**Paradigm Shifts and Price Wars:**
The Bright and Bumpy Future of Obesity Treatment

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# Disclosures

- Contracted Research: Sharecare, Inc.

*All relevant financial relationships have been mitigated.*

*The views and opinions expressed today are my own and do not represent the views and opinions of Kaiser Permanente.*

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# Objectives

| | |
|---|---|
| 📊 | Identify three major policy-level determinants of providing obesity treatment |
| 📋 | Recognize policy level gaps in evidence related to efficacy, safety, and costs of obesity treatment |
| 🎯 | Identify how the quintuple aim of healthcare relates to obesity treatment |

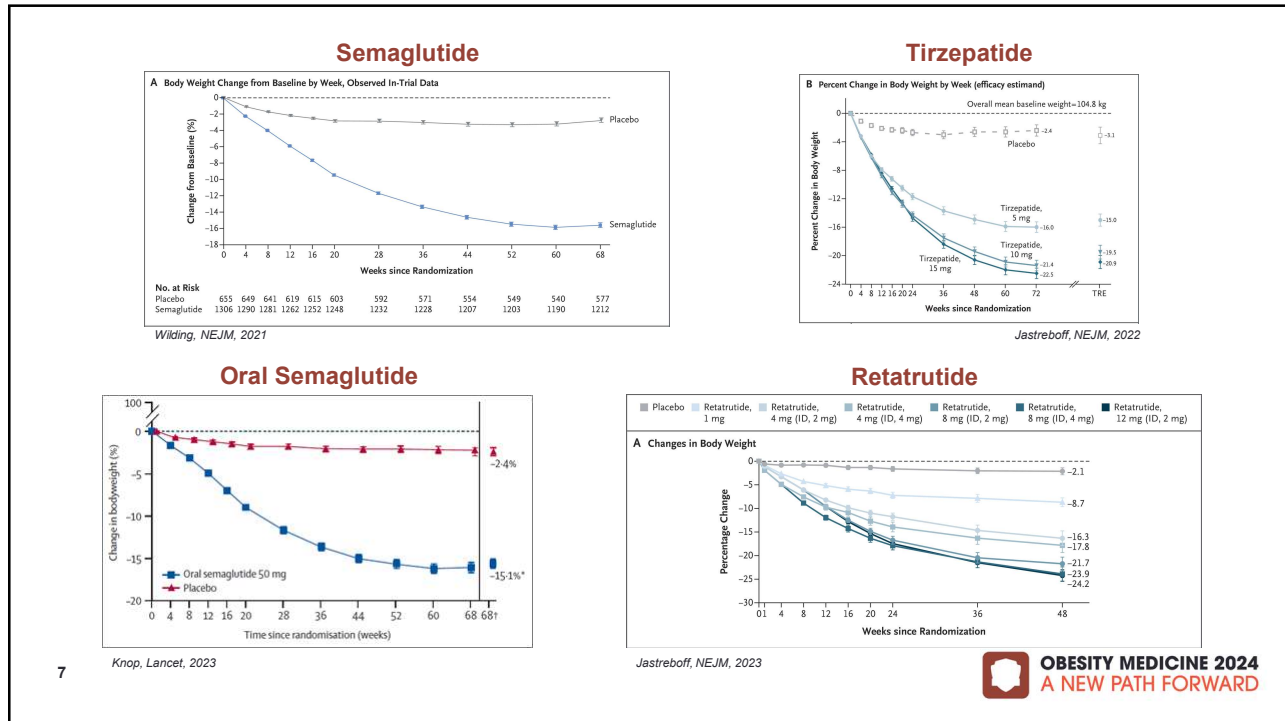4     **OBESITY MEDICINE 2024** A NEW PATH FORWARD

## Outline

- The paradigm shift
- Obesity prevalence and treatment: a quick look at one health care system
- Three major policy-level determinants of obesity treatment
- The coming price wars
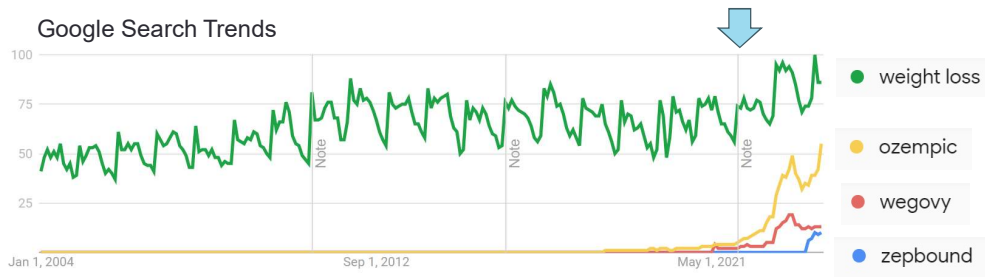- The future of obesity treatment: Achieving the Quintuple Aim

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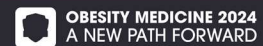A NEW PATH FORWARD

# The Paradigm Shift

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### Semaglutide

A  Body Weight Change from Baseline by Week, Observed In-Trial Data

*Wilding, NEJM, 2021*

### Tirzepatide

B  Percent Change in Body Weight by Week (efficacy estimand)

*Jastreboff, NEJM, 2022*

### Oral Semaglutide

*Knop, Lancet, 2023*

### Retatrutide

A  Changes in Body Weight

*Jastreboff, NEJM, 2023*

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# A Paradigm Shift in Public Interest in AOMs



Google Search Trends

- weight loss
- ozempic
- wegovy
- zepbound

https://trends.google.com/trends/yis/2023/GLOBAL/

**Kaiser Family Foundation Health Tracking Poll July 2023**
- 45% of US adults are interested in taking a weight loss drug
- That drops to 23% if the drug is administered as a weekly self-injection
- 59% of US adults who are currently trying to lose weight are interested

8  https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-july-2023-the-publics-views-of-new-prescription-weight-loss-drugs-and-prescription-drug-costs/

Paradigm Shifts and Price Wars

# Obesity Prevalence and Treatment in Kaiser Permanente

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## Kaiser Permanente



kaiserpermanente.org

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## Prevalence of Obesity among Adults in KP

Prevalence of BMI Categories in 2023

12.6 million members; 84% age 20+

➤ 41.2% of adults with BMI 30+

   • ~4.3 million adults with BMI 30+

➤ 17.3% of adults with BMI 35+

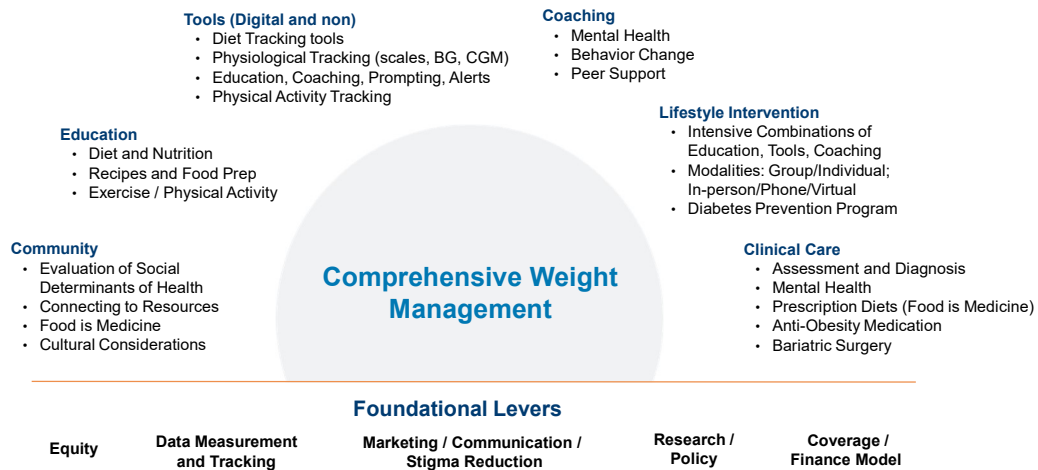   • ~1.8 million adults with BMI 35+

Pie chart categories:
- 1.7% — BMI <18.5
- 26.4% — BMI 18.5-24.9
- 30.7% — BMI 25-29.9
- 23.9% — BMI 30-34.9
- 17.3% — BMI 35+

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Unpublished internal data

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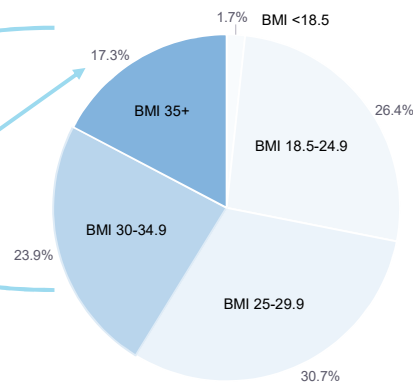
## KP Comprehensive Weight Management Program

**Tools (Digital and non)**
- Diet Tracking tools
- Physiological Tracking (scales, BG, CGM)
- Education, Coaching, Prompting, Alerts
- Physical Activity Tracking

**Coaching**
- Mental Health
- Behavior Change
- Peer Support

**Education**
- Diet and Nutrition
- Recipes and Food Prep
- Exercise / Physical Activity

**Lifestyle Intervention**
- Intensive Combinations of Education, Tools, Coaching
- Modalities: Group/Individual; In-person/Phone/Virtual
- Diabetes Prevention Program

**Community**
- Evaluation of Social Determinants of Health
- Connecting to Resources
- Food is Medicine
- Cultural Considerations

**Comprehensive Weight Management**

**Clinical Care**
- Assessment and Diagnosis
- Mental Health
- Prescription Diets (Food is Medicine)
- Anti-Obesity Medication
- Bariatric Surgery

**Foundational Levers**

| Equity | Data Measurement and Tracking | Marketing / Communication / Stigma Reduction | Research / Policy | Coverage / Finance Model |
|---|---|---|---|---|

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# Intensive Obesity Treatment

- Intensive behavioral/lifestyle interventions:
  - >40,000 adult members/year (0.8% of adults BMI 30+)
  - Diabetes prevention program and similar lifestyle programs, including digital therapeutics
- Anti-obesity medications:
  - >50,000 adult members (1% of adults BMI 30+)
  - Semaglutide (~45%) and phentermine (~40%) and (~15% other)
  - Four-fold growth in prescribing since 2019
  - 20-fold increase in spending since 2019
  - GLP-1 spending expected to exceed $1 Billion within a year; >10% of entire pharmacy budget
- Bariatric surgery:
  - >6,000 adult members/year (0.4% of adults BMI 35+)
  - 65% gastric sleeve and 35% gastric bypass

**13**  Unpublished internal data

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# How can we expand access to obesity treatment?

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## Major Determinants of Obesity Treatment Policy



Venn diagram showing three overlapping circles: Health Outcomes, Scalability, and Economic Impact, with a "?" at the center intersection.

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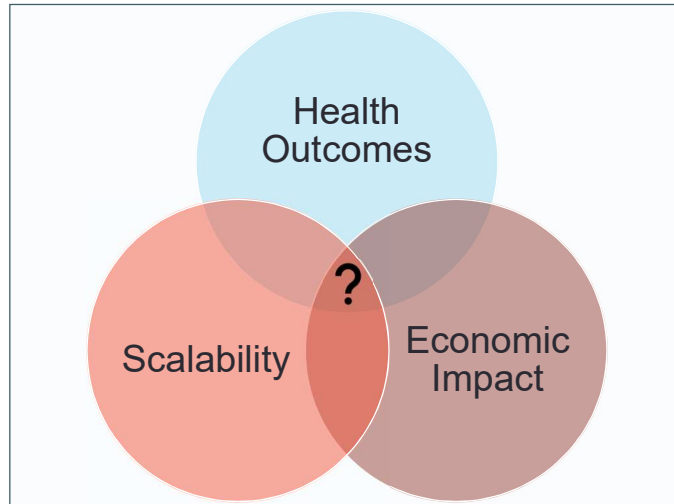
## Policy Determinant #1: Health Outcomes

**Efficacy**
- **How well does the intervention work under ideal conditions?**
- Intermediate outcomes: weight loss, blood pressure, cholesterol, HbA1c
- Hard outcomes: incident diabetes, cardiovascular events, mortality

**Safety**
- **How tolerable and safe is it?**
- Short- and long-term tolerability and safety data

**Durability**
- **Does the health impact last long-term?**
- Also, how long must the intervention be continued to be effective?

**Effectiveness**
- **How well does it work when implemented in the real world?**
- Intermediate outcomes: weight loss, improvements in blood pressure, cholesterol, HbA1c
- Hard outcomes: incident diabetes, cardiovascular events, mortality

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# Summary of Health Outcomes Evidence: Mar 2024

| | Efficacy (RCTs) | | | Safety | Durability | Effectiveness (RWE) | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | Intermediate Outcomes (e.g., wt, BP) | Hard Outcomes (DM / CVD) | Mortality | | 2+ years | Intermediate Outcomes (e.g., wt, BP) | Hard Outcomes (DM, CVD) | Mortality |
| Brief Education/ Coaching/ Counseling | ☑ | ? | ? | ☑ | ☒ | ☑ | ? | ? |
| Intensive Lifestyle Intervention | ☑ | ☑/☒ | ? | ☑ | ☑/☒ | ☑ | ? | ? |
| Anti-Obesity Medication | ☑ | ☑/☑ | ? | ☑ | ☑/☒ | ☑ | ? | ? |
| Bariatric/ Metabolic Surgery | ☑ | ☑/? | ? | ☑ | ☑ | ☑ | ☑ | ☑ |

RCTs = randomized controlled trials; RWE = real world evidence (observational)
*Wadden T, et al, Am Psychol, 2020; Lewis KH, et al, BMJ, 2024; Courcoulas AP, et al, BMJ, 2024*

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# Real World Evidence for Anti-Obesity Medications

- Among 4,255 AOM users in 2021, only 27% were adherent (had >80% fill rate) in first year of treatment
  *Leach J., Prime Therapeutics/Magellan, 2023*

- 41,223 adults treated with semaglutide or tirzepatide (67% with T2D) from May 2022-Sept 2023, mean duration of treatment was only 167 days, with 55% discontinuation  *Rodriguez P., MedRxiv preprint, 2023*
  - Among those who remained on treatment for 12 months, mean weight loss was:
    - 15.2% tirzepatide vs. 7.9% semaglutide

- Among 3,555 semaglutide users (87% with T2D) from March 2017-April 2022, 12-month weight loss was 4.4%.
  - Individuals with diabetes lost 7.4% vs. no diabetes 3.9%
  *Powell, Obesity, 2023*

- Among 4,144 liraglutide, 613 semaglutide, and 654 bupropion-naltrexone users from 2006-2020, use of GLP-1 agonists was associated with an increased risk of:  *Sodhi, JAMA Network, 2023*
  - Pancreatitis (adjusted hazard ratio (HR): **9.1** [95% CI, 1.3-66.0]),
  - Bowel obstruction (HR: **4.2** [95% CI, 1.02-17.4]),
  - Gastroparesis (HR: **3.7** [95% CI, 1.2-11.9]

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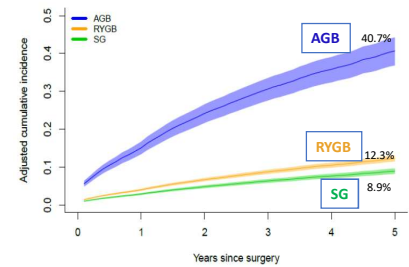
# The PCORnet Bariatric Study Collaborative

- Weight Loss: RYGB > SG > AGB
- DM Relapse: RYGB > SG > AGB
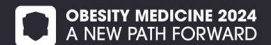- Reoperation: SG > RG > AGB
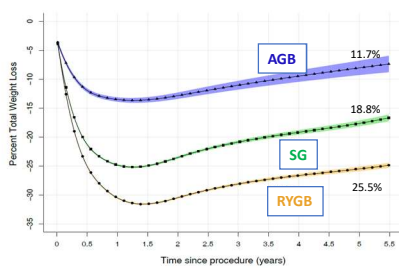


*Arterburn, Coleman, Courcoulas, McTigue. Ann Int Med. 2018*
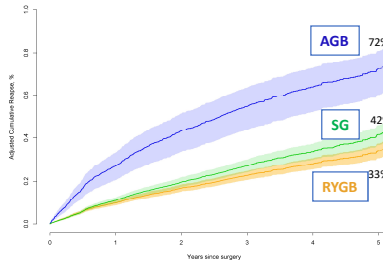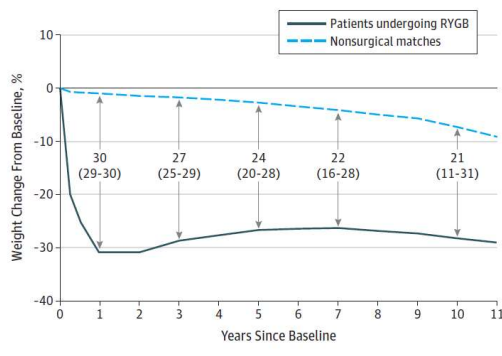
*McTigue, Coleman, Courcoulas, Arterburn. JAMA Surg. 2019*

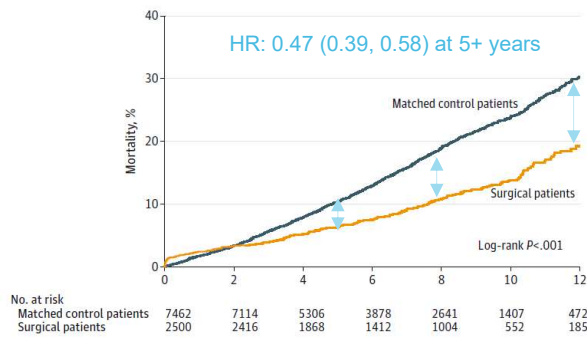*Courcoulas, Coleman, Arterburn, McTigue, Tavakkoli. 2019*

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# Department of Veterans Affairs

- 28% Total Weight Loss at 10 years after RYGB
- 50% Improvement Survival over Usual Care



*Maciejewski, Arterburn, Smith, Livingston, Olsen. JAMA Surgery. 2016*

*Maciejewski, Olsen, Livingston, Eid, Smith, Arterburn. JAMA. 2015*

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# Kaiser Permanente
and the Health Care Systems Research Network (HCSRN)

- 40% Lower Macrovascular Events
- 59% Lower Microvascular Events
- 33% Lower Incident Cancers

HR: 0.60 (0.42, 0.86)

Log-rank test: P < .001

HR: 0.41 (0.34, 0.48)

HR: 0.67 (0.60, 0.74)
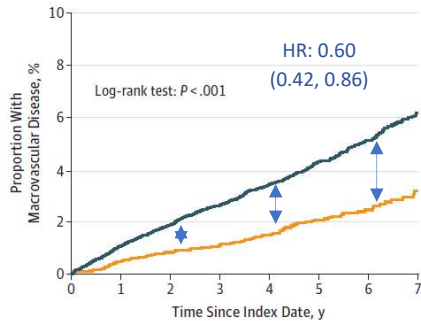
*Fisher, Arterburn, Coleman, et al. JAMA. 2018*
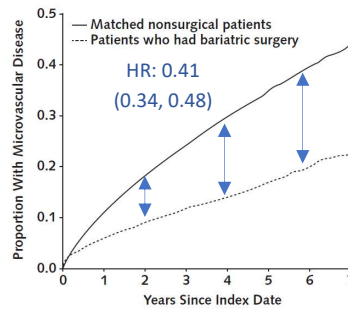
*O'Brien, Coleman, Fisher, Arterburn. Ann Int Med. 2018*
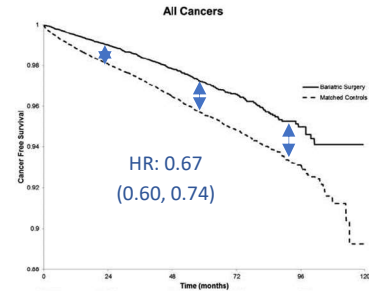
*Schauer DP, Yenemula, Arterburn. Ann Surg. 2017*

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We need more data on hard outcomes, durability, and real-world effectiveness to inform policy decisions

*(particularly for AOMs)*
*(and comparing AOMs to surgery)*

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# SURMOUNT-MMO

- N=15,000 patients without T2D, aged ≥40 with established CVD or ≥50 (≥55 for women) with multiple CV risk factors

- Tirzepatide vs. Placebo

- **Primary Outcome:** time to first occurrence of composite (all-cause death, nonfatal MI, nonfatal stroke, coronary revascularization, or heart failure)

- Start date: Oct 2022
- Expected completion: Oct 2027
- Clinical Trials.gov NCT05556512

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## Comparative Effectiveness of AOMs Using Real-World Administrative Data & Target Trial Methodology: The CARAT[2] Study

Retrospective, matched comparison of tirzepatide, semaglutide, liraglutide, phen/top, nal/bupr, and phentermine from 2012-2024

>350,000 AOM users from Marketscan (nationwide commercial claims database); 4 specific aims:

1. **Major cardiovascular events**
2. **Clinical outcomes**, including **incidence of type 2 diabetes**, **hypertension and dyslipidemia**
3. **Health care services use and associated costs**
4. **Exploration of heterogeneity**: examine whether key patient characteristics (**age, sex, baseline T2D, comorbidity burden**) modify the risks or benefits, to help tailor therapy in clinical settings
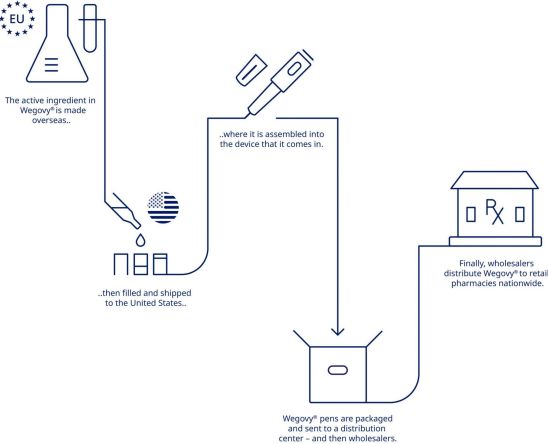
Funded by NHLBI in December 2023; R01 HL171293

Expected Completion: Aim 2 and 3, 2025; Aim 1, 2026; Aim 4, 2027

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# Supply chain will impact real-world evidence.



The active ingredient in Wegovy® is made overseas..

..where it is assembled into the device that it comes in.

..then filled and shipped to the United States..

Wegovy® pens are packaged and sent to a distribution center – and then wholesalers.

Finally, wholesalers distribute Wegovy® to retail pharmacies nationwide.

www.novonordisk-us.com/supply-update.html

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# Policy Determinant #2: Scalability

• Scalability = ability of a health innovation shown to be efficacious on a small scale and/or under controlled conditions to be expanded under real-world conditions to reach a greater proportion of the eligible population, while retaining effectiveness.

*Milat AJ, et al. Health Promot Int. 2013*

| Brief Education/ Coaching/Counseling | Intensive Lifestyle Intervention | Anti-Obesity Medication | Bariatric/Metabolic Surgery |
|---|---|---|---|
| ★ ★ ★ | ★ ★ (★)* | ★ ★ ★ (★)* | ★ |
| ★ | ★ | ★ ★ (★)† | ★ |

*Digital > Group > Individual

*How much lifestyle support is needed?

† More RWE needed

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**Anti-Obesity Medication is the most scalable obesity treatment**

*(even more so if it can be effectively delivered with low-intensity lifestyle support)*

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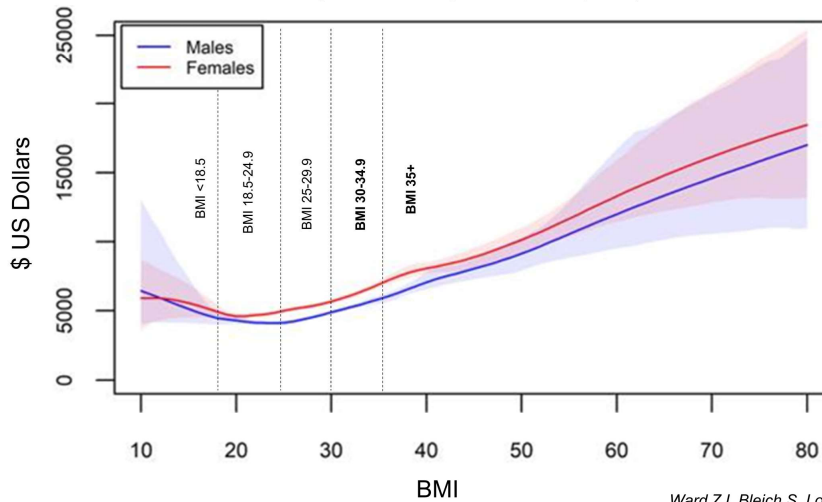# Policy Determinant #3: Economic Impact

- Cost = per unit cost of the intervention

| Brief Education/ Coaching/Counseling | Intensive Lifestyle Intervention | Anti-Obesity Medication | Bariatric/Metabolic Surgery |
|---|---|---|---|
| $-$$/yr | $$$/yr | $$$-$$,$$$/yr | $$,$$$ 1x |

- Budget Impact = total cost of implementing the intervention in a defined population =
  - unit cost *x* size of the population taking the intervention
- Cost Offsets = any cost savings from implementing the treatment

- Most health insurance plans' time horizon of interest is <u>5 years</u>
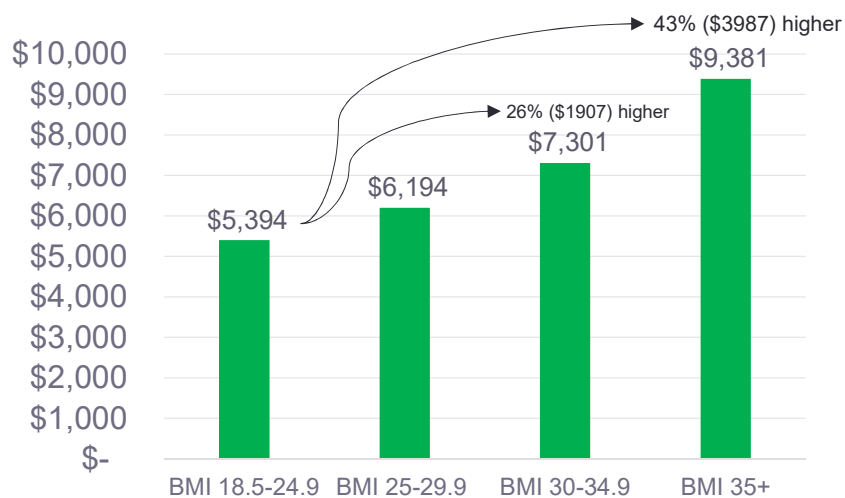- US Congressional Budget Office time horizon of interest is <u>10 years</u>
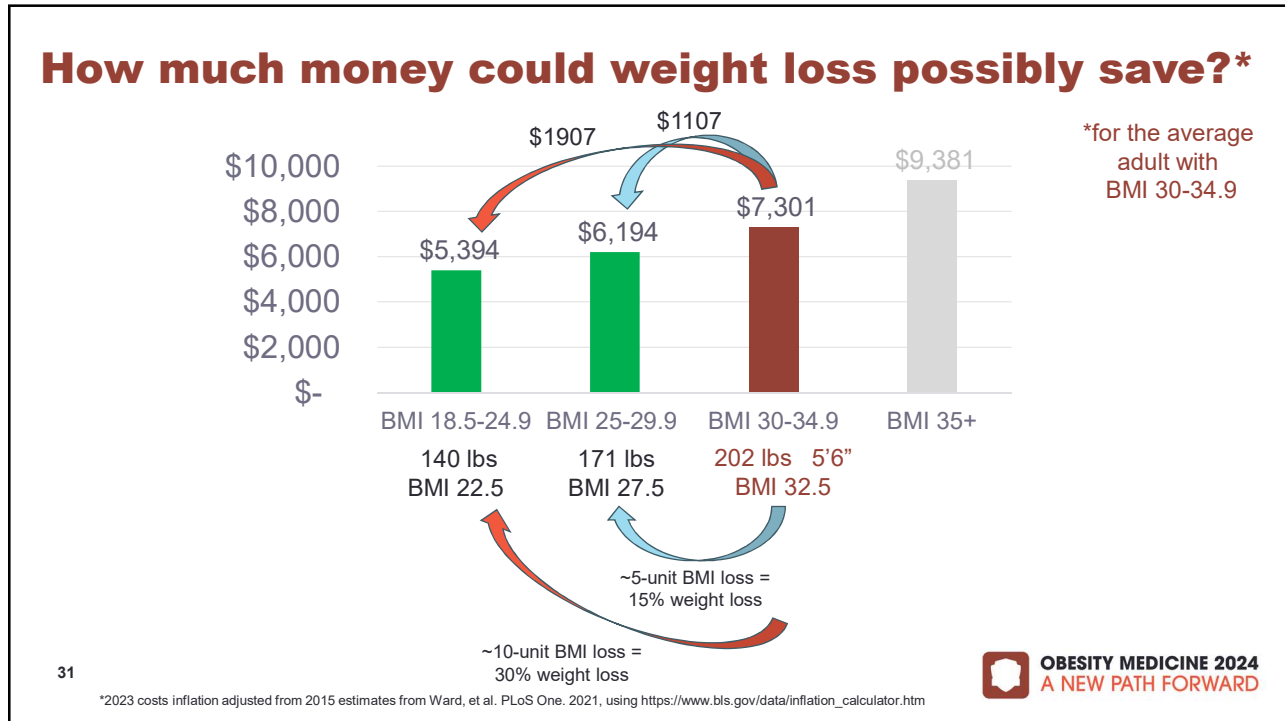
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## U.S. Medical Expenditure Panel Survey (MEPS) 2011-2016

Per capita annual expenditures, $ (2015)



*Ward ZJ, Bleich S, Long M, Gortmaker S. PLoS One. 2021*

## Adult Per Capita Medical Expenditures by BMI, 2023*



43% ($3987) higher

26% ($1907) higher

$5,394 — BMI 18.5-24.9
$6,194 — BMI 25-29.9
$7,301 — BMI 30-34.9
$9,381 — BMI 35+

30   *2023 costs inflation adjusted from 2015 estimates from Ward, et al. PLoS One. 2021, using https://www.bls.gov/data/inflation_calculator.htm

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## How much money could weight loss possibly save?*

$1907   $1107

$10,000
$8,000
$6,000
$4,000
$2,000
$-

$5,394   $6,194   $7,301   $9,381

*for the average adult with BMI 30-34.9

BMI 18.5-24.9   BMI 25-29.9   BMI 30-34.9   BMI 35+
140 lbs          171 lbs         202 lbs  5'6"
BMI 22.5         BMI 27.5        BMI 32.5

~5-unit BMI loss = 15% weight loss

~10-unit BMI loss = 30% weight loss

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*2023 costs inflation adjusted from 2015 estimates from Ward, et al. PLoS One. 2021, using https://www.bls.gov/data/inflation_calculator.htm

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**For Anti-Obesity Medication* to be cost-saving among adults with BMI 30-34.9, it would have to cost <$1,907 per year, reduce body weight by 15-30%, and lower costs of health care to those of adults with BMI <25.**

*Or any other obesity intervention

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2023 costs inflation adjusted from 2015 estimates from Ward, et al. PLoS One. 2021, using https://www.bls.gov/data/inflation_calculator.htm

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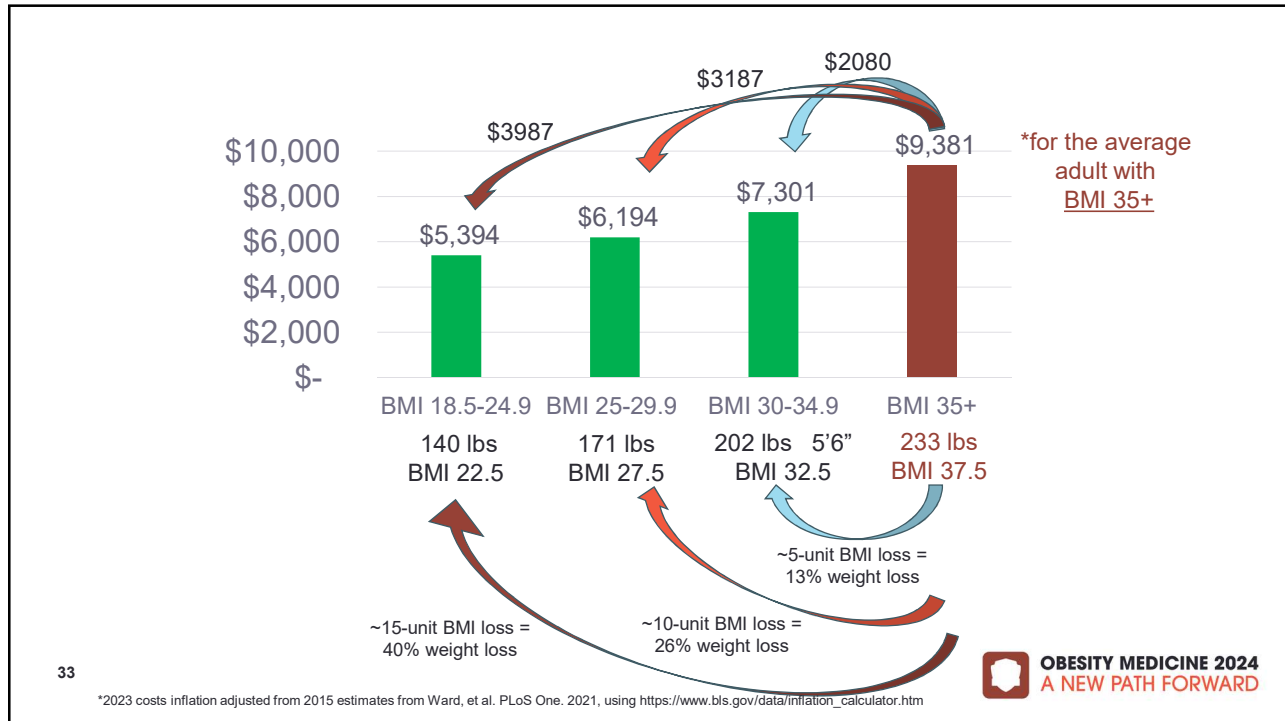
**For Anti-Obesity Medication to be cost-saving among adults with BMI 35+, it would have to cost <$3,187 per year, reduce body weight by ~13-26%, and lower costs of health care to those of adults with BMI 25-29.9.**
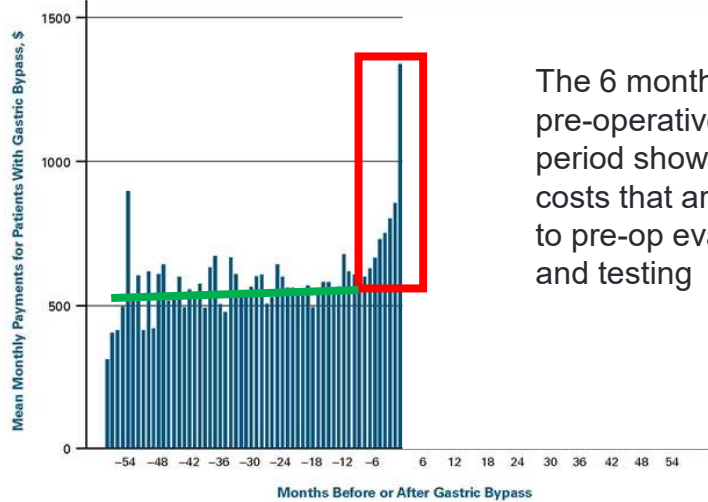
Paradigm Shifts and Price Wars

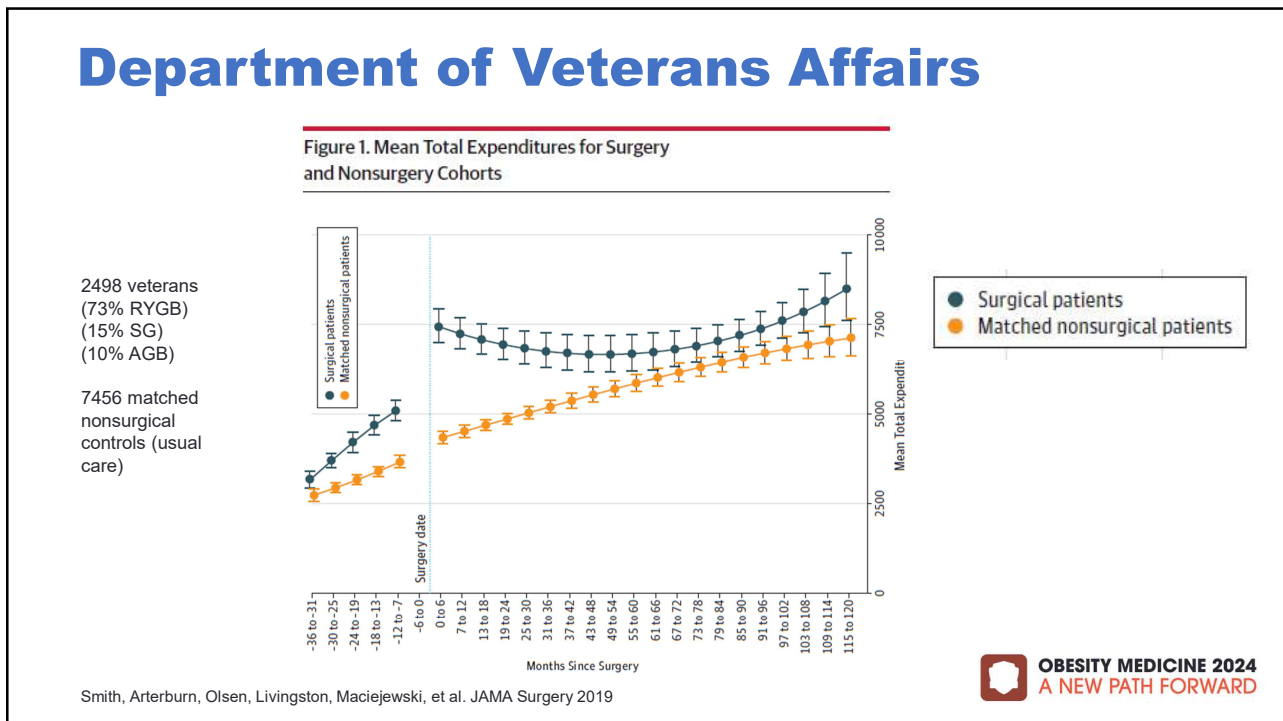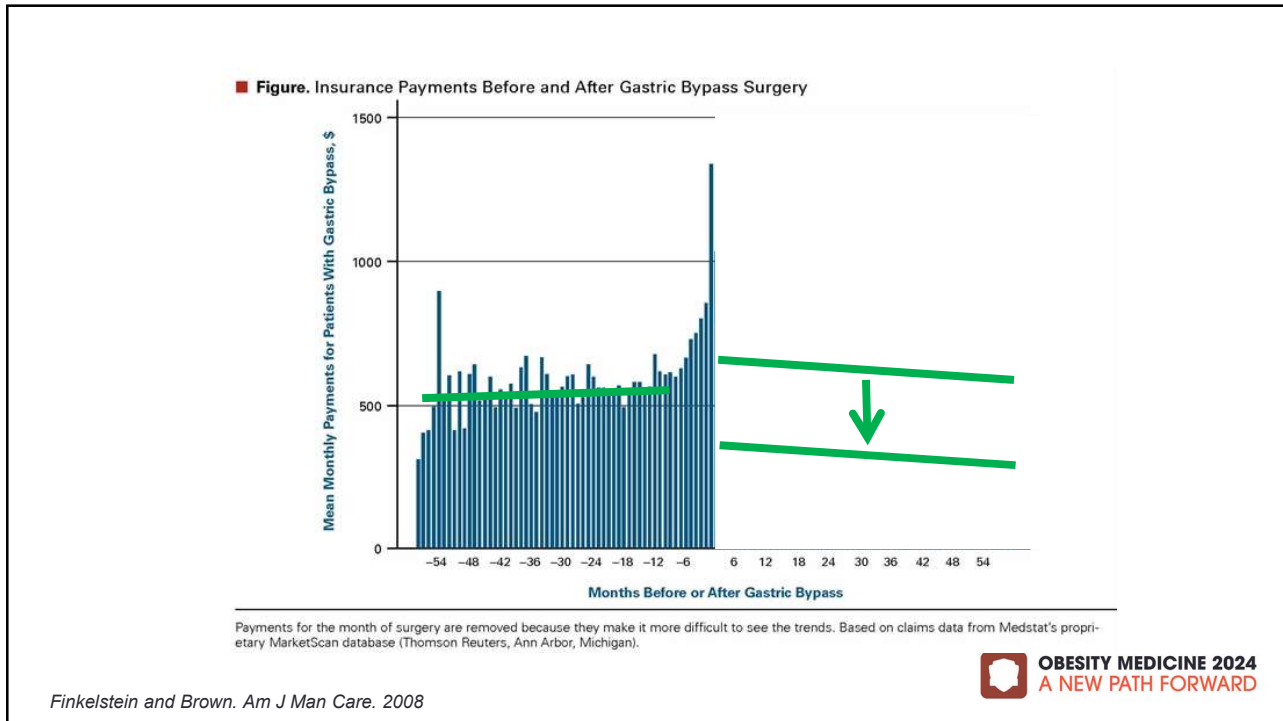# Key question: do obesity treatments lower health care costs?

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**Figure.** Insurance Payments Before and After Gastric Bypass Surgery

The 6 month pre-operative period shows escalating costs that are likely due to pre-op evaluation and testing

Payments for the month of surgery are removed because they make it more difficult to see the trends. Based on claims data from Medstat's proprietary MarketScan database (Thomson Reuters, Ann Arbor, Michigan).

*Finkelstein and Brown. Am J Man Care. 2008*

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**Figure. Insurance Payments Before and After Gastric Bypass Surgery**

Payments for the month of surgery are removed because they make it more difficult to see the trends. Based on claims data from Medstat's proprietary MarketScan database (Thomson Reuters, Ann Arbor, Michigan).

*Finkelstein and Brown. Am J Man Care. 2008*

# Department of Veterans Affairs



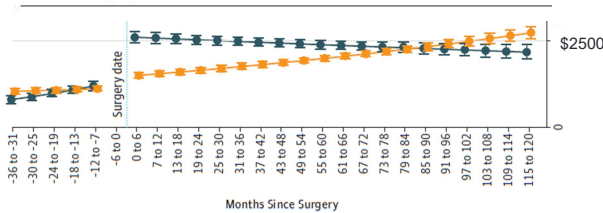Figure 1. Mean Total Expenditures for Surgery and Nonsurgery Cohorts

2498 veterans
(73% RYGB)
(15% SG)
(10% AGB)

7456 matched nonsurgical controls (usual care)

Smith, Arterburn, Olsen, Livingston, Maciejewski, et al. JAMA Surgery 2019

**Department of Veterans Affairs**

Figure 3. Mean Inpatient Expenditures for Surgery and Nonsurgery Cohorts

Figure 4. Mean Outpatient Pharmacy Expenditures for Surgery and Nonsurgery Cohorts
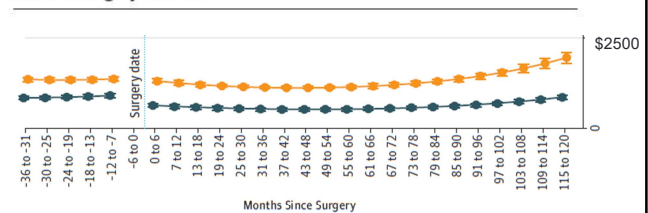
Surgical patients
Matched nonsurgical patients

Smith, Arterburn, Olsen, Livingston, Maciejewski, et al. JAMA Surgery 2019

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**PESOS study: R01 DK12530**
**Predicting Expenditures in Subgroups after Obesity Surgery**

- Goals:
  - 1) To compare 5-year health expenditures between patients with severe obesity who do vs. do not undergo metabolic/bariatric surgery from 2012-2018 in Kaiser Permanente
  - 2) … in patients with severe obesity and T2DM
  - 3) To identify clinical subgroups that may have more favorable cost trajectories

- Study Design
  - Matched retrospective cohort using Kaiser Permanente data from Washington and Southern California

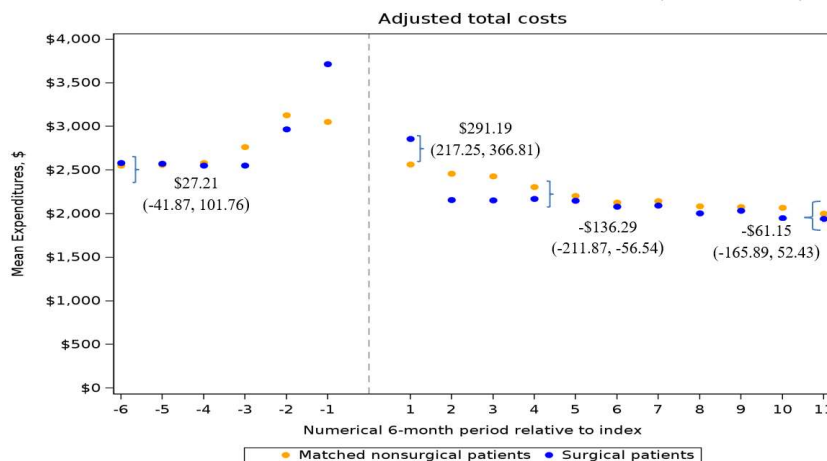- Collaborators: Maciejewski (Co-PI), Kawatkar, Smith, Zepel, Sloan, Kane

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## Methods: Cohort Matching

- Cohorts
  - **25,523** RYGB and SG patients from **1/2012 - 12/2019**
  - **1,269,362** potential matches based on BMI
- Exact Matching
  - Demographics: age (+/- 5 years), sex, race
  - Clinical factors: BMI, diabetes status, insulin use, count of comorbid conditions
  - Insurance type
  - Utilization in 6-12 months prior to surgery: hospitalization, ER visits, outpatient visits
  - Study site
- 3:1 Match, using sequential stratification
  - RYGB (**n=7,127**) and matched (**n=20,770**) cohort
  - SG (**n=15,571**) and matched (**n=45,999**) cohort

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## Total Expenditures



Adjusted total costs

$27.21
(-41.87, 101.76)

$291.19
(217.25, 366.81)

-$136.29
(-211.87, -56.54)

-$61.15
(-165.89, 52.43)

Mean Expenditures, $

Numerical 6-month period relative to index

Matched nonsurgical patients • Surgical patients

Excellent pre-op cost match

But no significant difference at 3 or 5 years

*Unpublished data*

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Paradigm Shifts and Price Wars

It will be challenging for any obesity treatment to <u>save money</u> in a 5-10 year time horizon for the <u>average patient</u> with obesity.

Some clinical <u>subgroups</u> may be cost saving.

Once prices of newer AOMs fall significantly, the chances of cost savings will increase.

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# The coming price wars...

- Current list price of anti-obesity medications

| | Average 30 day cost | Average 1 year cost |
|---|---|---|
| Phentermine | $10 | $120 |
| Phen/Top ER | $216 | $2,592 |
| Nal/Bupr ER | $513 | $6,156 |
| Liraglutide | $1,269 | $15,228 |
| Semaglutide | $1,349 | $16,188 |
| Tirzepatide | $1,060 | $12,720 |

- Phen + top & nal + bupr generics
- Liraglutide coming off patient soon...



Key:
- ⑤ Phase 3
- ④ Phase 2
- ③ Phase 1
- ②⑩ Pre clinical

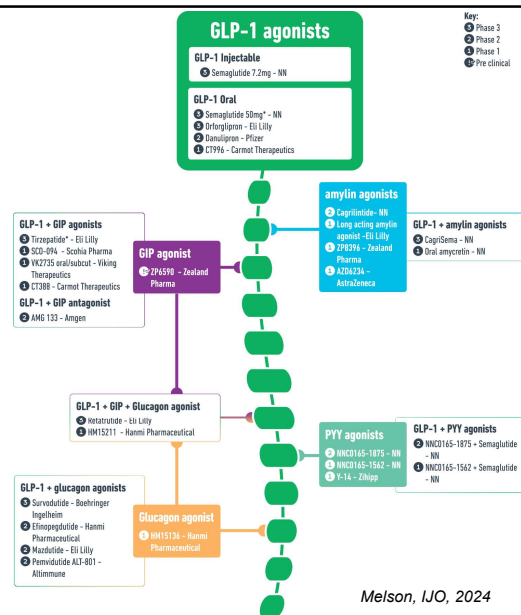**GLP-1 agonists**
GLP-1 Injectable
- ⑤ Semaglutide 7.2mg – NN

GLP-1 Oral
- ⑤ Semaglutide 50mg* – NN
- ⑤ Orforglipron – Eli Lilly
- ② Danuglipron – Pfizer
- ① CT996 - Carmot Therapeutics

**amylin agonists**
- ⑤ Cagrilintide– NN
- ① Long acting amylin agonist –Eli Lilly
- ① ZP8396 – Zealand Pharma
- ① AZD4234 - AstraZeneca

**GLP-1 + amylin agonists**
- ⑤ CagriSema – NN
- ① Oral amycretin - NN

**GLP-1 + GIP agonists**
- ⑤ Tirzepatide* – Eli Lilly
- ⑤ SCO-094 – Sciohia Pharma
- ④ VK2735 oral/subcut – Viking Therapeutics
- ① CT388 - Carmot Therapeutics

**GIP agonist**
- ② ZP6590 – Zealand Pharma

**GLP-1 + GIP antagonist**
- ② AMG 133 - Amgen

**GLP-1 + GIP + Glucagon agonist**
- ④ Retatrutide – Eli Lilly
- ① HM15211 - Hanmi Pharmaceutical

**GLP-1 + glucagon agonists**
- ⑤ Survodutide – Boehringer Ingelheim
- ① Efinopegdutide – Hanmi Pharmaceutical
- ② Mazdutide – Eli Lilly
- ② Pemvidutide ALT-801 – Altimmune

**Glucagon agonist**
- ① HM15136 – Hanmi Pharmaceutical

**PYY agonists**
- ⑤ NNC0165-1875 – NN
- ⑤ NNC0165-1562 – NN
- ① Y-14 - Zihipp

**GLP-1 + PYY agonists**
- ② NNC0165-1875 + Semaglutide – NN
- ① NNC0165-1562 + Semaglutide – NN

*Melson, IJO, 2024*

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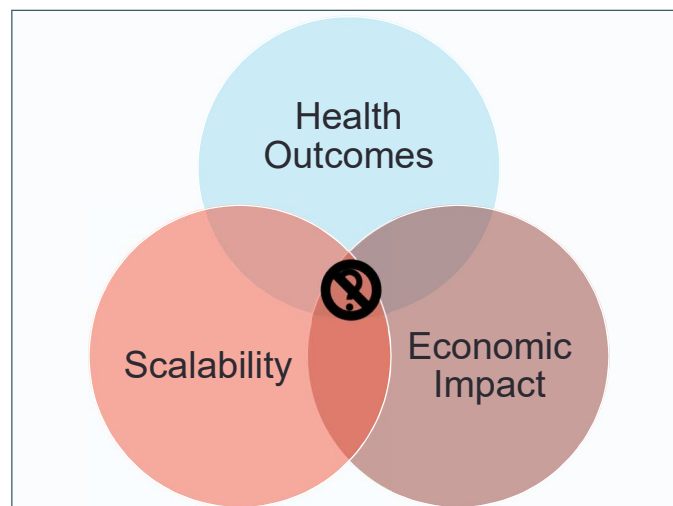
# Step Therapy Approach to AOMs

- Consider step therapy beginning with less expensive medications, while allowing patients and providers to choose from multiple options
- Allow consideration of combination therapy

Phentermine ⟷ Phen / top ⟷ Nal / bupr ⟷ Orlistat

Liraglutide*

Semaglutide ⟷ Tirzepatide

*generic

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# Major Determinants of Obesity Treatment Policy

Health Outcomes

Scalability

Economic Impact

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Paradigm Shifts and Price Wars
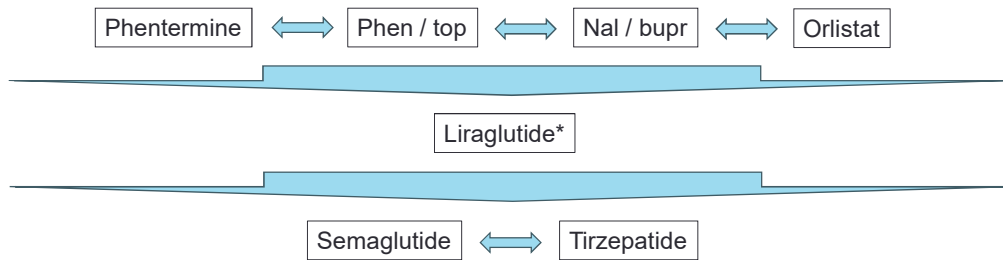
# The Quintuple Aim for Health Care Improvement

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## Quintuple Aim for Health Care Improvement

Improving Population Health

Reducing Costs

Enhancing Patient Care Experience

Fostering Care-Team Wellbeing

Health Equity

54   *Nundy, JAMA Network, 2022*

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## Quintuple Aim for Obesity Care

| | |
|---|---|
| **Improving Population Health** | • Scalable interventions that have long-term evidence of improved health outcomes |
| **Reducing Costs** | • Possible for some clinical subgroups; will improve as price of newer AOMs falls<br>• Until then, focus on improving affordability and treating those most likely to benefit |
| **Enhancing Patient Care Experience** | • Reducing weight stigma in health care |
| **Fostering Care-Team Wellbeing** | • Designing care pathways that are feasible and reduce clinician burnout |
| **Health Equity** | • Insuring opportunity for all people to access effective treatment |

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## The Bright and Bumpy Future of Obesity Treatment



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