

Treat Weight First

Improving Anti-Obesity Medication Prescribing To Meet The
Demand of the Obesity Epidemic

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Co-Owner

Progress Weight Management

Fargo, ND



DISCLOSURES

I have no relevant financial disclosures to report.

This presentation contains off label prescribing practices. Every effort will be made to identify these practices at the time of discussion.

LEARNING OBJECTIVES

At the completion of this activity, learners will be able to:

1. Identify anti-obesity medication therapies currently available.
2. Articulate to patients the appropriate therapies for weight loss and other cardiometabolic benefits.
3. Explain medication therapy management of anti-obesity medications in an outpatient setting.
4. Discuss the importance of preventing the dissemination of unhelpful misconceptions about the growing use of anti-obesity pharmacotherapy.

Who Am I?



PROGRESS
weight management

- PA-C with 6 years experience in primary care and obesity medicine
- Advanced Certification from Obesity Medicine Association – 2019
- Co-Owner of Progress Weight Management, est. July 2023
- Clinical interests: obesity, diabetes, PCOS, cardiometabolic medicine, exercise, pharmacotherapy

Defining Obesity

American College of Clinical Endocrinologists: “a chronic disease characterized by pathophysiological processes that result in increased adipose tissue mass and which can result in increased morbidity and mortality. “

Obesity Medicine Association: “a chronic, relapsing, multi-factorial, neurobehavioral disease, wherein an increase in body fat promotes adipose tissue dysfunction and abnormal fat mass physical forces, resulting in adverse metabolic, biomechanical, and psychosocial health consequences.”

World Health Organization: “abnormal or excessive fat accumulation that presents a risk to health.”

American Medical Association (2013): “obesity is a disease requiring a range of medical interventions to advance obesity treatment and prevention.”

Centers for Disease Control: BMI ≥ 30 kg/m²

Consensus Definition of Obesity - 2022

Obesity is a highly prevalent chronic disease characterized by excessive fat accumulation or distribution that presents a risk to health and requires lifelong care. Virtually every system in the body is affected by obesity. Major chronic diseases associated with obesity include diabetes, heart disease, and cancer.

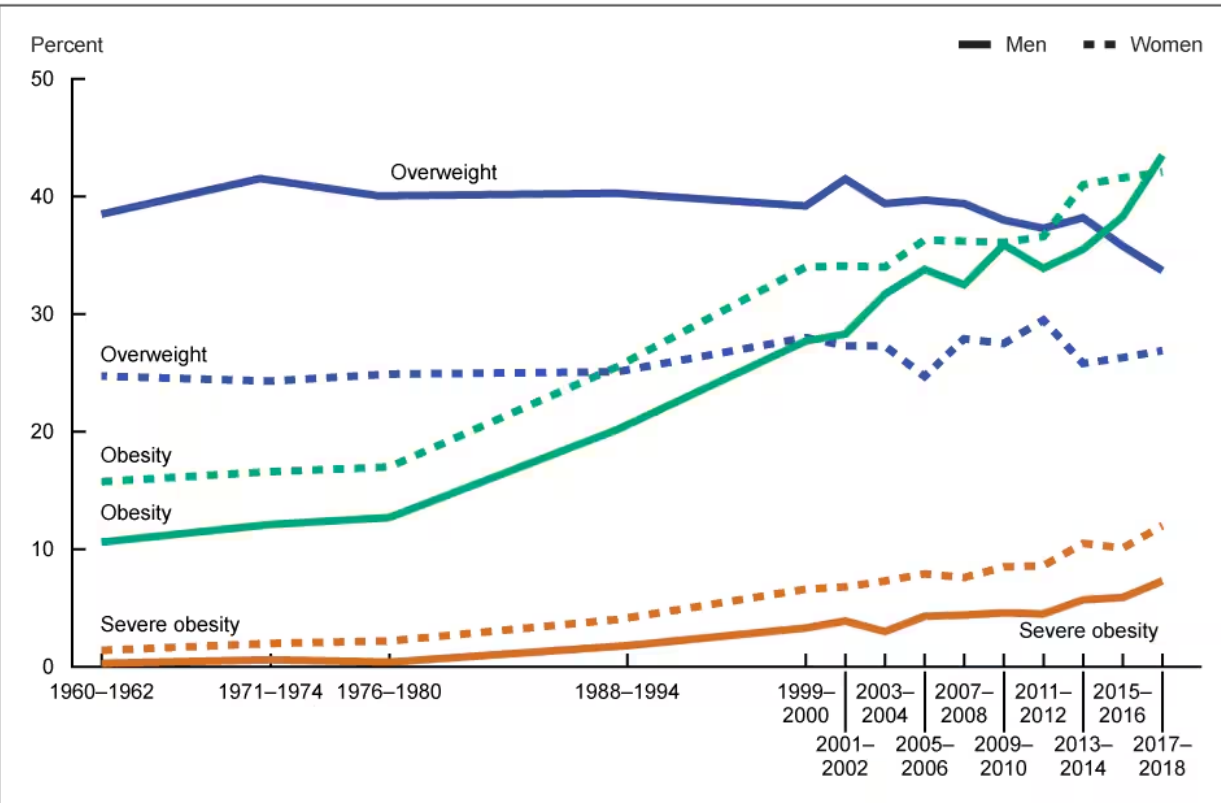
The body mass index (weight in kg/height in meters²) is used to screen for obesity, but it does not displace clinical judgment. BMI is not a measure of body fat. Social determinants, race, ethnicity, and age may modify the risk associated with a given BMI.

Bias and stigmatization directed at people with obesity contributes to poor health and impairs treatment.

Every person with obesity should have access to evidence-based treatment.



Obesity Prevalence



Year	Overweight (BMI 25-29.9)	Obesity (BMI 30-39.9)	Severe Obesity (BMI 40+)	BMI 25+
1960-1962	31.5	13.4	0.9	45.8%
1999-2000	33.6	30.9	5.0	64.5%
2017-2018	30.3	42.8	9.6	82.7%

Chart and Table Source: Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults Aged 20 and Over: United States, 1960-1962 Through 2017-2018. Published 2024. Accessed April 10, 2024. <https://www.cdc.gov/nchs/data/hestat/obesity-adult-17-18/obesity-adult.htm#Figure>

NOTES: Data are age adjusted by the direct method to U.S. Census 2000 estimates using age groups 20-39, 40-59, and 60-74. Overweight is body mass index (BMI) of 25.0-29.9 kg/m². Obesity is BMI at or above 30.0 kg/m². Severe obesity is BMI at or above 40.0 kg/m². Pregnant women are excluded from the analysis. SOURCES: National Center for Health Statistics, National Health Examination Survey and National Health and Nutrition Examination Surveys.

Causes of Obesity

- Energy In > Energy Out = Weight Gain
- “Eat less, move more” is technically a pattern that reduces obesity. HOWEVER...
- It’s **WAY** more complex than that!
- We don’t have as much control of our weight as we have been made to believe
- Body will resist weight change (metabolic adaptation)

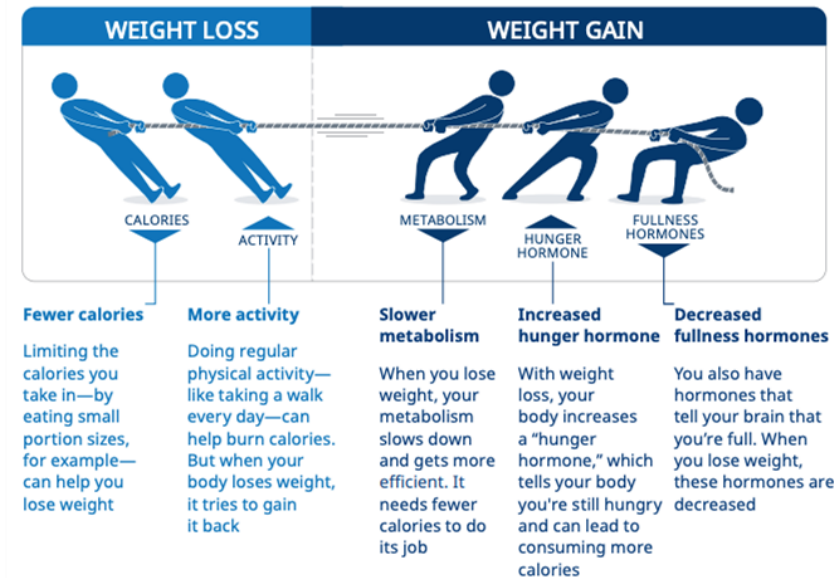
The Tug-of-War of Weight Management

The body’s response to weight loss makes it hard to maintain progress

Science shows that after losing weight, the body tries to put it back on.

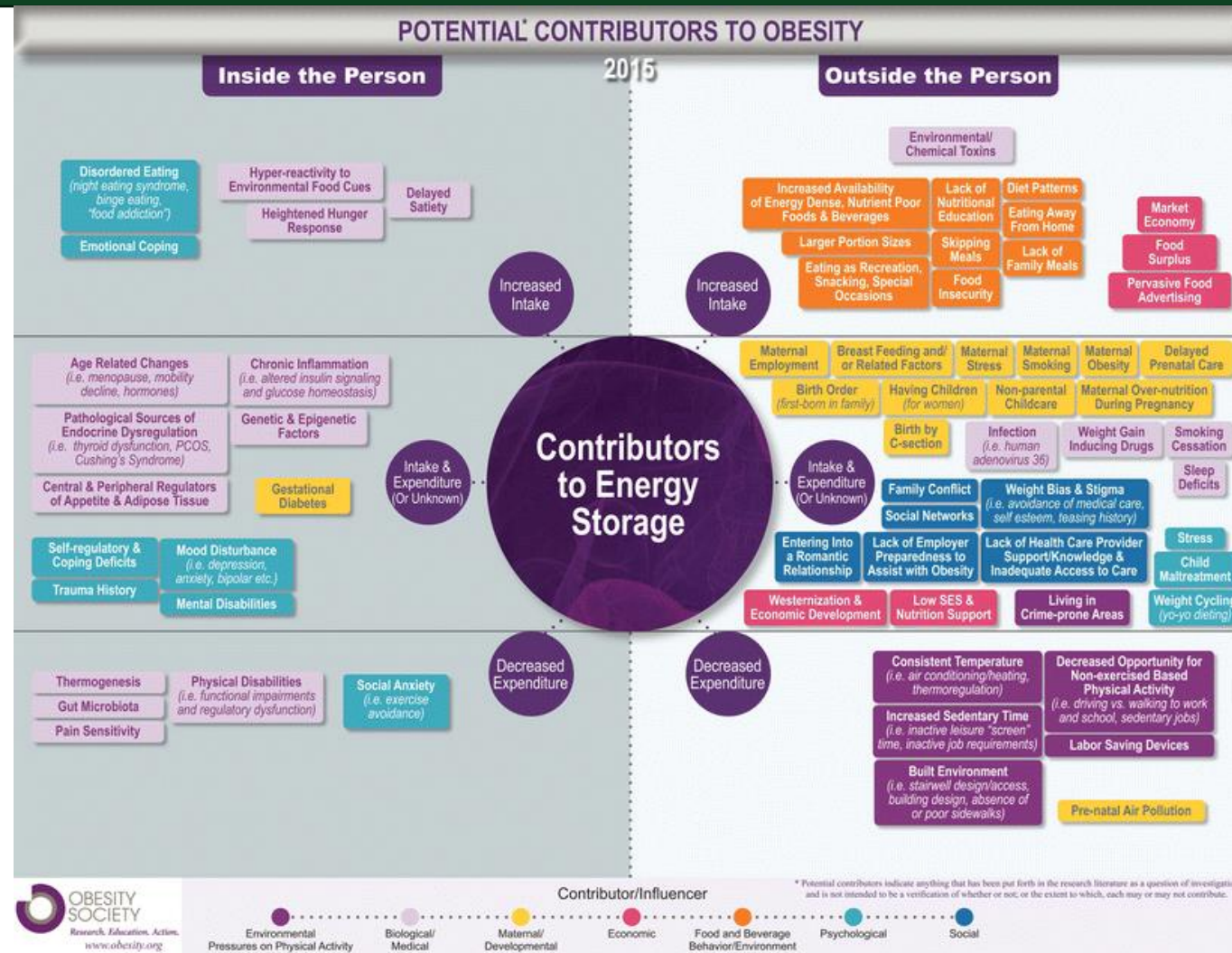
Following weight loss, the body’s metabolism slows down and appetite hormones change, making you feel more hungry and less full.

Here is how it works:



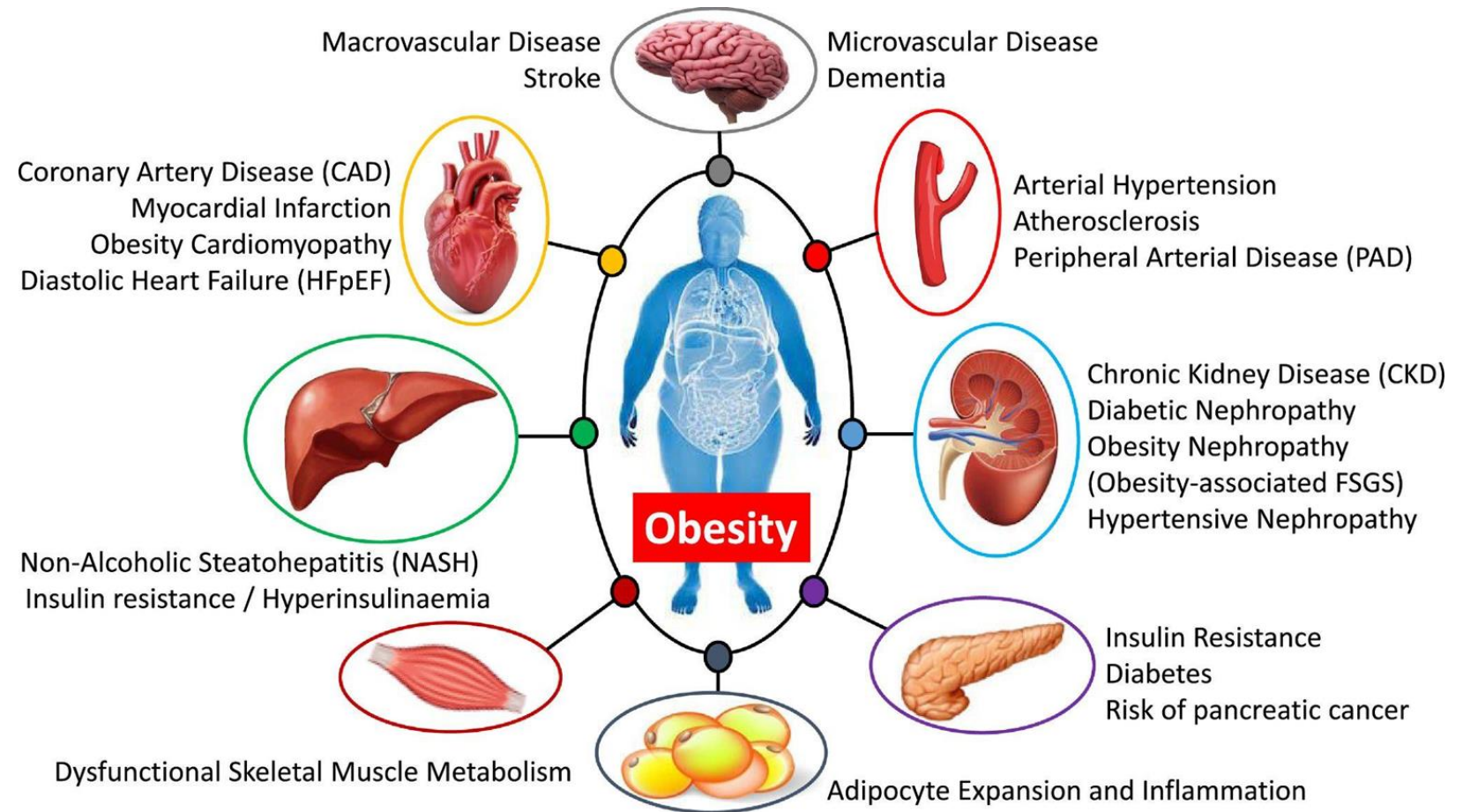
In a person with obesity, the body will try to put the weight back on for at least 12 months after weight loss

Causes of Obesity








Effects of Obesity





Obesity affects nearly every organ system and can increase risk or worsen outcomes of many chronic diseases.



Benefits of Obesity Treatment

- Treating obesity can prevent, halt progression, or even reverse chronic disease severity
- The first-line treatment recommendations for many chronic disease involves lifestyle changes, including weight loss
- Losing fat can improve several outcomes simultaneously
- Key Takeaway– **TREAT WEIGHT FIRST**

Diagnosis	Weight loss target %	Expected outcome
 Metabolic syndrome	10	Prevention of type 2 diabetes
 Type 2 diabetes	5-15	Reduction in HbA1c; reduction in diabetes medication; diabetes remission if short duration
 Dyslipidaemia	5-15	Lower triglycerides; increase HDL, decrease LDL
 Hypertension	5-15	Lower blood pressure; decrease in medication
 NAFLD	10-40	Reduction in intrahepatocellular lipids and inflammation

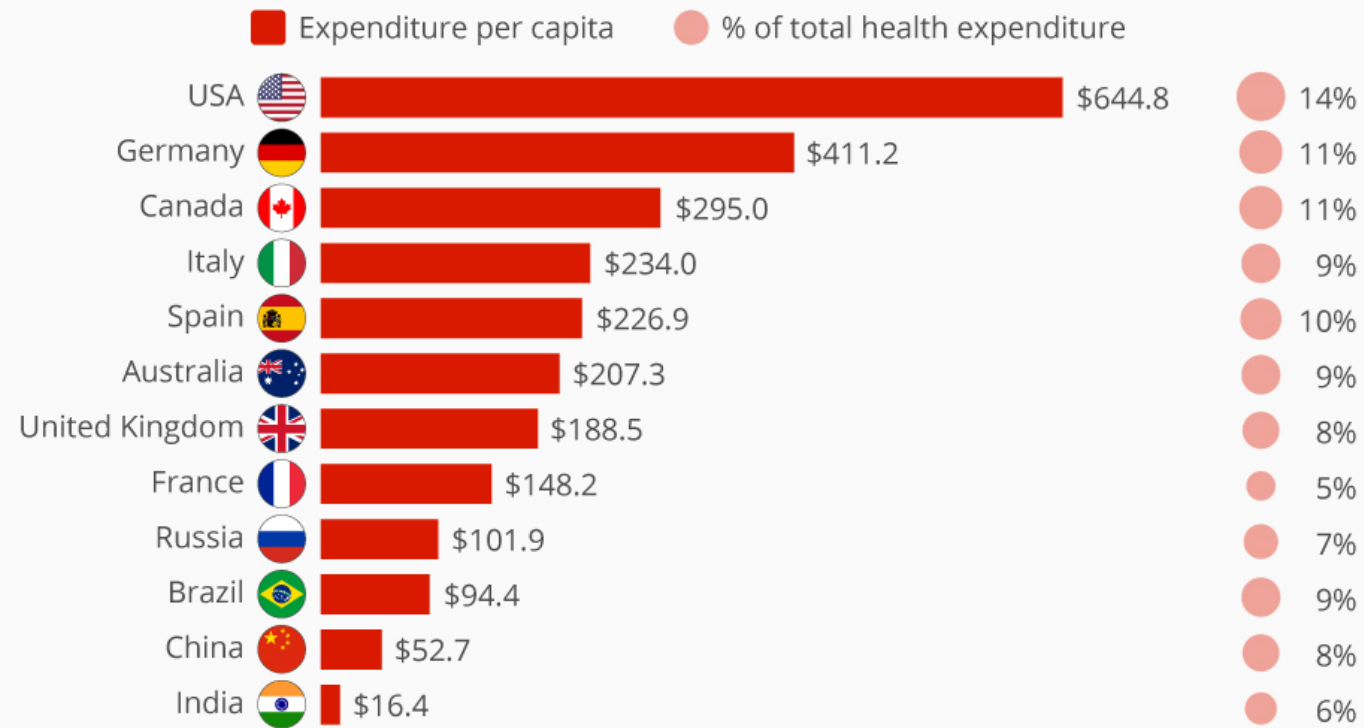
Diagnosis	Weight loss target %	Expected outcome
 PCOS	5-15	Ovulation; reduction of hirsutism; decrease in androgen levels; increase insulin sensitivity
 Sleep apnoea	7-11	Decrease apnoea/hypopnoea index
 Asthma	7-8	Improvement of FEV1
 GERD	≥10	Reduced symptoms

Novo Nordisk. Benefits of 10-15% weight loss on health. Rethinkobesity.global. Published 2022 <https://www.rethinkobesity.global/global/en/weight-and-health/benefits-of-10-15-weight-loss-on-health.html>

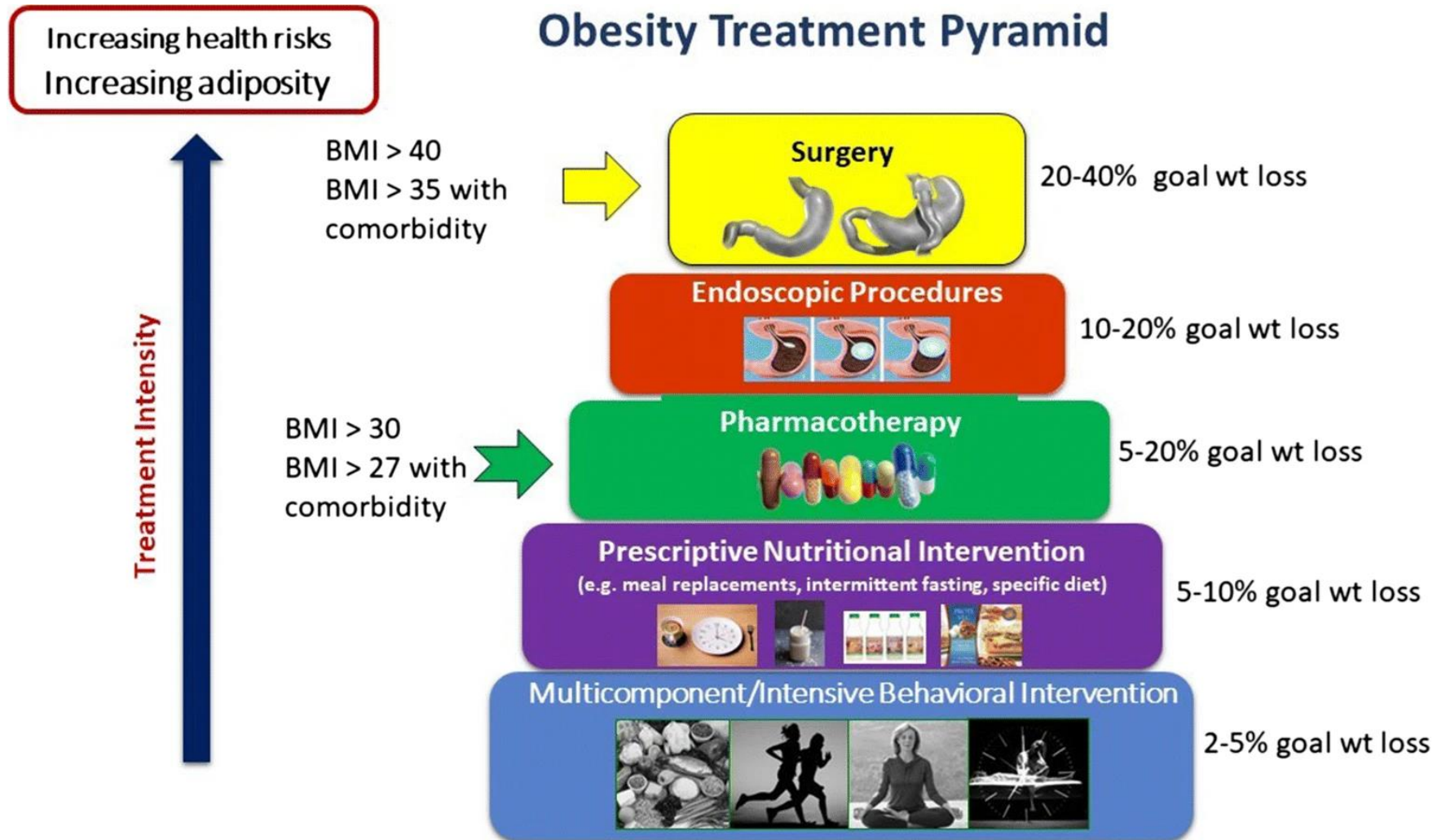
Cost of Obesity

Where Obesity Places The Biggest Burden On Healthcare

Average annual health expenditure per capita due to obesity from 2020-2050*



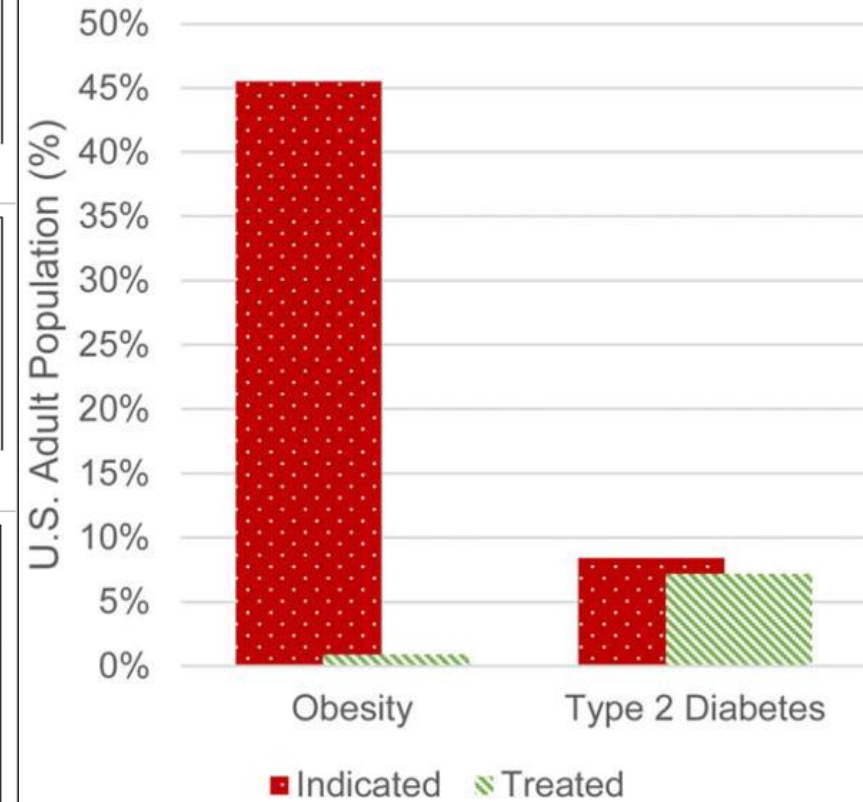
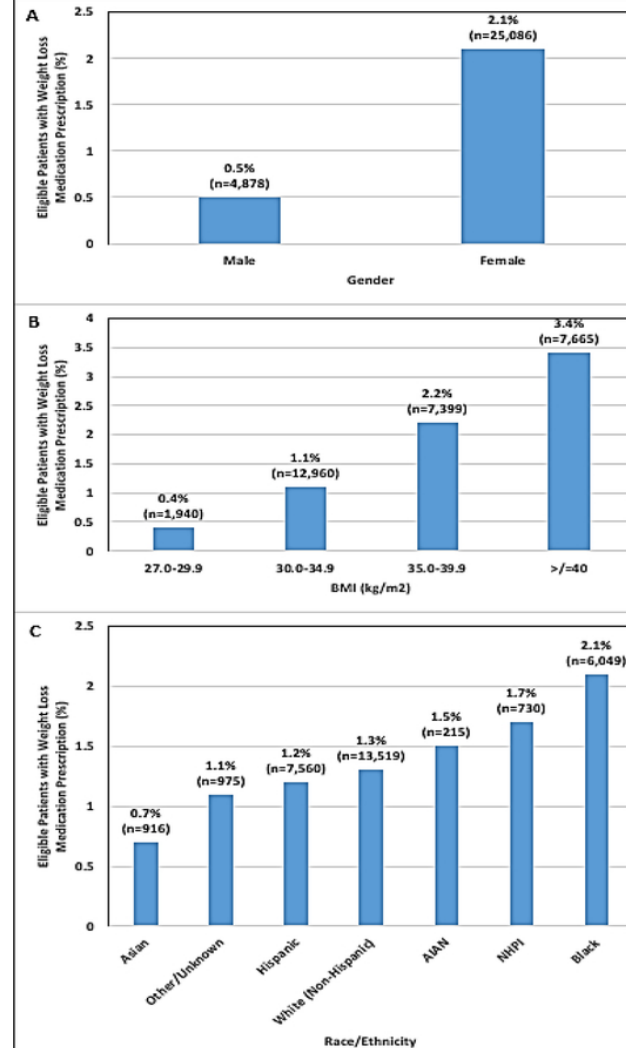
Treatment Options



Treatment Resistance

Very few patients who meet eligibility criteria for anti-obesity medication are offered treatment.

Factors include prescriber inertia, cost, obesity bias, lack of medical education focus on obesity.

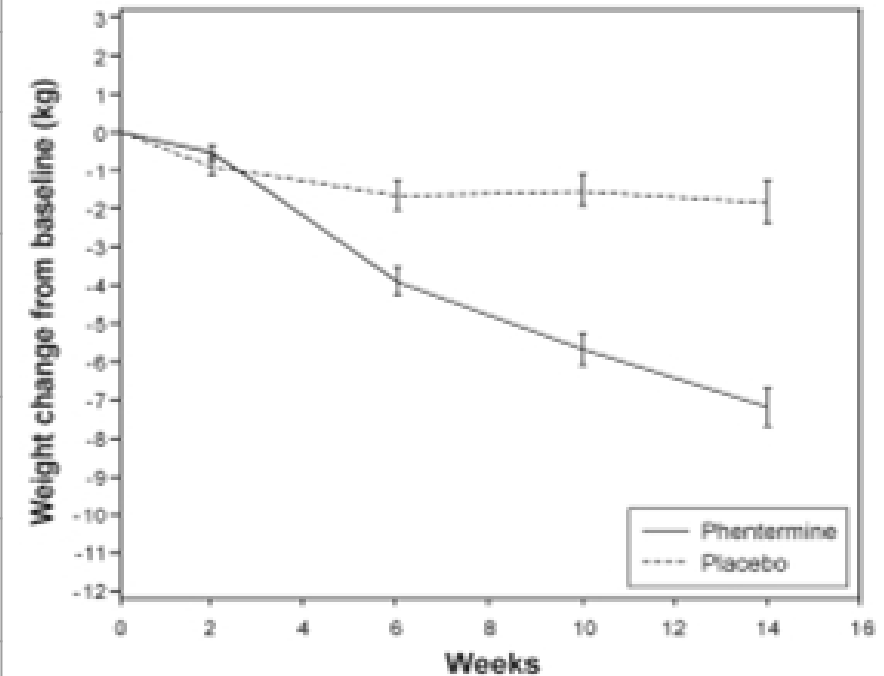


Current Anti-Obesity Therapies



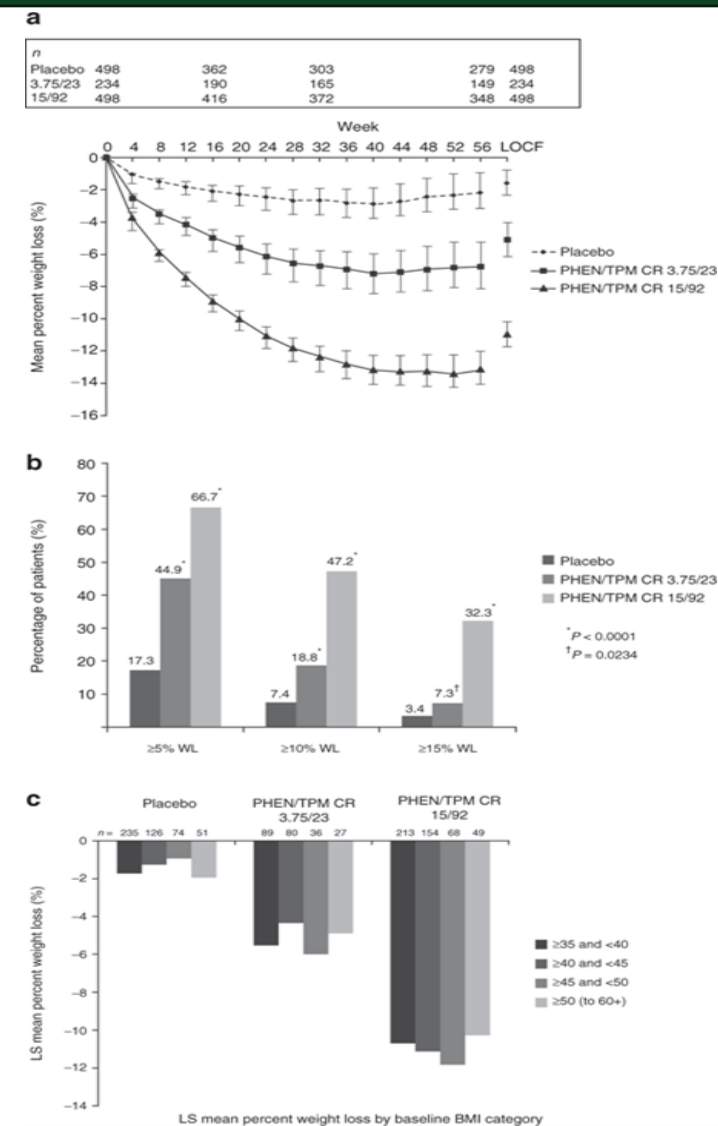
Phentermine

Year Approved	1959
MOA	CNS stimulant, increased norepinephrine
Avg Weight Loss	6-7% (placebo-controlled); relative lack of long-term phentermine monotherapy trials
Dosing	<ul style="list-style-type: none"> • 8mg up to 3x/daily before meals • 15mg-37.5mg once daily • 18.75mg twice daily
Adverse Effects	Increase in heart rate, blood pressure*, insomnia, dry mouth, constipation, nervousness.
Contraindications	Coronary artery disease, pulmonary hypertension; hyperthyroidism, glaucoma; caution with hx of substance abuse, anxiety disorders
Additional Information	Frequent prescriber hesitancy/caution due to stimulant/controlled substance designation; minimal abuse potential; FDA approval for short-term use, but clinical experience and expert opinion support long-term use; Most commonly used anti-obesity medication w/ >2 million annual prescriptions filled in the US
Cost	\$10-15 (30 tablets)



Phentermine-Topiramate ER

Year Approved	2012
MOA	CNS stimulant/norepinephrine (phentermine); GABA/POMC pathway (topiramate)
Avg Weight Loss	9% (placebo-controlled)
Dosing	Initial: 3.75mg/23mg x 14 days, then 7.5mg/46mg until 12 weeks. If >3% weight loss not achieved, can increase further with max dose of 15mg/92mg
Adverse Effects	Dry mouth, taste disturbance, constipation, paresthesias, depression, anxiety, elevated heart rate, cognitive disturbances, insomnia (higher dose)
Contraindications	Pregnancy (category X), hyperthyroidism, glaucoma; caution with hx of CAD, kidney stones, concomitant stimulant use for ADHD
Notable	Often easier and more cost effective to prescribe phentermine/topiramate separately. 8, 15, 30 or 37.5mg phentermine + topiramate 25mg QD, titrating as high as 50mg BID (off-label)
Cost	Retail: \$251 retail for 30 day supply; \$98 with manufacturer's mail-order pharmacy



Bupropion-Naltrexone ER

Year Approved	2014
MOA	Bupropion increases POMC activity and suppresses appetite; naltrexone enhances this effect
Avg Weight Loss	4.8% (placebo-controlled)
Dosing	<u>Initial</u> : 90mg bupropion / 8mg naltrexone; increase every 2 weeks. <u>Maximum</u> : 360mg/32mg
Adverse Effects	Nausea, constipation, headache, vomiting, dizziness, insomnia, dry mouth.
Contraindications	Uncontrolled hypertension, seizure disorder, eating disorder, use of other bupropion-containing products, chronic opioid use
Clinical Pearls	Consider using in patients with comorbid depression, excessive alcohol use, or nicotine use; frequently split prescribed– 150-300mg XL QD or 200mg SR BID; ¼ - ½ tab up to 1 tab QD naltrexone (off-label)
Cost	\$515 for 120 caps (30 day supply); \$99 via manufacturer's mail-order pharmacy

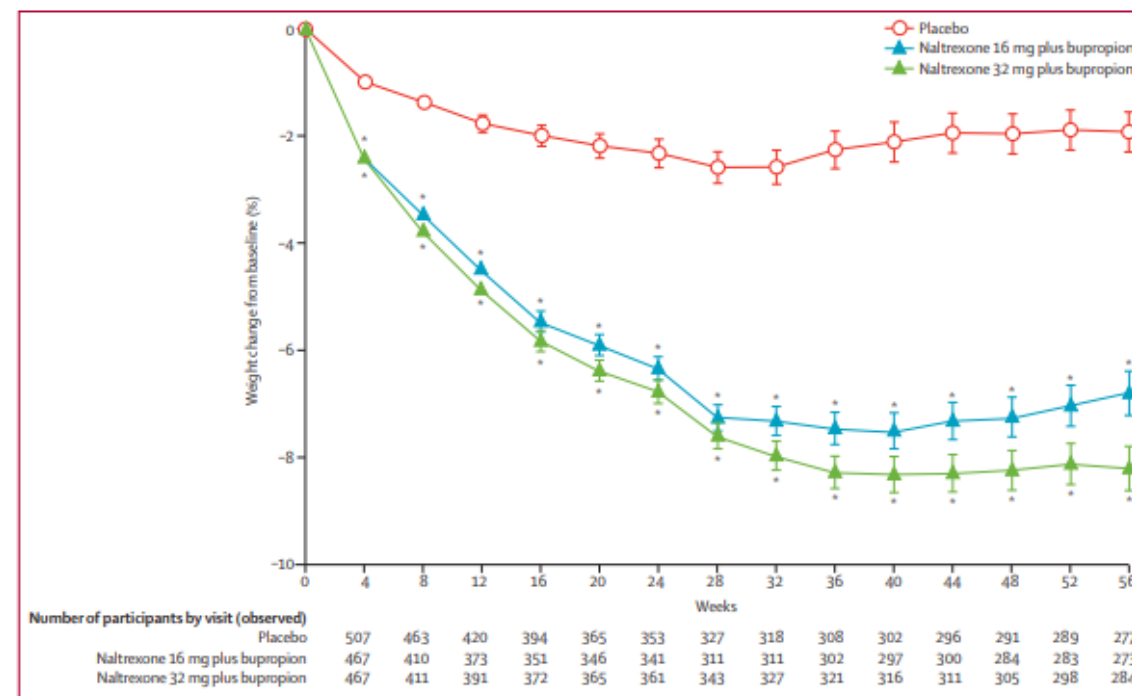


Figure 2: Change in bodyweight. Observed least squares mean (SE) percentage change from baseline in bodyweight and number of participants at each visit during 56 weeks. *p<0.0001 compared with placebo.

Bupropion-Naltrexone ER

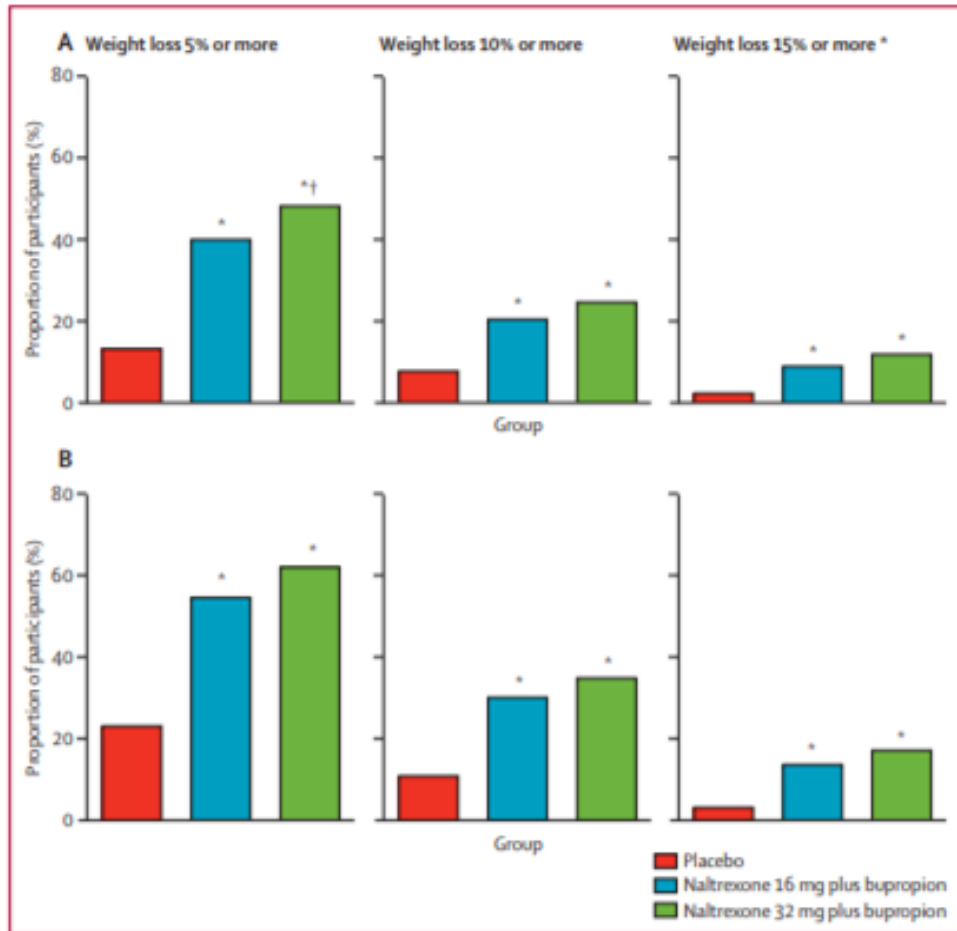


Figure 3: Proportion of participants who lost at least 5%, 10%, and 15% of baseline weight at week 56
 (A) Primary analysis population. (B) Participants who completed 56 weeks of treatment. * $p < 0.0001$ compared with placebo. † $p = 0.0099$ for naltrexone 32 mg plus bupropion compared with naltrexone 16 mg plus bupropion (exploratory analysis performed for primary analysis population only).

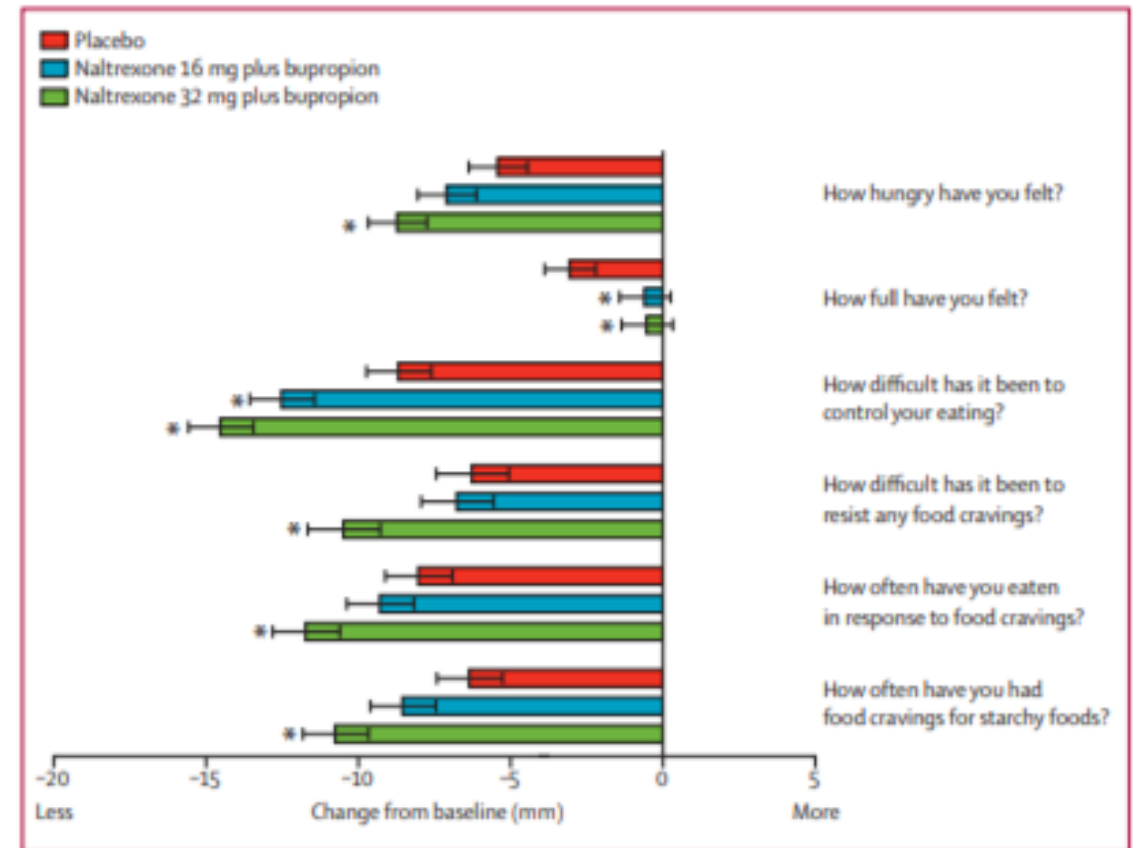


Figure 4: Change in selected items from the Control of Eating Questionnaire at week 56
 Least squares mean (SE) change from baseline in hunger, eating, and food craving-related items that showed improvements ($p < 0.05$) for naltrexone 32 mg plus bupropion compared with placebo at weeks 8 and 56; primary analysis population. Responses reflect experiences during the 7 days before answering the questionnaire. * $p < 0.05$

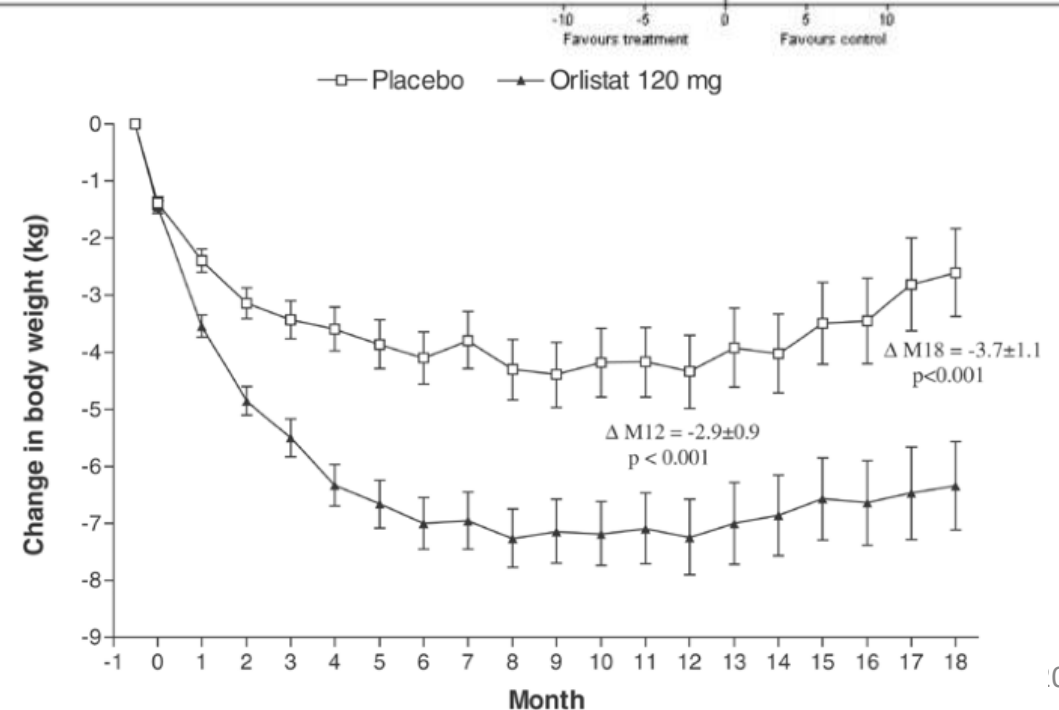
Orlistat

Year Approved	1999 (Rx); 2007 (OTC)
MOA	Inhibits lipase, leading to reduced absorption of fat (~30% of fat kcals)
Avg Weight Loss	3% (placebo-controlled)
Dosing	120mg with fat-containing meals, up to 3x/day. OTC- 60mg up to 3x/day
Adverse Effects	Cramps, flatulence, fecal incontinence, oily spotting. Absorption of fat-soluble vitamins
Contraindications	Chronic malabsorption or cholestasis; avoid w/ history of oxalate-induced kidney stones.
Clinical Pearls	Rarely used; MOA/side effects limit patient satisfaction; consider as adjunct if another AOM is causing constipation
Cost	\$556 (Rx); \$78 (Alli OTC)

Table 2 Outcomes for orlistat 120 mg tid vs. placebo at 1 year

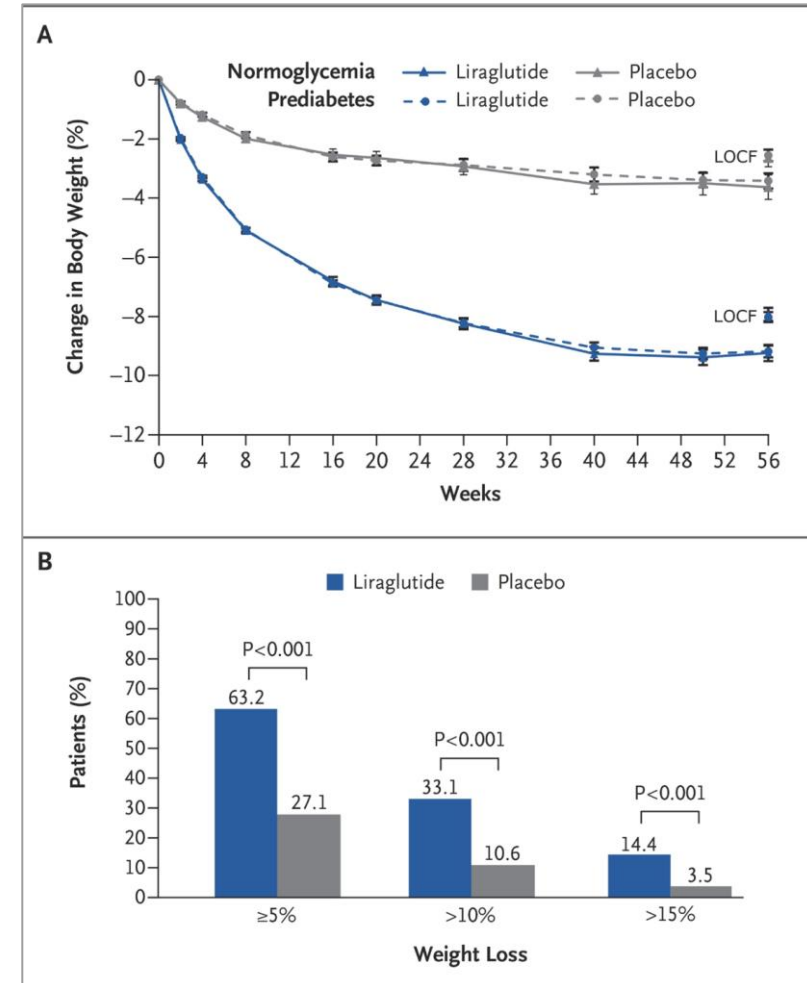
Study	Treatment		Control		WMD (95%CI Random)	Weight %	WMD (95%CI Random)
	n	mean(sd)	n	mean(sd)			
Davidson et al	657	-8.76(9.50)	223	-5.81(10.00)	■	28.0	-2.95[-4.45,-1.45]
Hauptman et al	210	-7.94(8.30)	212	-4.14(8.20)	■	25.4	-3.80[-5.37,-2.23]
Rosner et al	244	-9.40(6.40)	243	-6.40(6.70)	■	46.5	-3.00[-4.16,-1.84]
Total(95%CI)	1111		678		◆	100.0	-3.19[-3.98,-2.40]

Test for heterogeneity chi-square=0.78 df=2 p=0.68



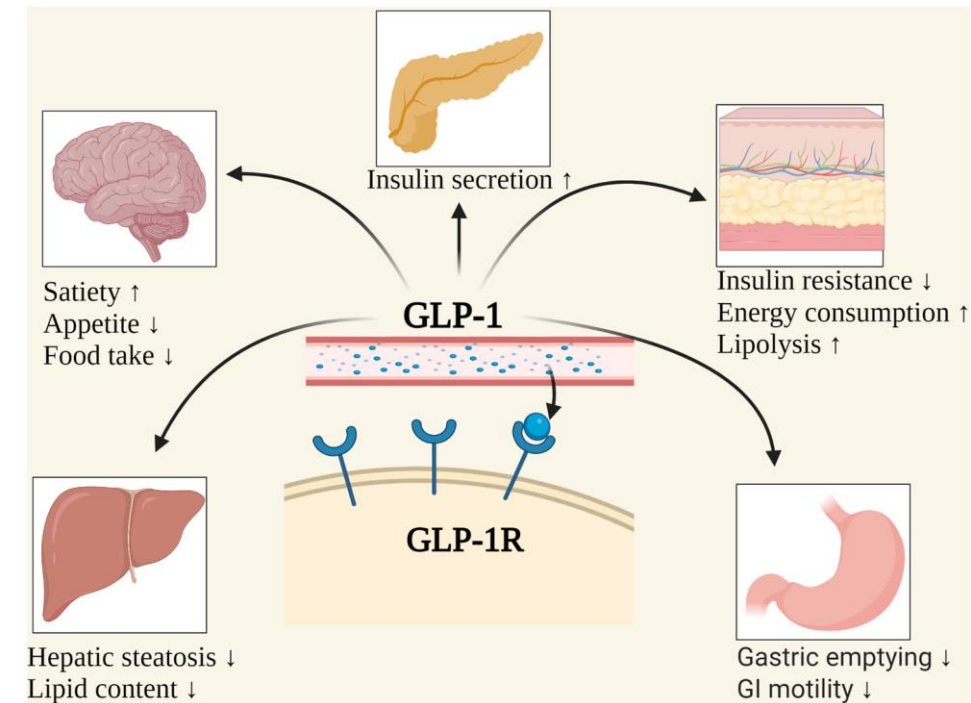
Liraglutide

Year Approved	2014
MOA	GLP-1 agonist
Avg Weight Loss	5.4% (placebo-controlled)
Dosing	0.6mg subQ daily, titrated up weekly to 3.0mg max dose
Adverse Effects	Nausea, vomiting, diarrhea, constipation, GERD, increased heart rate
Contraindications	FamHx of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
Clinical Pearls	Weekly GLP1s have replaced it due to convenience/effectiveness. Goes generic summer 2024
Monthly Cost	\$1,308



Semaglutide

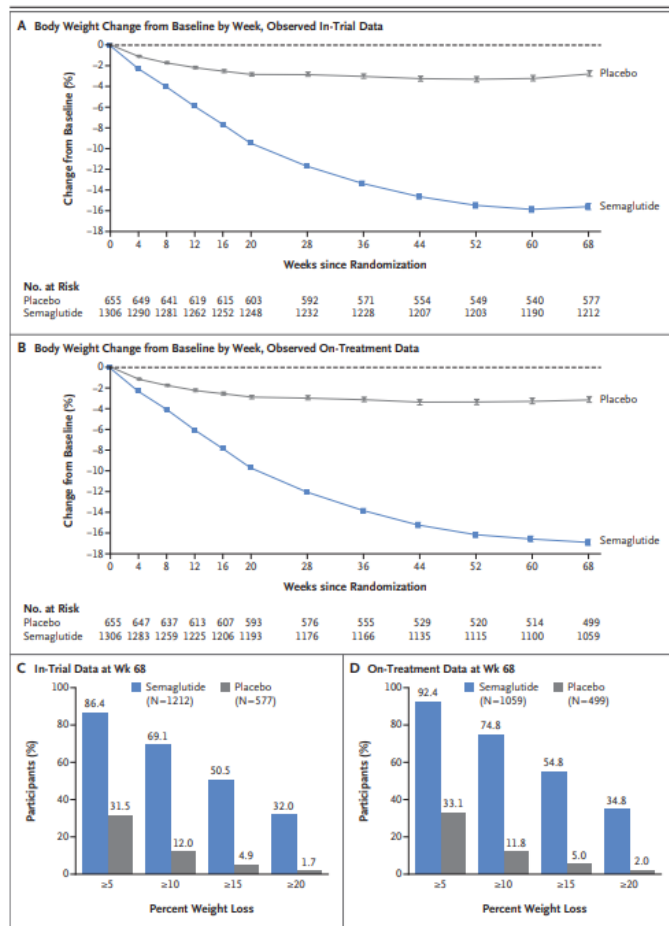
Year Approved	2021
MOA	GLP-1 agonist
Avg Weight Loss	14.8% (placebo-controlled)
Dosing	0.25mg once weekly, increased q4 weeks up to max of 2.4mg. 1.7mg and 2.4mg are the only approved "maintenance" doses
Adverse Effects	Nausea, vomiting, diarrhea, constipation, GERD, increased heart rate
Contraindications	FamHx of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
Clinical Pearls	Recently added cardiovascular disease indication following results of SELECT trial → Medicare coverage
Monthly Cost	\$1,349; \$225 off with manufacturer coupon



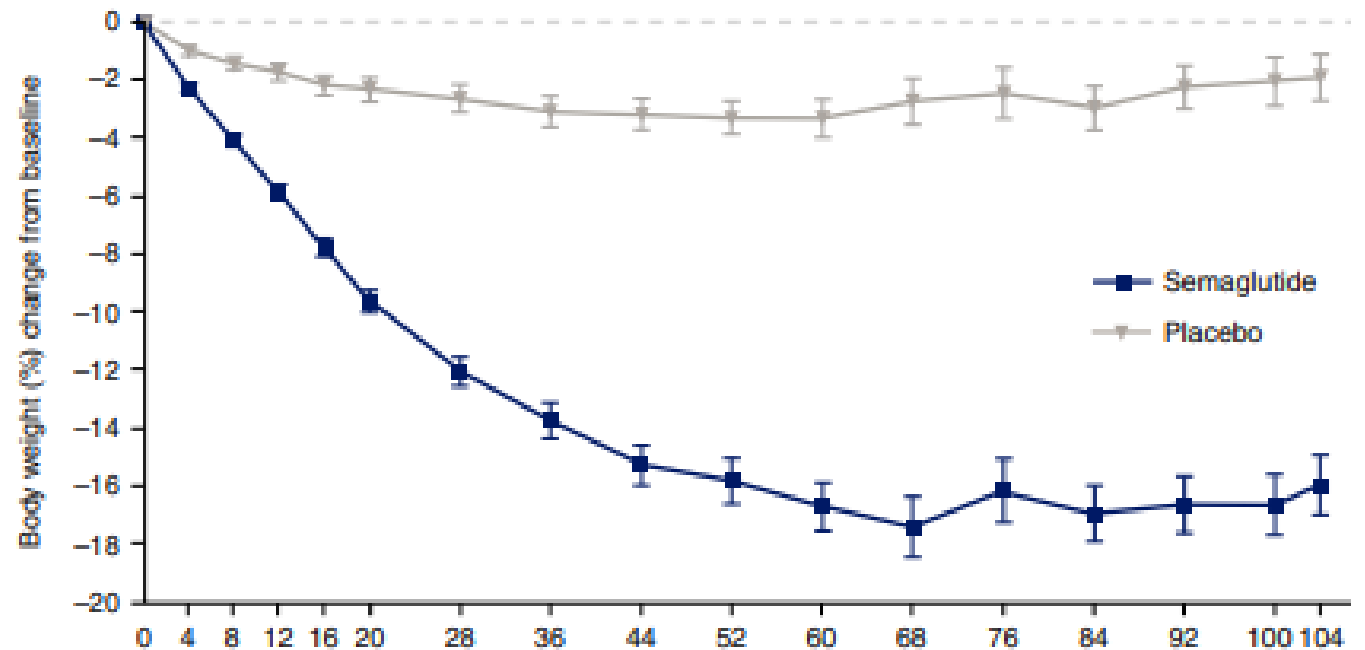
Wang, Jing-Yue, et al. "GLP-1 Receptor Agonists for the Treatment of Obesity: Role as a Promising Approach." *Frontiers in Endocrinology*, vol. 14, 1 Feb. 2023.

Semaglutide

STEP 1 Trial

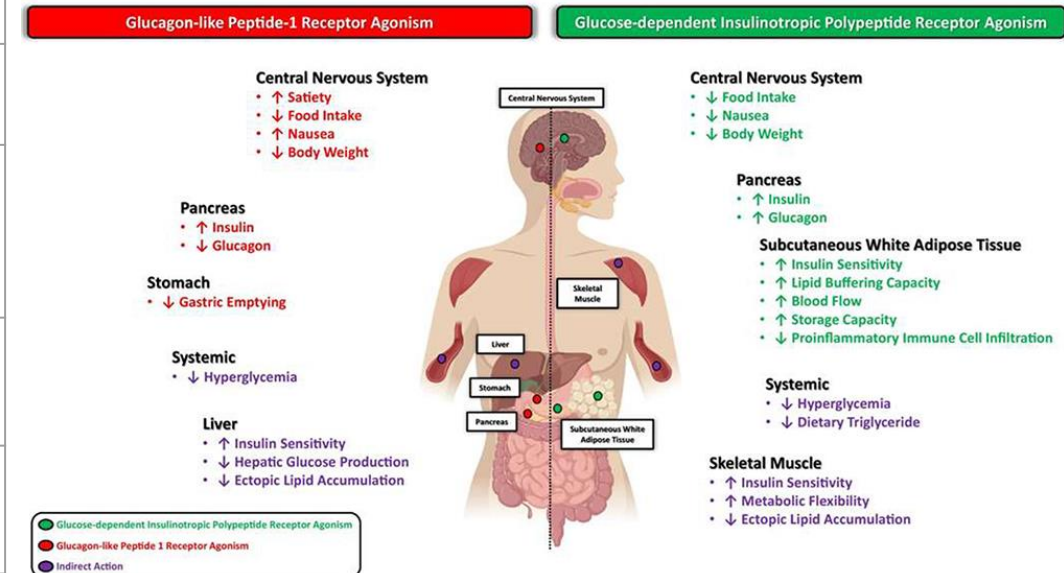


STEP 5 – 2 years of treatment



Tirzepatide

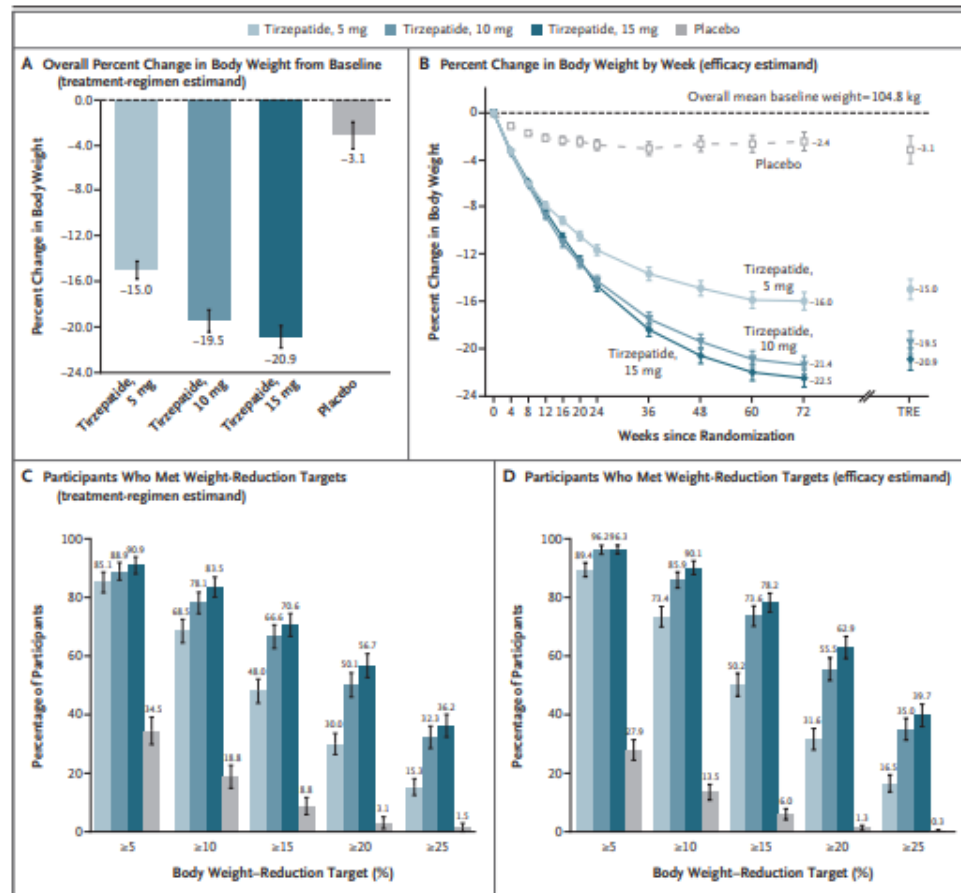
Year Approved	2023
MOA	GLP-1/GIP Agonist
Avg Weight Loss	5mg: 14.4%, 10mg: 19.0%, 15mg: 20.1%
Dosing	2.5mg subQ weekly x4 weeks. Increase in intervals of 2.5mg q4 weeks. 5, 10, or 15mg are recommended maintenance doses
Adverse Effects	Nausea, vomiting, diarrhea, constipation, GERD, increased heart rate; much better tolerated than semaglutide
Contraindications	FamHx of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
Clinical Pearls	Patients report more control of “food noise” vs semaglutide. Better side effect profile + higher WL% makes it a clear choice.
Monthly Cost	\$1,060/box; \$550/box with coupon



Rizvi, Ali A, and Manfredi Rizzo. "The Emerging Role of Dual GLP-1 and GIP Receptor Agonists in Glycemic Management and Cardiovascular Risk Reduction." *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy*, vol. Volume 15, 1 Apr. 2022, pp. 1023–1030.

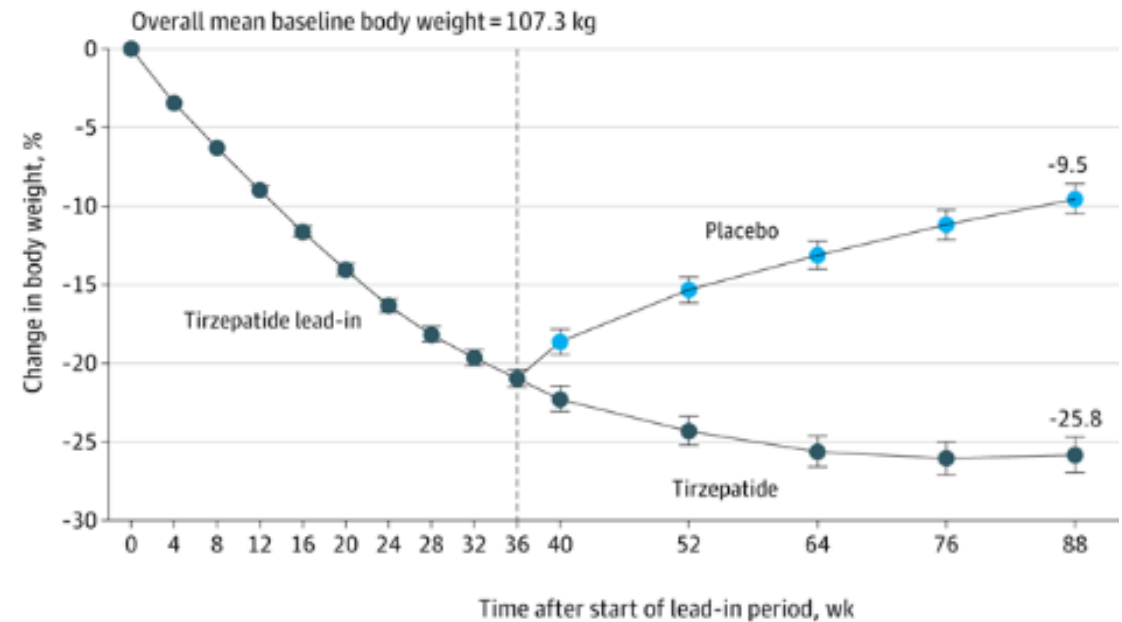
Tirzepatide

SURMOUNT 1 Trial



SURMOUNT 4 - 15mg treatment group randomized to placebo or continued tirzepatide use for additional 52 week period

Percent change in body weight (week 0-88)



- Treatment group- 25.8% weight loss in 88 weeks
- 45% of weight loss retained after 1 year in placebo group

CARDIOMETABOLIC BENEFITS- SELECT TRIAL

Demographics

- Existing ASCVD
- BMI ≥ 27
- No T2DM
- Age ≥ 45
- 17,604 patients
- Mean duration 39.8 months

Endpoints

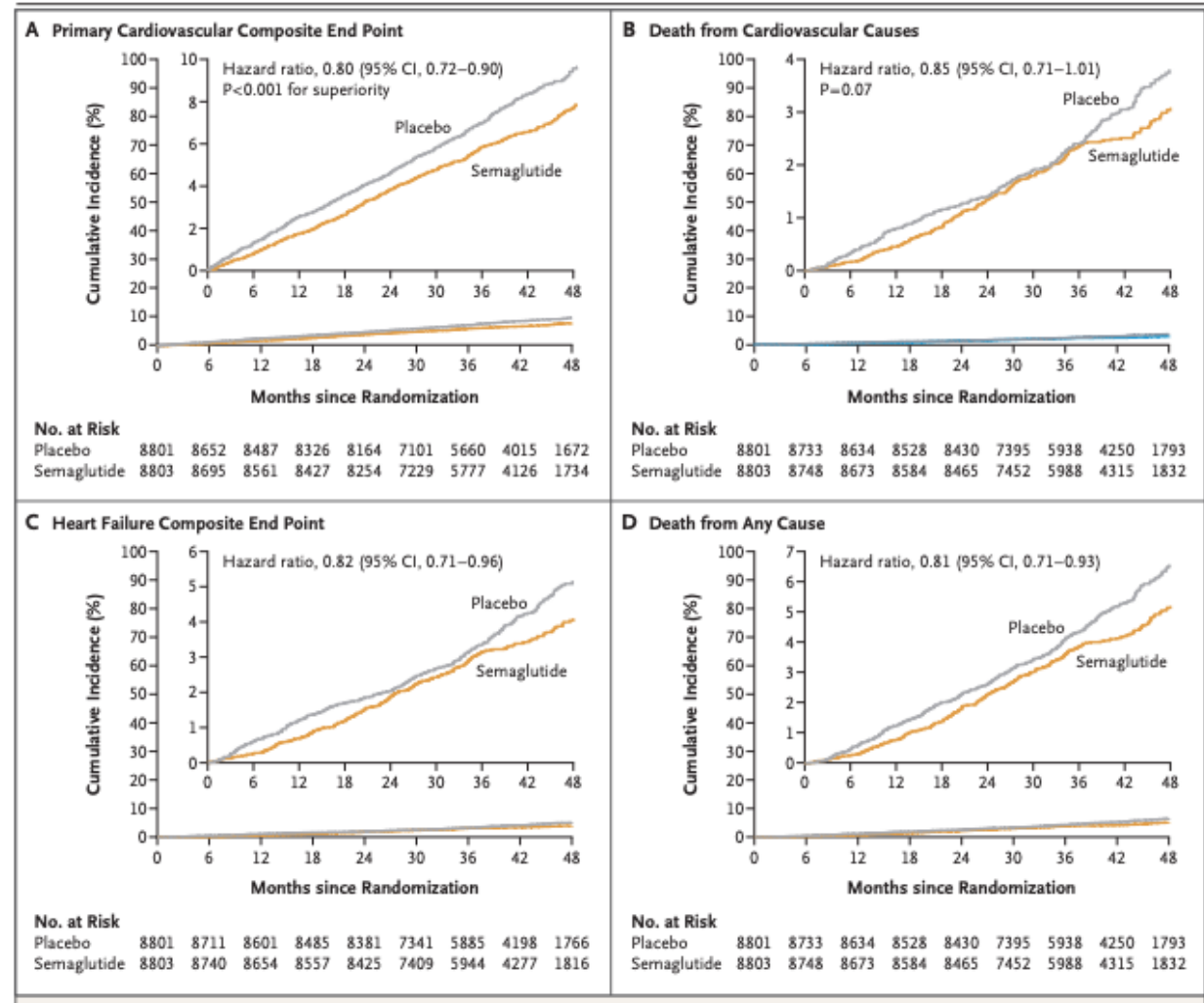
- Death from CV cause
- Nonfatal MI/CVA

Results

- 20% RR reduction in treatment group
- 6.5% vs 8% primary endpoints

Effects

- Increased AOM coverage(?)
- Additional on-label indications
- 1st AOM w/ Medicare coverage!



OTHER AOM CARDIOVASCULAR EFFECTS

Liraglutide

- CV Benefit
- Likely class effect of CV benefit w/ GLP-1 agonists

Phentermine/Topiramate, Bupropion/Naltrexone, Orlistat

- No demonstrated negative CV impact
- Some CV marker improvement
- Lack of long-term trial data

MASLD/MASH

- GLP-1 benefits

Ongoing trials for peptide agonists

- OSA, osteoarthritis, MAFLD

OTHER MEDS TO CONSIDER

Metformin

- Off label; 5% WL; anecdotally, higher dosage (2000mg) needed for appreciable weight loss benefit; more helpful in PCOS, menopause patients; paired with phentermine for dual therapy with different MOAs

Diethylpropion

- 25 mg IR tid or 75mg ER qd
- Less stimulating than phentermine; IR can be used later in the day than phentermine

Benzphetamine, Phendimetrazine

- CIII stimulants, little research data; similar MOA/benefit of other stimulant AOM

Zonisamide - 400mg for maximal WL benefit, night time dosing. Similar effect as topiramate

Plenity - absorbent hydrogel; discontinued 2022 due to bankruptcy

Pramlintide - amylin analog; off label; previous obesity studies showed ~7-8% WL

SGLT2i - modest WL, improved glucose/BP/kidney function

PRESCRIBING APPROACH

- Comprehensive medication review
- Identify weight-promoting medications
 - Psych Meds- careful w/ changing, work with prescriber
 - Beta blockers- not first line HTN therapy
 - Contraceptives- IUD preferred
- Review past AOM use
 - Benefits/Side Effects, reason(s) for discontinuing
- Look for opportunities for dual therapy or combination meds
- **Dual AOM use often effective and appropriate** based on severity of obesity and other comorbidities
- Have an “off-ramp” around 12 weeks
 - If 3-5% weight loss not achieved, stop or switch AOM therapy

HOW CAN PHARMACISTS HELP?

- Expand access with MTM visits/Collaborative Practice Agreements
- Better medication adherence
- Fewer med interactions
- Adverse effect prevention & management
- Can suggest other med changes as weight loss occurs
 - Diabetes, Hypertension, Lipids, Mental Health
- Help reinforce lifestyle recommendations
- Increase revenue
- Remote Patient Monitoring
 - Scales, BP Machines, Glucometers

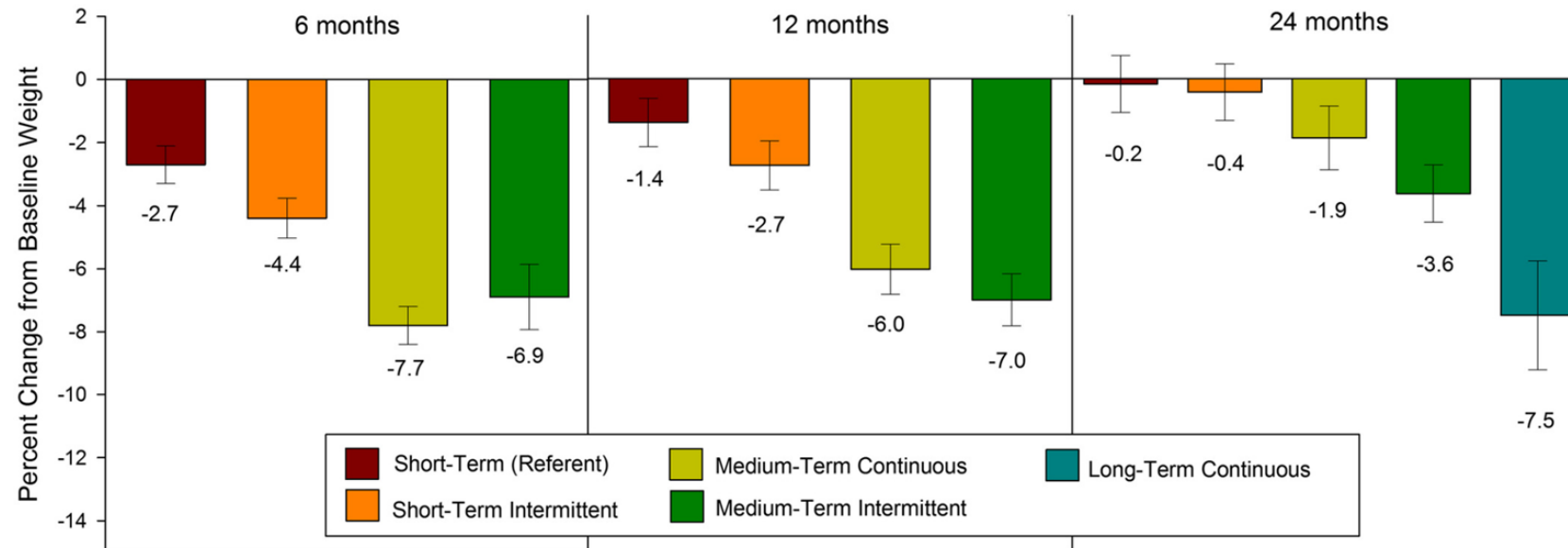
MOST IMPORTANTLY– helping separate fact from fiction about anti-obesity medications.

Misconceptions of Anti-Obesity Medications

Phentermine Misconceptions

Phentermine should NOT be used long-term.

1. FDA Approval for 12 weeks based on 1959 study length
2. No specific or additional long-term adverse effects noted
3. Phentermine/Topiramate (brand name Qsymia) approved for long-term use



Phentermine Misconceptions

“Phentermine is a controlled substance; therefore it has high risk of abuse/dependence.”

Addiction potential of phentermine prescribed during long-term treatment of obesity

EJ Hendricks¹, M Srisurapanont², SL Schmidt², M Haggard¹, S Souter¹, CL Mitchell¹, DG De Marco¹, MJ Hendricks¹, Y Istrati¹ and FL Greenway⁴

“This report is the first clinical trial conducted in which patients treated with phentermine for obesity have been examined with validated, currently used addiction medicine metrics. The study was conducted among patients in a fee-for-service obesity medicine specialty practice that has existed over two decades. Our data strongly suggest that **long-term phentermine pharmacotherapy for obesity for up to 21.5 years and at doses up to 112.5 mg per day does not induce abuse or psychological dependence (addiction)**, that long-term phentermine pharmacotherapy does not induce phentermine drug craving, and that abrupt treatment cessation does not induce amphetamine-like withdrawal. These trial data suggest **fears of causing addiction with long-term phentermine are exaggerated and present a needless barrier** to better care for overweight and obese patients worldwide.”

A Study of Abrupt Phentermine Cessation in Patients in a Weight Management Program

Hendricks, Ed J MD^{1*}; Greenway, Frank L MD²

[Author Information](#) ⓘ

American Journal of Therapeutics 18(4):p 292-299, July 2011. | DOI: 10.1097/MJT.0b013e3181d070d7

There was a striking and significant difference in individual and total scores between the phentermine-treated subjects and the amphetamine-dependent subjects. **Cravings for the substance abused**, the hallmark characteristic of substance dependence and withdrawal, **were entirely absent in the phentermine-treated subjects.** Abrupt **cessation of long-term phentermine therapy does not induce amphetamine-like withdrawal.** Long-term phentermine therapy does not induce phentermine cravings. **Symptoms observed after abrupt phentermine cessation represent loss of therapeutic effect and are not withdrawal.**

Phentermine Misconceptions

“Phentermine will increase blood pressure and should be avoided in patients with hypertension.”

Long-term phentermine use associated with **improvement** in BP regardless of initial BP status (normal, pre-, or hypertensive)

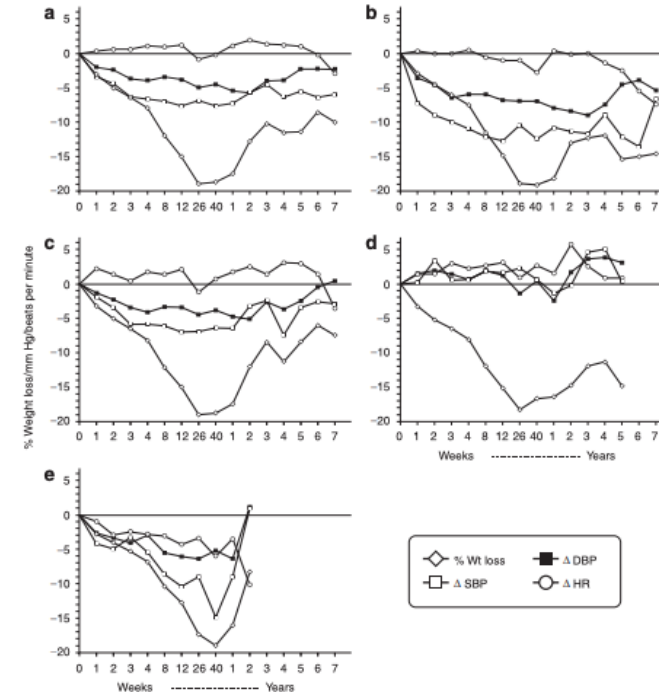


Figure 1 Weight loss, systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate change by weeks/years of therapy. (a) All phentermine-treated subjects (weight $P < 0.0001$, SBP week 26, 52, 104 $P \leq 0.0001$, and week 156–312 $P > 0.05$), DBP week 26, –156 $P > 0.04$, and week 260–312 $P > 0.05$, HR $P > 0.05$). (b) phentermine-treated hypertensive subjects: weight $P \leq 0.0001$, SBP week 26, 52, 104, 156 $P \leq 0.0001$, week 208 $P = 0.0217$, week 260 $P = 0.0074$, week 312 $P = 0.0047$, DBP week 26, 52, 104 $P < 0.0001$, week 156 $P = 0.0002$, week 208 $P = 0.0041$, 260 $P > 0.05$, week 312 $P > 0.05$, HR $P > 0.05$. (c) phentermine-treated prehypertensive subjects (weight $P < 0.01$, SBP week 25 and 52 $P < 0.0001$, week 104–312 $P > 0.05$, DBP $P > 0.05$, HR $P > 0.05$). (d) phentermine-treated normotensive subjects (SBP $P > 0.05$, DBP $P > 0.05$, HR $P > 0.05$), and (e) phentermine-untreated subjects. (Weight week 52 $P < 0.0001$, week 104 $P > 0.05$, SBP week 52 $P < 0.04$, week 104 $P > 0.05$, DBP week 52 $P < 0.04$, week 104 $P > 0.05$, HR $P > 0.05$).

GLP-1 Agonist Misconceptions

GLP-1 meds increase risk of thyroid cancer

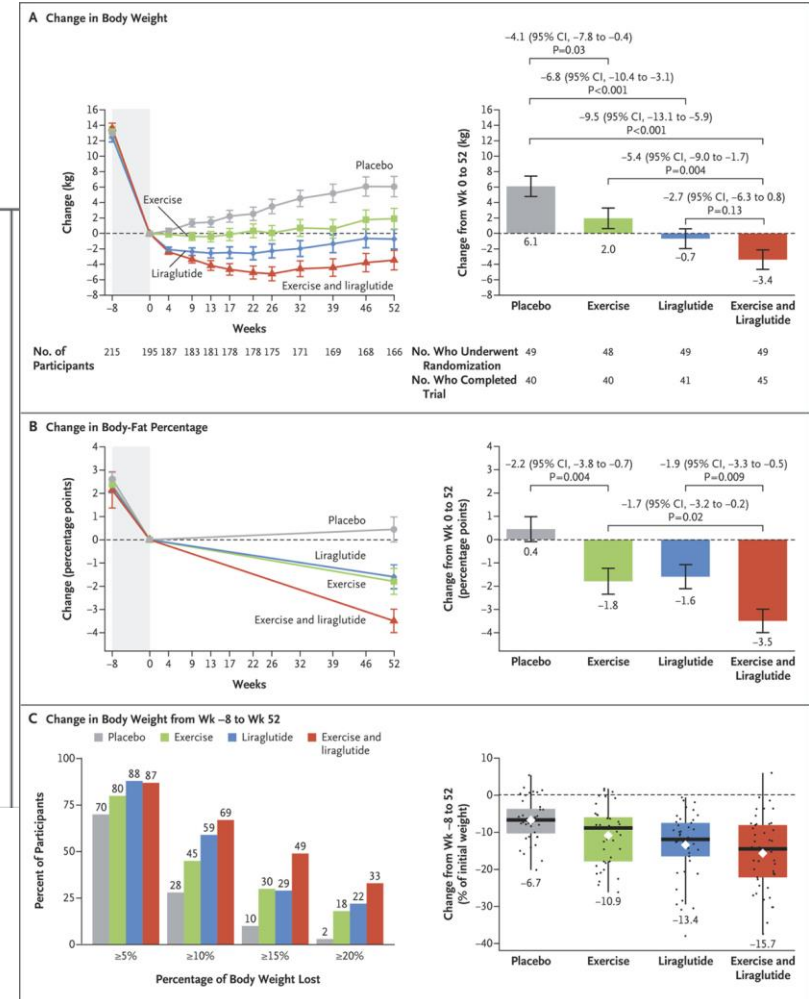
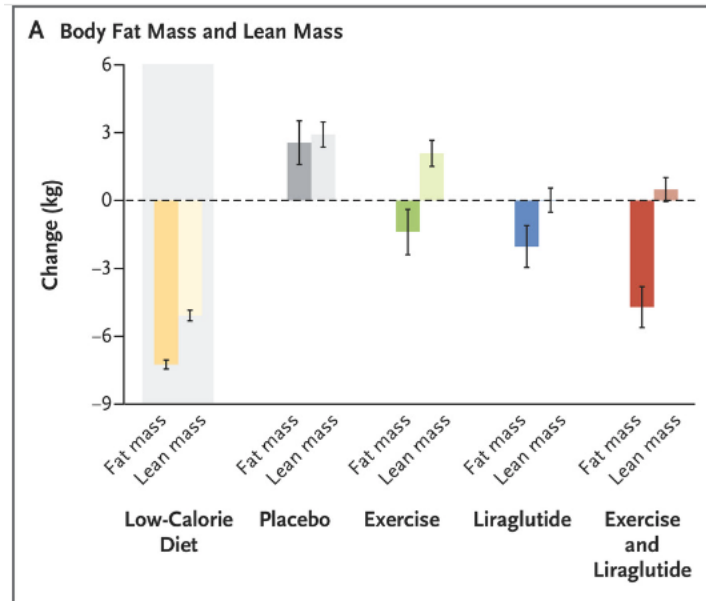
- No evidence of increased incidence; black box warning based on rodent studies

Patients will lose lots of lean mass on GLP-1 meds, which is just as bad for metabolic health.

- Rate of weight loss, protein intake, and resistance training can all mitigate lean mass loss

GLP-1 meds cause pancreatitis, stomach paralysis, etc

- Severe side effects are rare; benefits > side effects in almost all scenarios



GLP-1 Agonist Misconceptions

Once they stop the GLP-1 medication, the patient will gain the weight back.

- Weight gain is much more likely if discontinued, however...
 - Obesity is a chronic disease which requires chronic management
 - GLP-1 meds are approved for long-term use.
- When a chronic disease is appropriately managed, the patient should be continued on the same plan as long as it remains effective.

Patients using GLP-1 meds for weight loss are causing shortages for patients with type 2 diabetes who need them more

- All chronic diseases are important and worthy of accessible treatment
- Manufacturers have failed to consistently produce adequate supply despite known and projected popularity

Anti-Obesity Medication Use in Pediatric Patients

Several currently approved medications for pediatric obesity treatment

- Semaglutide
- Liraglutide
- Orlistat
- Phentermine/Topiramate
- Metformin (off-label)

2023 American Academy of Pediatrics Clinical Practice Guidelines for Treatment of Obesity

- “In contrast to previous recommendations, these clinical guidelines highlight the urgency of providing **immediate, intensive obesity treatment to each patient as soon as they receive the diagnosis of obesity.**”
- “Pediatricians and other PHCPs should offer adolescents 12yo+ with obesity (BMI \geq 95th percentile) weight loss pharmacotherapy, according to medication indications, risks, and benefits, as an adjunct to health behavior and lifestyle treatment.”

Summary

- ✓ Obesity is a chronic disease.
- ✓ Several current pharmacotherapy options exist for the treatment of obesity.
- ✓ Pharmacotherapy for obesity is dramatically underutilized in the current healthcare system.
- ✓ Effective treatment with pharmacotherapy should be continued indefinitely and monitored at regular intervals.
- ✓ Treating obesity improves outcomes and reduces risk of many other weight-related comorbidities.
- ✓ Pharmacists play a key role in the care team for treatment of obesity.
- ✓ Many misconceptions exist about anti-obesity medication.
- ✓ Clarifying these misconceptions with the medical community and general population may help patients get appropriate treatment.

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Questions?

