# MCT2D Learning Community Monthly Calls

Weight Loss Medications

# To receive CME/CE credit TEXT 66612 to 833-256-8390

(by 1:00 PM on November 18)

# Complete the evaluation online by December 3 at https://beaumont.cloud-cme.com



**Beaumont** 

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**CME/CE Accreditation:** In support of improving patient care, Beaumont Health is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

This activity was planned by and for the healthcare team, and learners will receive 1.0 Interprofessional Continuing Education (IPCE) credit for learning and change.

**Medicine CME:** Beaumont Health designates this live activity for a maximum of 1.0*AMA PRA Category 1 Credit*<sup>™</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

**Nursing CE:** Beaumont Health designates this activity for a maximum of 1.0 ANCC contact hour. Nurses should claim only the credit commensurate with the extent of their participation in the activity.

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**Dietetic CPEU:** 

Commission on Dietetic Registration Academyof Nutrition and Dietetics Completion of this RD/DTH profession-specific or IPCE activity awards CPEUs (One IPCE credit = One CPEU). If the activity is dietetics-related but not targeted to RDs or DTRs, CPEUs may be daimed which are commensurate with participation in contact hours (One 60 minute hour = 1 CPEU).

RD's and DTRs are to select activity type 102 in their Activity Log. Sphere and Competency selection is at the learner's discretion.

### **Beaumont**

# Disclosure

The following speakers and/or planning committee members have identified the following relevant financial relationship(s) with ineligible companies. All other individuals involved with this activity have no relevant financial relationships with ineligible companies to disclose.

• Lauren Oshman, M.D. (Course Co-Director): Stocks in publicly traded companies or stock options, excluding diversified mutual funds – Abbott, AbbVie, Johnson & Johnson, Merck & Co.

**Mitigation of Conflicts of Interest:** In accordance with the ACCME Standards for Integrity and Independence in Accredited Continuing Education, Beaumont Health implemented mechanisms to identify and mitigate relevant financial relationships with ineligible companies for all individuals in a position to control content of this activity.





# The role of anti-obesity medications in T2DM management

#### Michigan Collaboration for Type 2 Diabetes

#### Dina Griauzde, MD, MSc

Assistant Professor, Department of Internal Medicine University of Michigan VA Ann Arbor Healthcare System Diplomate, American Board of Obesity Medicine Research Director, Michigan Medicine Weight Navigation Program Co-medical Director, Weight Management and Metabolic Health Program, VAAAHS

## **Overview**

- 1. Pathophysiologic link between obesity and T2DM
- 2. Mechanism of action, efficacy, and safety of incretin mimetics for the treatment of obesity
- 3. Role for older anti-obesity medications in patient-centered obesity treatment
- 4. Case examples



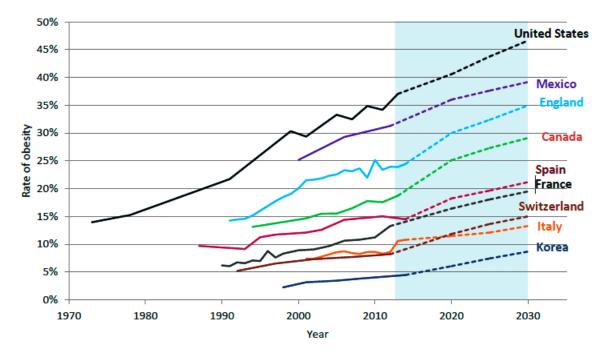
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# **Obesity is a public health crisis**

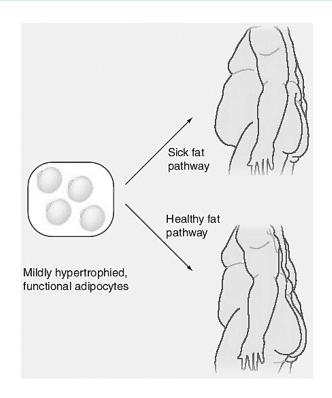
#### Projected global increase in obesity

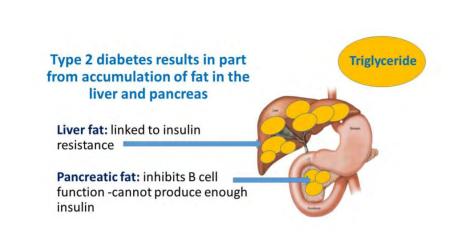




Obesity-Update-2017.pdf (oecd.org)

# Pathophysiologic link between obesity and T2DM







Bays et. al, *Expert Rev Cardiovasc Ther.* 2006 Hollingsworth et al. *Diabetologia.* 2011

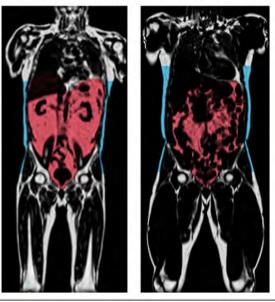
# Heterogeneity of obesity and its consequences

#### Visceral fat $\rightarrow$ metabolic dysfunction

Visceral fat (relative to BMI)

- Increased in South Asians
- Decreased in blacks

67 year old male BMI 25 kg/m<sup>2</sup> Visceral fat 2.58 L/m<sup>2</sup>



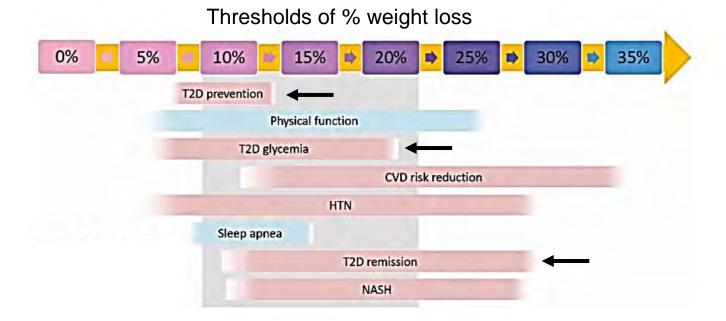
53 year old male BMI 30 kg/m<sup>2</sup>

Visceral fat 0.88 L/m<sup>2</sup>

Figure 1. Extreme variation in abdominal fat distribution.



# Weight loss improves health



*"the essential goal of weight loss therapy is not the quantity of weight loss as an end unto itself but rather the prevention and treatment of complications to enhance health and mitigate morbidity and mortality.* 



# AOMs are one option to support weight loss

# BMI > 30 kg/m<sup>2</sup> OR > 27 kg/m<sup>2</sup> + $\geq$ 1 obesity-related condition\*

#### AND

Non-achievement of weight or health goals with lifestyle change

#### OR

Suboptimal weight loss or weight regain after bariatric surgery

\*If Asian, consider if BMI  $\ge$  25 or  $\ge$  23 + co-morbidities



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#### Intended for long-term use in conjunction with lifestyle change

Generally, ≤ 5% weight loss after 3 months on max dose is an indication to stop the medication and try something else



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# What are incretin hormones?

Nutrient-stimulated gut hormones

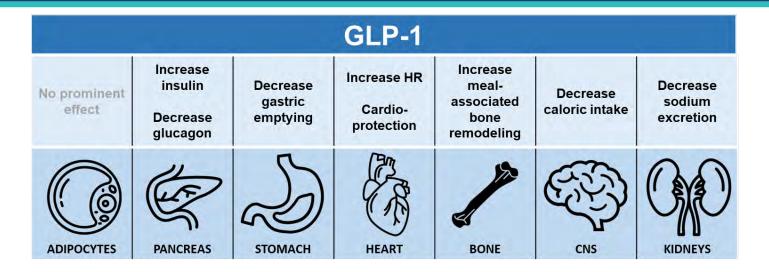
Stimulate insulin secretion in response to a meal

Two key hormones:

- 1. Glucagon-like peptide-1 (GLP-1)
- 2. Glucose-dependent insulinotropic polypeptide (GIP)



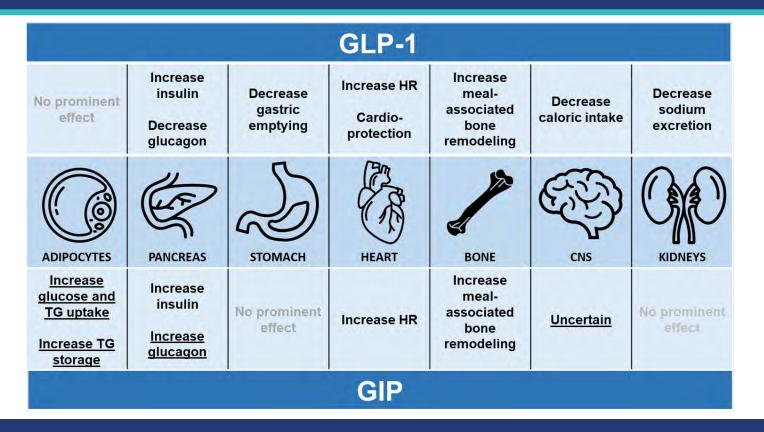
## **Mechanism of action**





Adapted from Nauck, Diabetes Obes. Metab. 2021

## **Mechanism of action**





Adapted from Nauck, Diabetes Obes. Metab. 2021

# GLP-1 (and GIP) receptor agonists for T2DM

Generic drug name (brand name)	Dosing frequency
Exenatide (Byetta)	Twice daily
Exenatide extended release (Bydureon)	Weekly
Liraglutide (Victoza)	Daily
Dulaglutide (Trulicity)	Weekly
Semaglutide (Ozempic, Rybelsus)	Weekly, Daily
Tirzepatide* (Mounjaro)	Weekly
<b>BOI D</b> -bigher doses $EDA_{2}$ approved for	weight menagement

**BOLD=**higher doses FDA-approved for weight management \*Dual GLP/GIP receptor agonist



# **GLP-1** receptor agonists for weight management

Liraglutide (Saxenda)

- Once daily injection
- Titrated weekly





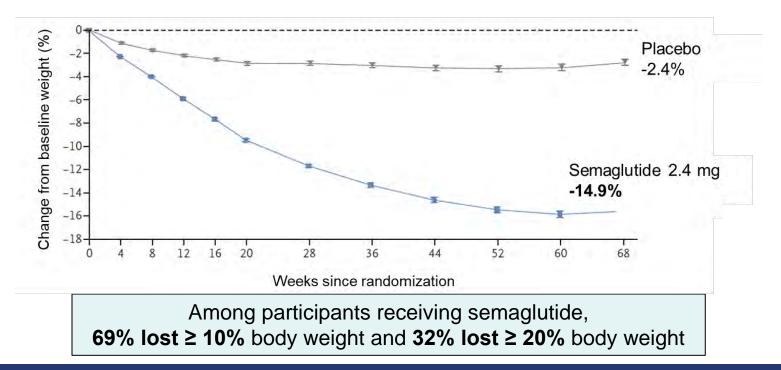
- Once weekly injection
- Titrated monthly





### Semaglutide 2.4 mg among patients with obesity (STEP 1 trial)



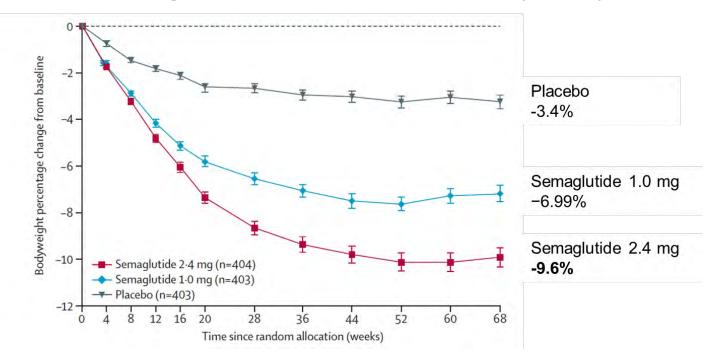




Wilding et al., NEJM, 2021

### Semaglutide 2.4 mg among patients with T2DM (STEP 2 trial)

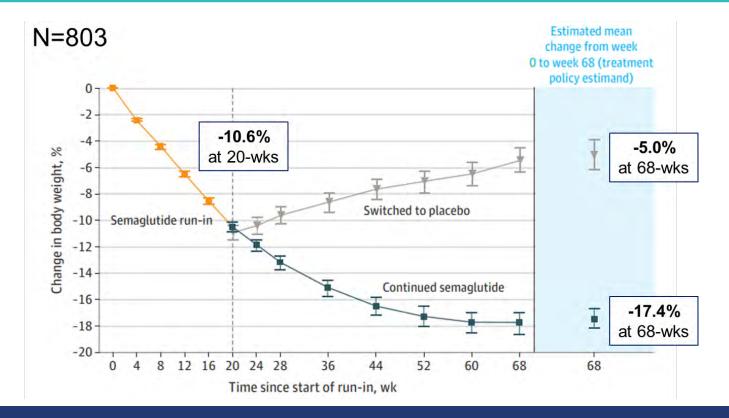






Davies et al. Lancet. 2021

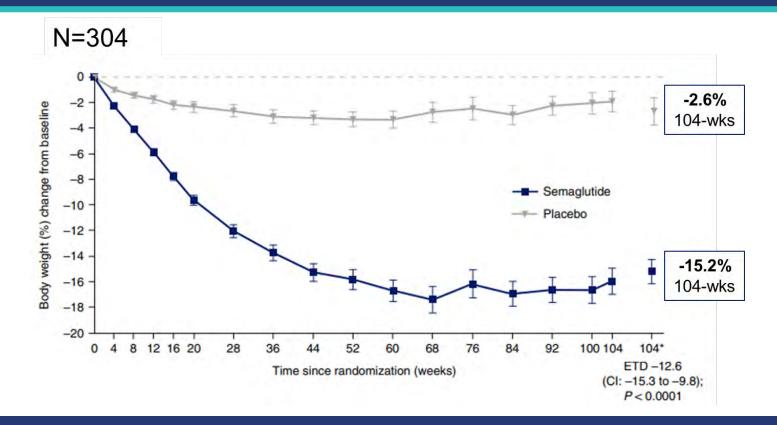
### Weight regain with discontinuation (STEP 4 trial)





Rubino et al. JAMA, 2021

### Long-term efficacy (STEP 5)





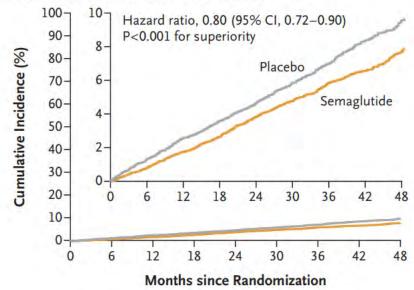
Garvey et al. *Nature Medicine*, 2022

### **Cardiovascular benefit**

#### **SELECT trial**

- N=17,604 (41 countries)
- BMI  $\geq$  27, CVD, no T2DM
- Semaglutide 2.4 mg vs. placebo
- Followed for 5 years
- <u>Primary end point</u>: composite of death from CV causes, nonfatal MI, nonfatal stroke

#### A Primary Cardiovascular Composite End Point



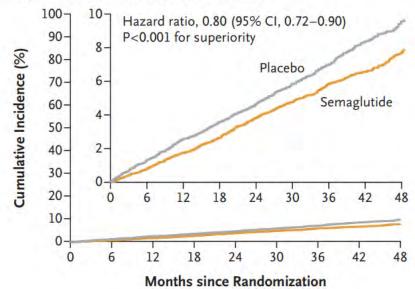


### **Cardiovascular benefit**

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- Followed for 5 years
- <u>Primary end point</u>: composite of death from CV causes, nonfatal MI, nonfatal stroke

#### A Primary Cardiovascular Composite End Point



Consistent with outcomes from SUSTAIN-6 trial (CVD + T2D)



### **Renal benefit**

#### **FLOW trial\***

- N=3,534 (28 countries)
- T2DM + CKD
- Semaglutide 1.0 mg vs. placebo
- <u>Primary end point</u>: kidney failure or initiation of chronic kidney replacement therapy, persistent ≥ 50% reduction in eGFR, or death from kidney or CV causes

#### Novo Nordisk stops trial of Ozempic in kidneys as interim analysis shows success

Novo Nordisk already has a strong presence in the type 2 diabetes (T2D) and obesity markets.

GiobalData GlobalData Healthcare October 17, 2023



\*Trial pending publication



### Contraindications

#### WARNING: RISK OF THYROID C-CELL TUMORS See full prescribing information for complete boxed warning.

- In rodents, semaglutide causes thyroid C-cell tumors at clinically relevant exposures. It is unknown whether WEGOVY® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined (5.1, 13.1).
- WEGOVY<sup>®</sup> is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors (4, 5.1).

Avoid in specific populations (MTC / MEN 2)

Benefits generally outweigh risks, as weight loss supports reduction in many other cancers



### Warnings / Precautions

- Acute pancreatitis
- Acute gallbladder disease
- Hypoglycemia
- Acute kidney injury
- Increased heart rate
- Suicidal behavior / ideation
- Hypersensitivity reactions
- Diabetic retinopathy\*

Endocrinology > Type 2 Diabetes

FDA Adds Intestinal Blockage Reports to Ozempic Labeling – Joins other approved GLP-1 receptor agonists in noting the potential adverse reaction

by Sophie Putka, Enterprise & Investigative Writer, MedPage Today September 28, 2023



\*Risk of retinopathy elevated among patients with T2DM if: baseline retinopathy and/or on insulin with suboptimal glycemic control. *FOCUS trial (NCT03811561) pending.* 



### Side effects

Adverse Events	Semaglutide (n=1306)	Placebo (n=655)
Any adverse event	89.7%	86.7%
Serious adverse event	9.8%	6.4%
Serious AEs leading to discontinuation	7%	3.1%
Adverse events reported in ≥ 10% of participants		
Nausea	44.2%	17.4%
Vomiting	31.5%	15.9%
Diarrhea	22%	19%
Headache	15.2%	12.2%
Abdominal pain	10%	5.5%
Constipation	23.4%	9.5%



### **Tirzepatide (GIP/GLP-1 RA)**

FDA NEWS RELEASE

# FDA Approves New Medication for Chronic Weight Management

For Immediate Release: November 08, 2023





### **Tirzepatide (GIP/GLP-1 RA)**

FDA-approved for treatment of T2DM since 2022

Acts at receptors for GLP-1 & GIP



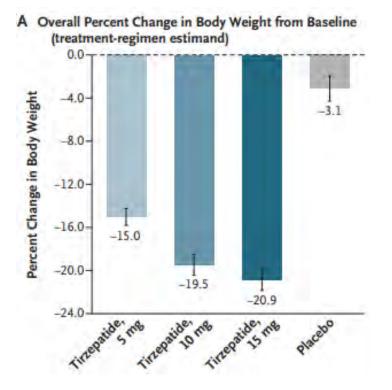


### **Tirzepatide (GIP/GLP-1 RA) for obesity**

N=2,539

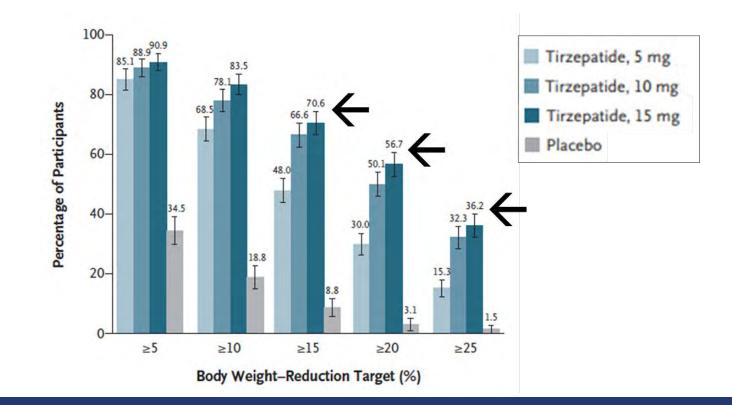
BMI  $\ge$  30 or  $\ge$  27 + weight-related condition (not T2DM)

Mean baseline BMI=38.0





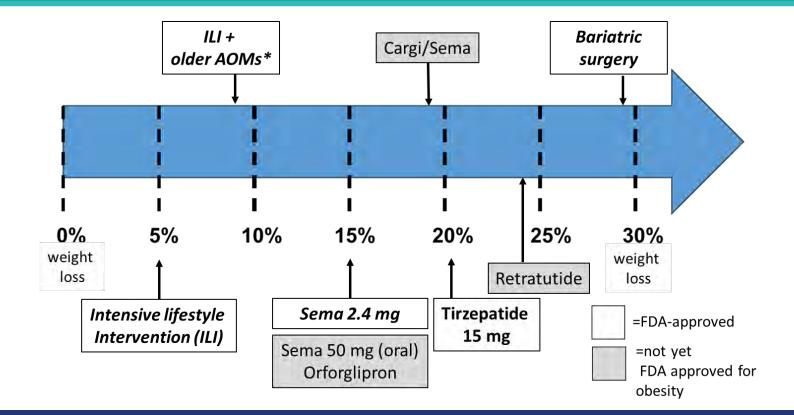
#### Achievement of weight loss thresholds





Jastrebroff et al. NEJM. 2022

### **Closing the weight management treatment gap**





# Challenges to use of injectable AOMs

- 1. Limited insurance coverage
- 2. High out-of-pocket cost
- 3. Drug shortages / limited availability



### Limited insurance coverage

72% of health plan leaders expect GLP-1s to grow by 25% or more in 2023

Health plan leaders are already seeing the impact of increased GLP-1 utilization with 72% saying they expect a 25% or more increase in 2023 alone. This could upend an organization's cost of care models, significantly increase pharmacy costs and threaten profitability and growth for the next decade.

Pharmaceutical manufacturers, like Pfizer, have even more ambitious predictions, saying, "We're going full guns on this" (Bill Sessa, chief scientific officer at Pfizer's Internal Medicine Research Unit'). New oral GLP-1s are entering the drug pipeline in order to capitalize on growing market share. And Bank of America analyst, Geoff Meacham, predicts that GLP-1 Mounjaro could be the first \$100 billion drug, which is 4–5x the current best selling drug, Humira.<sup>2</sup>

Reuters, "Novo Nordisk rivals see room to compete in \$100 billion

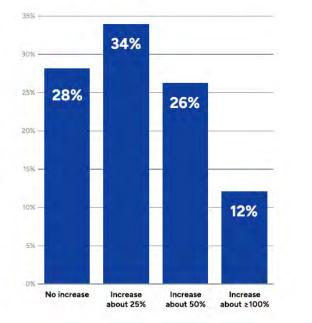
2 Market Watch, "Bank of America: Lilly's tirzepatide could be the first

weight-loss drug market," May 4, 2023

\$100 billion drug," October, 2022.

1

Expected Increase in Utilization of GLP-1 Prescriptions for Obesity and Weight Loss in 2023 (n=80)



A typical employer's drug spending could increase by more than 50% if half of employees who were eligible for Wegovy were to take it,

MCT2D

#### How Health Plan Leaders Are Handling the GLP-1 Cost Crisis [Survey Report] | Virta Health

#### Limited insurance coverage

COVERAGE for nti-Obesity Meds	SAXENDA Liraglutide Inectable - Daily	WEGOVY Semaglutide	PHENTERMINE Generic - High Dose Grail Dai(/ )// Meals	LOMAIRA Phentermine 8 Low Dose Oral - Daily w/ Meals	QSYMIA Phentermine Topiramate Oral - Carly	CONTRAVE Naltrexone HCI - Bupropion HC Orisi 2 Day	
AETNA	Preferred	Preferred	Preferred	Not Covered	Preferred	Not Covered	PA
BCBSM*	ISSSIS Non-Preferred PA	SSSSS Non-Preferred PA	Preferred	sssss Non-Preferred	SSSSSE Non-Preferred	188355 Non-Preferred PA	Prior Auth ST Step
EXPRESS SCRIPTS National Preferred	Non-Preferred	Preferred PA	Preferred (PA)	Preferred	SIESSE Non-Preferred	SISSIS Non-Preferred	See last guide fo to availa prior aut
НАР	Not Covered	Not Covered	Preferred	Not Covered	SISSIS Non-Preferred PA	Not Covered	step the docume
PRIORITY (TRADITIONAL)	Not Covered	Not Covered	Preferred	SSSSSS Non-Preferred ST Must try generic first	SSIESS Non-Preferred** ST Must try generic first	SSSESS Non-Preferred ST Must try generic first	
PRIORITY (OPTIMIZED)	Not Covered	Not Covered	Preferred	Not Covered	155555 Non-Preferred ST Must try generic first	255152 Non-Preferred ST Must try generic first	
UNITED	Not Covered	Not Covered	Not Covered May be excluded your coveringe or subject to PA in cT. NJ and NV	Not Covered May be excluded from coveringe or subject to PA In cT NA and NV	Not Covered	Not Covered May be excluded from coverage or subject to PA in CT. NJ and NY	

Disclaimer: Information based on general formularies, unless otherwise noted and may not reflect employer-group specific policies and plans with pharmacy carve outs.

\*\*Priority coverage for Qsymia determined by: "Employers plan rider determines weight loss coverage"

#### Affording your Weight Loss Medication Weight loss medications can be expensive and not covered by health insurance. If you have a diagnosis of

Weight loss medications can be expensive and not covered by health insurance. If you have a diagnosis of type 2 diabetes, some of the medications may be more affordable. If you do not have a diagnosis of type 2 diabetes, please complete this worksheet and return it to Dr. Oshman. You can return this as an attachment on the portal.

Find your insurance company contact information on the back of your insurance card. If you cannot locate your card, you can search the web for your insurance companies phone number. Basic information Do I have prescription drug coverage? Do I have a deductible for medications?

Yes [] No
[] Yes [] No

EXAMPLE CARD BACK

If yes, what is my yearly deductible? How m

How much of my deductible has been met? \$\_\_\_\_\_

For each medication answer the following questions:

Medication name	Covered?	Preferred ?	Co-pay?
Wegovy (semaglutide)	Y or N	Y or N	Y or N
Saxenda (semaglutide)	Y or N	Y or N	Y or N
Contrave (bupropion/naltrexone)	Y or N	Y or N	Y or N
[] Qsymia (phentermine/topiramate)	Y or N	Y or N	Y or N
[] Adipex-P (high dose phentermine)	Y or N	Y or N	Y or N
[] Generic phentermine	Y or N	Y or N	Y or N
[] Lomaira (low dose phentermine)	Y or N	Y or N	Y or N



#### High out-of-pocket cost

GoodRx Q semaglutide			
Local pharmacy prices Choose a pharmacy to get a coupon			
Ann Arbor, MI			Lowest price •
Rite Aid	<del>\$1,761</del> retail Save 26%	\$1,313	Get free savings
meijer Meijer Pharmacy	<del>\$1,653</del> retail Save <mark>1</mark> 9%	\$1,333	Get free savings
CVS Pharmacy	<del>\$1,500</del> retail Save 12%	\$1,391	Get free savings

Tirzepatide for weight management (Zepbound) list price: \$1059.87 Approximately 20% less than semaglutide 2.4 mg.



## **Drug shortages**

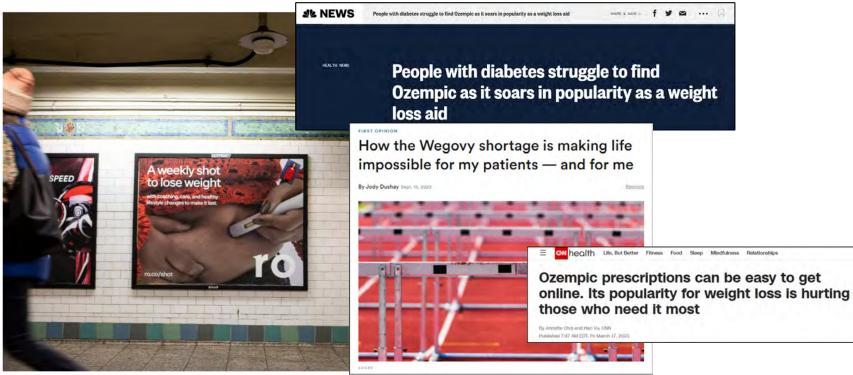


Photo by Amelia Holowaty Krales / The Verge





## **Compounded semaglutide**

Compounding is legal when drugs are on shortage

Safety concerns relate to unauthorized use of salt vs. base form of semaglutide.

Patients who choose to use compounded semaglutide should obtain the medication **from state-licensed pharmacies** and informed of **potential limitation** of compounded peptides. Obesity Medicine Association Issues a Position Statement on Compounded Peptides

Published Date: March 30, 2023



Know the risks: Before buying prescription medicine online, visit www.FDA.gov/BeSafeRx.





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#### Patient-centered obesity treatment

# No one-sizefits-all obesity treatment

Image source: One Size Does Not Fit All - MacuLogix Academy



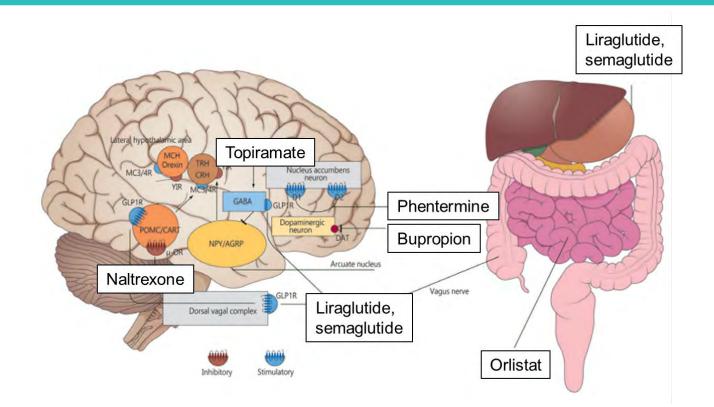
#### Older AOMs may be ideal for some patients





#### What's New in Obesity Treatment? (verywellhealth.com)

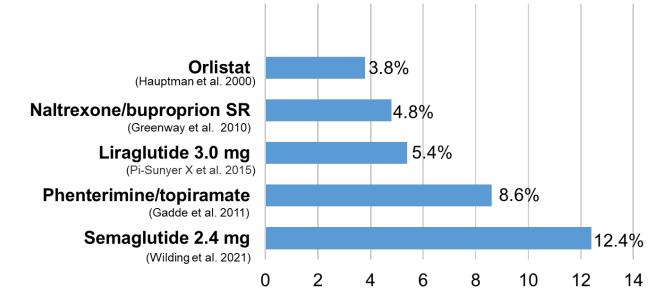
#### Mechanisms of actions





Son et al, Diabetes Metab J. 2020

### Average efficacy of AOMs at 1 year\*



Average placebo-subtracted weight loss (%)

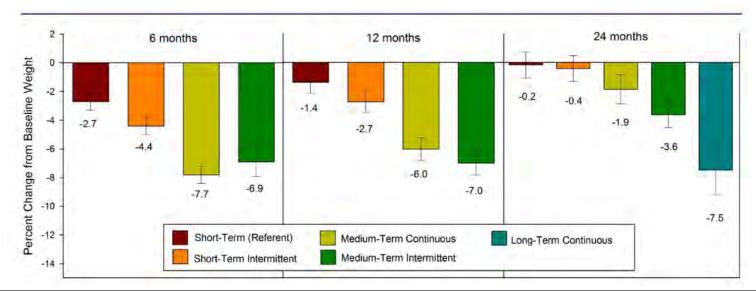
\*At max dose among patients without T2DM

Tchang et al. *Endotext.* 2021 Srivastava and Apovian. *Nat. Rev. Endocrinol.* 2017



#### **Phentermine monotherapy**

N=13,972



Observational data suggests effective and safe long-term; know state prescribing law and document off-label use



Lewis et al. Obesity. 2019

### All AOMs can support ≥5% and ≥10% weight loss

Anti-obesity medication	≥ 5% weight loss
Tirzepatide 15 mg <sup>1</sup>	91%
Semaglutide 2.4 mg <sup>2</sup>	86.4%
Phentermine/topiramate <sup>3</sup>	70%
Liraglutide <sup>4</sup>	63%
Naltrexone/bupropion <sup>5</sup>	48%
Phentermine <sup>6</sup>	46%
Orlistat <sup>7</sup>	25%

<sup>1</sup>Jastrebroff et al. *NEJM*. 2022 <sup>2</sup>Wilding et al., *NEJM*, 2021 <sup>3</sup>Gadde et. al, Lancet, 2011 <sup>4</sup>Greenway et. al, Lancet, 2010 <sup>5</sup>Pi-Sunyer, *NEJM*, 2015 <sup>6</sup>Bays et al, *Obesity Pillars*. 2022 <sup>7</sup>PI\_Xenical-brand\_FINAL.PDF



## All AOMs can support ≥5% and ≥10% weight loss

Anti-obesity medication	≥ 5% weight loss	≥ 10% weight loss	_
Tirzepatide 15 mg <sup>1</sup>	91%	83%	
Semaglutide 2.4 mg <sup>2</sup>	86.4%	69.1%	
Phentermine/topiramate <sup>3</sup>	70%	48%	
Liraglutide <sup>4</sup>	63%	33%	
Naltrexone/bupropion <sup>5</sup>	48%	25%	<sup>1</sup> Jastrebroff et al. <i>NEJM</i> . 2022 <sup>2</sup> Wilding et al., <i>NEJM</i> , 2021
Phentermine <sup>6</sup>	46%	21%	<sup>3</sup> Gadde et. al, Lancet, 2011 <sup>4</sup> Greenway et. al, Lancet, 2010 <sup>5</sup> Pi-Sunyer, <i>NEJM, 2015</i>
Orlistat <sup>7</sup>	25%	17%	<sup>6</sup> Bays et al, <i>Obesity Pillars.</i> 2022 <sup>7</sup> PI_Xenical-brand_FINAL.PDF



#### **Consider co-morbidities**

Co-morbidity	AOM option		
Depression Substance use disorder	Bupropion/naltrexone		
Migraines Seizures	Phentermine/topiramate		
ADD/ADHD	Phentermine		
T2DM Prediabetes Cardiovascular disease HFpEF	GLP-1 (GIP) RA		



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#### Case: Mr. C





https://www.obesityaction.org/gallery/lifestyle/?paged=77

#### Case: Mr. C

- 65-year-old male w/ obesity (BMI 51), T2DM (on glipizide, HbA1c 7.5%), HTN & history of gastric sleeve
  - Highest pre-surgical weight: 385 lb.
  - Weight at time of surgery: 301 lb.
  - Post-surgical weight target: 238 lb.
  - Post-surgical weight nadir: 280 lbs.
- Current weight: 354 lb.
- Patient-reported barriers:
  - Shame and sense that he's disappointing others
  - Diet high in processed carbohydrates and fast food
  - Eating many small low-fat meals / snacks throughout the day to control
  - Food cravings

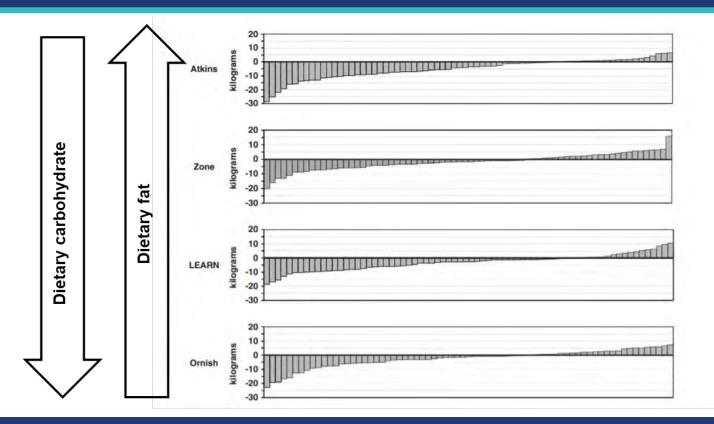


#### Case: Mr. C

- Address and minimize shame
- □ Stop obesogenic obesity treatments
- Develop individually-tailored dietary plan
- Select medication



#### There is no "one-size-fits-all" diet



Gardner CD. International Journal of Obesity Supplements; 2012



#### Example low-carbohydrate meal plan

#### Modified Ketogenic Diet Meal Planning: Plan Your Plate

#### The Basics:

- 1) Fill half the plate with non-starchy vegetables.
- 2) Cook vegetables in healthy fats or use a fatty dressing or sauce.
- 3) Add 3-5 ounces of protein.
- 4) Other foods to include in moderate amounts with meals or snacks:
  - a. Nuts and seeds (see below for total carbs in each)
  - b. Small amounts of certain fruit
  - c. Full fat dairy
  - d. Sauces and condiments (choose low carb versions)
  - e. Lots of herbs and spices
  - f. Small amounts of keto-friendly sweeteners
- 5) Drink plenty of water and other carbohydrate free beverages.







#### Initiated and titrated liraglutide

Week	Dose
1	0.6 mg
2	1.2 mg
3	1.8 mg
4	2.4 mg
5 +	3.0 mg



#### 3-month follow-up

#### 3-month follow-up:

- 298 lb. (←354 lb.); **16% weight loss**
- Improved mood, self-confidence, and mobility
- Expressed desire to lose an additional 60 lbs.
- Switched from liraglutide (Saxenda) to semaglutide (Wegovy)



#### **Switching between GLP-1 RAs**

Weekly to daily medication: advise patient to take first dose of the daily medication 7 days after the last dose of the weekly medication.

**Daily** to a **weekly** medication: advise patient to take the first dose of the weekly medication one day after the last dose of the daily medication. Choose equivalent or a lower dose when switching to avoid side effects.

Agent	Frequency	Equivale	ent Doses					
Dulaglutide	Weekly		0.75 mg	1.5 mg	3.0 mg	4.5 mg		
Semaglutide	Weekly		0.25 mg	0.5 mg	1.0 mg	2.0 mg		
Liraglutide	Daily	0.6 mg	1.2 mg	1.8 mg	2.4 mg	3.0 mg		
Oral Semaglutide	Daily	3 mg	7 mg	14 mg	-			1200
Tirzepatide	Weekly		2.5 mg	5.0 mg	7.5 mg	10 mg	12.5 mg	15.0 mg



### 6-month follow-up

- 268 lb. (← 298 lb. ← 354 lb.); **24 % weight loss**
- Waxing and waning motivation adhere to low-carb, despite high enjoyment of the eating pattern
- Food costs = primary barrier
- Discussed budget-friendly low carb foods/meals



#### **Obesity medicine training**



AMERICAN BOARD of OBESITY MEDICINE

Physicians 60 CMEs 4-hour exam Home - American Board of Obesity Medicine (abom.org)





NP/PA 60 CE credits

NP and PA Certificate in Obesity Medicine - Obesity Medicine Association Pharmacists 20.5 hrs. of ACPE CE 70-question exam Weight Management Certificate (ashp.org)



## Summary

- Weight loss can improve glycemic control among patients with T2D
- GLP-1 RAs and dual GLP-1 / GIP agonists are the most effective options, on average, for medical weight management
- All AOMs can be highly effective for many patients and can be used as part of patient-centered care
- Ensure patients understand the need for lifestyle change and need for lifelong use

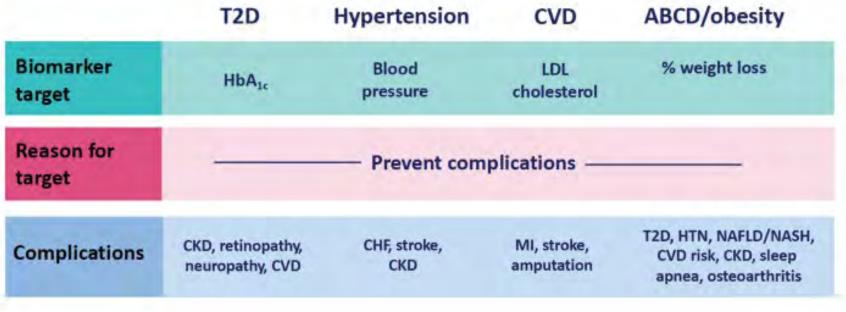




### **Questions?**

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# Weight-centric approach to chronic disease management



\*May require tailoring to patients' preferences



Garvey. J Clinical Endo and Met., 2022