U.S. dollars



Note: Figures converted from Danish kroner to U.S. dollars, at rate of 1 krone = \$0.145.

Source: Novo Nordisk annual reports, accessed through U.S. Securities and Exchange Commission's EDGAR database.

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# Continued growth in market size is expected



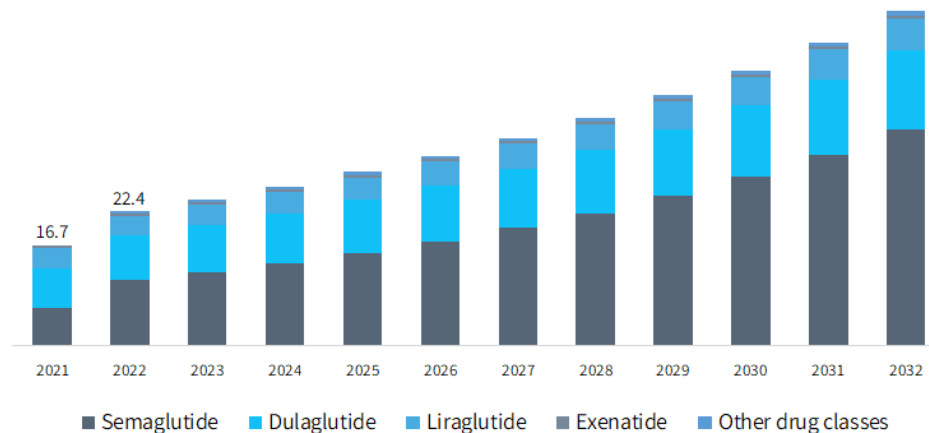
Treatment of obesity = significant increase in usage



Larger sample size for monitoring

## GLP-1 T Receptor Agonist Drug Class Segmentation

GLP-1 Receptor Agonist Market Size, By Drug Class, 2021 - 2032 (USD Billion)



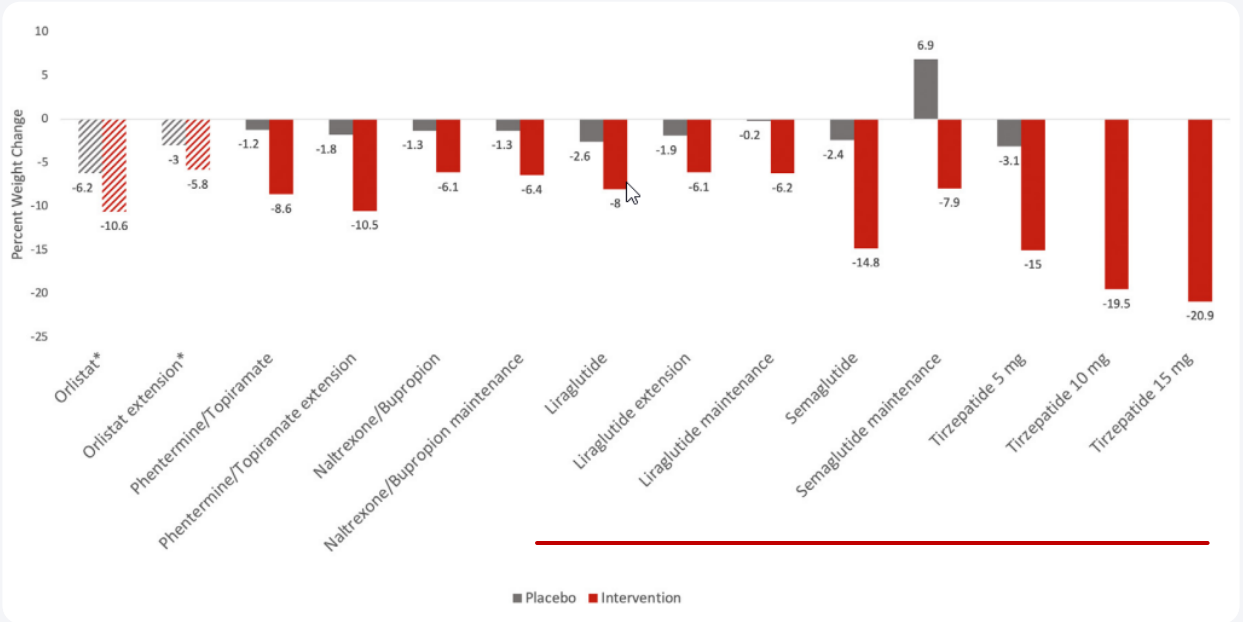
Source: [www.gminsights.com](http://www.gminsights.com)



# Obesity Medication Overview

Brand Name (Brand approved for DM)	Drug/Guideline	FDA Approval/Guideline Release
Alli, Xenical	Orlistat	1999
Qsymia	Phentermine/topiramate	2012
	<a href="#">ACC/AHA/TOS guidelines</a>	2013
Contrave	Naltrexone/bupropion	2014
Saxenda (Victoza)	Liraglutide	2014
	<a href="#">AACE/ACE guidelines</a>	2016
Wegovy (Ozempic, Rybelsus)	Semaglutide	2021
	<a href="#">AGA guidelines</a>	2022
Zepbound (Mounjaro)	Tirzepatide*	2023

Mean percent (%) weight change reported in the main phase 3 and extension trials of the FDA approved anti-obesity medications.



Efficacy  
Favors the  
GIP/GLP-1  
receptor  
Agonists

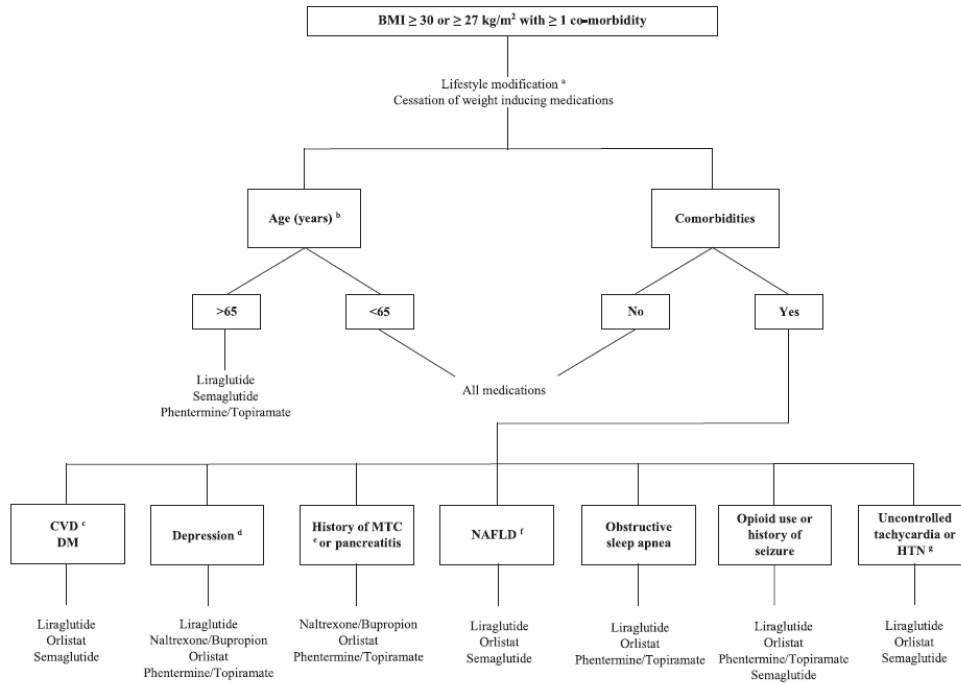


Fig. 3: Suggested algorithm for the selection of anti-obesity medications, taking into consideration the availability of drug safety, contra-indications, and preliminary efficacy data for a specific patient profile.<sup>a</sup> CVD, cardiovascular disease; DM, diabetes mellitus; HTN,

# Added Benefits



**The OG:** Glycemic control

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**Now we know:** Weight loss

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**Makes sense:** Improved lipid profiles

- Including nonalcoholic fatty liver disease & nonalcoholic steatohepatitis
- 



**New Indications:** Cardiovascular and renal protection

- Beyond just downstream benefits of controlled blood sugar
- 



**New Frontiers:**

- Dependency: Opioids, alcohol
- Parkinson's Disease

# Cardiovascular Benefits

## ○ Reduce Major Adverse Cardiovascular Events (MACE)

- Cardiovascular death, nonfatal myocardial infarction, nonfatal stroke

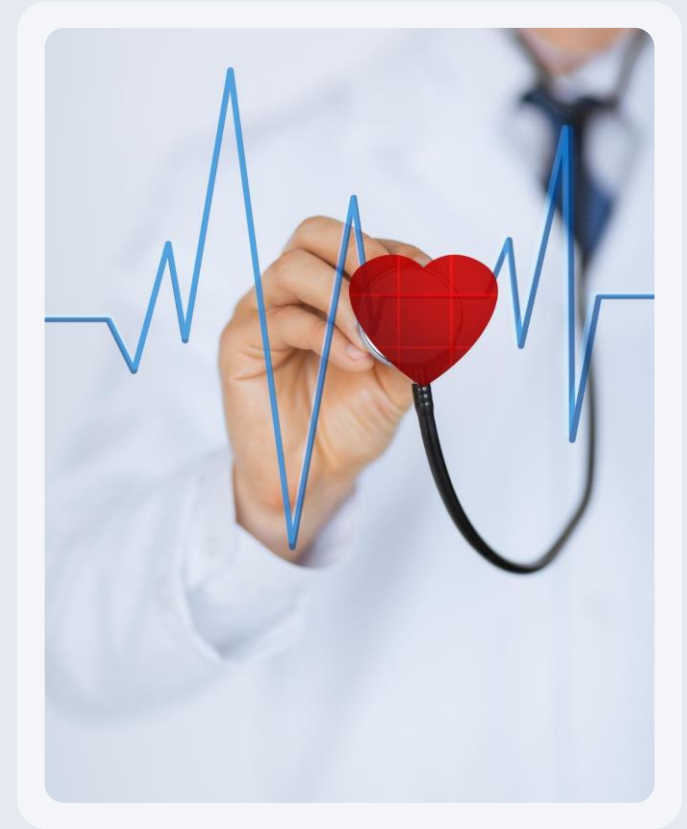
## ○ Reduce All Cause Mortality

## ○ Reduce Blood Pressure

## ○ Improve Endothelial Function

## ○ Anti-Inflammatory Effects

	MACE in DM	All-Cause Mortality
Liraglutide*	13%	15%
Semaglutide*	26%	19%
Tirzepatide	TBD	TBD





# Renal (Kidney) Benefits

## ○ Reduce risk of nephropathy

- Onset and progression of albuminuria
- Slow decline of GFR
- Less progression to CKD

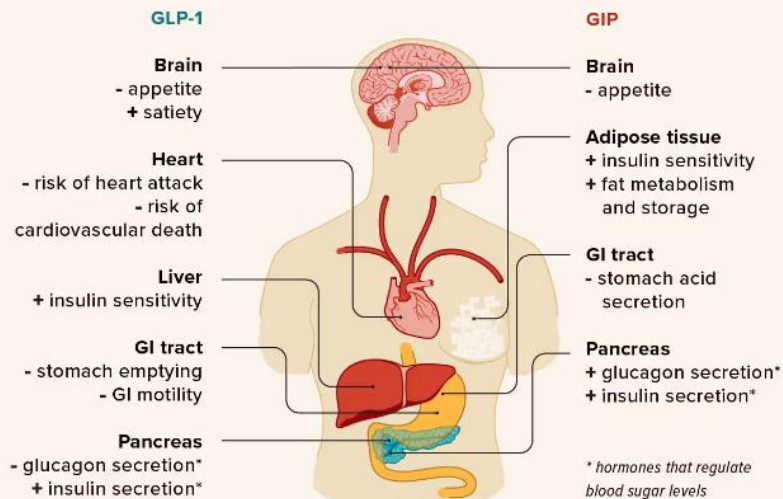
## ○ For Diabetics:

- + SGLT2 inhibitors = even greater nephroprotection

## ○ Improve renal hemodynamics

## How do GLP-1 Medications Work?

GLP-1 medications work by mimicking one or two naturally produced hormones: glucagon-like peptide-1 (**GLP-1**) and gastric inhibitory polypeptide (**GIP**).



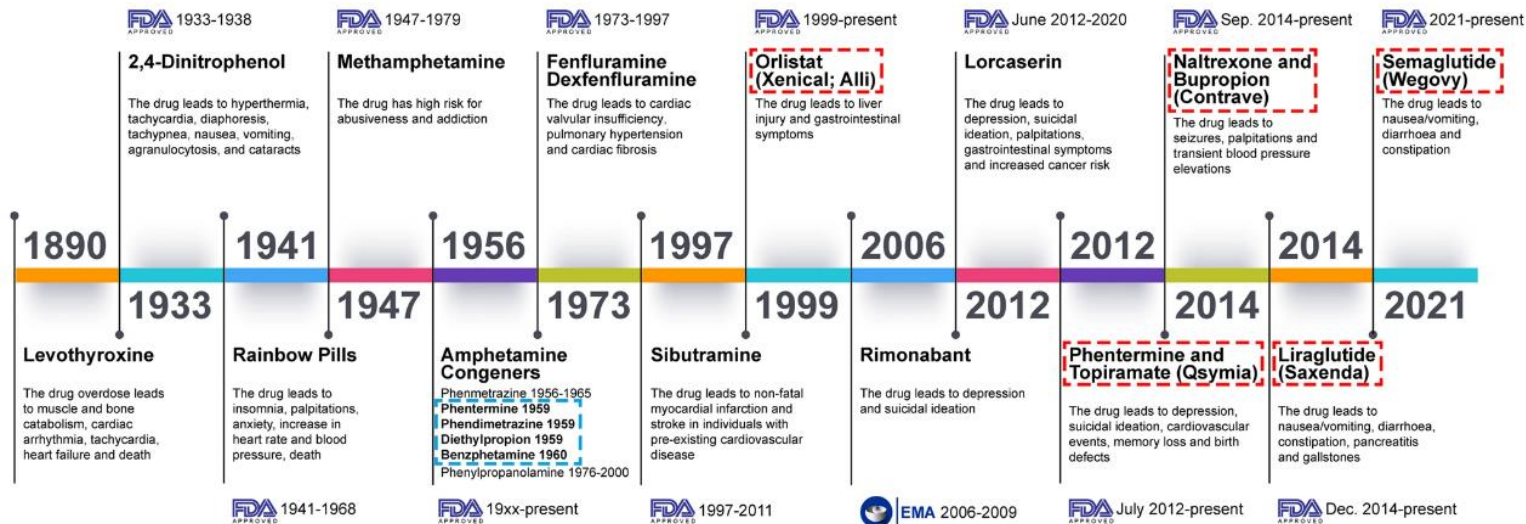
Many GLP-1 drugs (like Ozempic and Wegovy) act by binding to GLP-1 receptors, resulting in the same effects of GLP-1 seen above.

However, some medications (like Mounjaro and Zepbound) are unique in that they bind to GLP-1 and GIP receptors, resulting in a combined effect.

**healthline**

# The Risks: We've been burned before....

From: [Signaling pathways in obesity: mechanisms and therapeutic interventions](#)



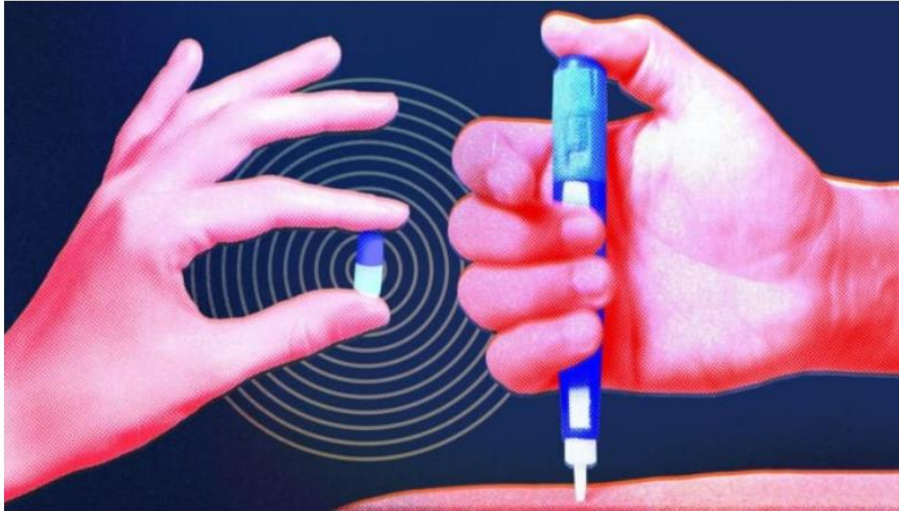
Timeline of anti-obesity medications approved by the FDA or EMA from the late nineteenth century until today (the red dashed line indicates long-term use while the blue dashed line indicates short-term use)



# Fen-Phen Again? Why Ozempic and New Weight-Loss Drugs Are Different

Some people fear that new obesity drugs will inevitably prove to be dangerous, but there are key distinctions from the fen-phen crisis of the 1990s.

By Ed Cara | Published April 15, 2024 | Comments (10)



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# Adverse Effects

## What We Know

- **Gastrointestinal**
  - Nausea, vomiting, constipation, diarrhea
  - Pancreatitis, gallstone disease
- **Thyroid:** ↑ risk of Medullary Thyroid Cancer\*
  - Only found in rodent studies

## What We're Watching

- **Psychiatric:** ↑ risk of depression and suicidality\*
- **Eyes:** Nonarteritic anterior ischemic optic neuropathy\*
- **Risk of using unauthorized drugs:** Compounded/unregulated, counterfeit, out of country

### Kate Moss' Sister Lottie Was Hospitalized After Misusing Ozempic: 'Worst Decision I Ever Made'

After getting the medication "below board" without a proper prescription, Lottie said she "never felt so sick in my life"

By [Ingrid Vasquez](#) Published on September 12, 2024 06:11 PM EDT

73 COMMENTS



Lottie Moss: PHOTO: DAVID N. BENNETT/DAVE BENNETT/GETTY

People

## U.S. FDA finds no evidence yet linking weight-loss drugs to suicidal thoughts

By **Bhanvi Satija** and **Mariam E Sunny**

January 11, 2024 1:45 PM EST · Updated 3 months ago



Novo Nordisk's Wegovy is displayed in New Columbia, Pennsylvania, U.S., November 13, 2023. REUTERS/Hannah Beier/Illustration/File Photo [Purchase Licensing Rights](#)

## EU regulator rules out link between weight-loss drugs and suicidal thoughts

By **Bhanvi Satija** and **Eva Mathews**

April 12, 2024 10:26 AM EDT · Updated 3 days ago



[1/2] Wegovy pens move along a packaging line at Novo Nordisk's facility in Hillerod, Denmark, March 8, 2024. REUTERS/Tom Little/File Photo [Purchase Licensing Rights](#)

# Adverse Effects

# Access



## ○ Insurance coverage is limited

- Federal law prevents Medicare from covering weight loss drugs
- 25% of people who took GLP-1s in 2023 were covered by insurance

## ○ Spiking demand outpaced supply

## ○ \$\$\$\$

# Cost is a Major Barrier to Access

## Wegovy costs with and without insurance

Wegovy costs \$1,349 per month if you pay full price or about \$405 per month if you have insurance coverage.

Wegovy could cost \$180 per month if you use insurance and a Wegovy coupon from the manufacturer.

### Monthly cost of Wegovy



ValuePenguin | lendingtree

The Wegovy coupon from the drug manufacturer can help you save \$225 to \$500 per month, whether or not your insurance covers Wegovy.



## News Release

Lilly releases Zepbound® (tirzepatide) single-dose vials, expanding supply and access for adults living with obesity

August 27, 2024



*Distributed through LillyDirect®'s self-pay channel, Zepbound single-dose vials are at least 50% less than the list price of all other incretin medicines for obesity*



# Approach to Underwriting

- **If weight loss recent, follow company guidelines for recent weight loss**
- **Rate for underlying disease(s)**
  - Look for related evidence (i.e. build, A1c, cholesterol)
- **When considering the medication...**
  - Look at potential adverse effects
- **Consider additional favorable/unfavorable factors**
  - Acquired without Rx → no monitoring
  - Circumstances around starting med
- ***Surveillance is ongoing. If there is new information, guidelines will be revised.***



# Case #1



- 33 y.o. male
- Disclosed
  - Nonsmoker
  - Hypertension on losartan, hctz, and amlodipine
  - Mild OSA, uses CPAP 1 night per week
- Exam: BMI 27.98, BP & labs normal
- Medical Record: Confirms HTN and OSA.
  - Began Wegovy (semaglutide) 2 months prior to application
  - Lost 7 lbs

# Case #2



- 43 y.o. male nonsmoker
- Disclosed
  - Depression on Sertraline
  - Zepbound for obesity
- BMI 37
- Mild depression x 4 years, stable dose Sertraline x 2 years
- No hospitalizations, no prior suicidal ideation
- On Zepbound (liraglutide) for 4 months: Lost 13 lbs



# Case #2b



- Client returns for additional coverage 6 months later
- Zepbound now out of stock
- Signed up for an online telehealth platform 5 months ago: Getting compounded semaglutide
  - Has lost additional 15 lbs.

# Case #3



- 60 y.o. female
- Disclosed
  - Hypertension on metoprolol
  - Hypothyroidism on Synthroid
- Prescription history notes Mounjaro since 11/2023.
- BMI 22.8, BP normal
- Medical Record: PI requested Mounjaro (tirzepatide) to help with drinking and eating a lot. Also reports she feels she has a compulsion for shopping.
- 3 months later, she has decreased alcohol intake and compulsive buying.
  - What do you think of her risk?
  - What else would you want to know?



**ANY QUESTIONS?**

