# ANTI-OBESITY MEDICATIONS IN THE TREATMENT OF OVERWEIGHT AND OBESITY:

## THE DISCONNECT BETWEEN EVIDENCE AND ACCESS

# Speakers


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# Obesity: Declared a disease by the American Medical Association in 2013


"Obesity is defined as a **chronic**, **progressive**, **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**."

Obesity Medicine Association, 2013

# Obesity: Consensus Definition

Defined by the following:

- Overweight: Body Mass Index >25 – 29.9 $kg/m^2$
- Class I Obesity: Body Mass Index >30 – 34.9 $kg/m^2$
- Class II Obesity: Body Mass Index 35 – 39.9 $kg/m^2$
- Class III: Body Mass Index >40 $kg/m^2$

- Ongoing discussion and debate about the utility of BMI- variations exist for persons of varying ethnicities; Body Composition might be more meaningful

# Texas Diabetes Council

## Council Statements

**Vision:** A Texas free of diabetes and its complications

**Mission:** To effectively reduce the health and economic burdens of diabetes in Texas

**Position:** Specific initiatives to improve outcomes and minimize barriers to impact diabetes care in Texas communities for improved delivery of care through system reforms that lead to increased access and high quality, affordable, effective, and efficient care for people with diabetes and coordination of State services.

# TDC Recommendations in 2023 State Plan

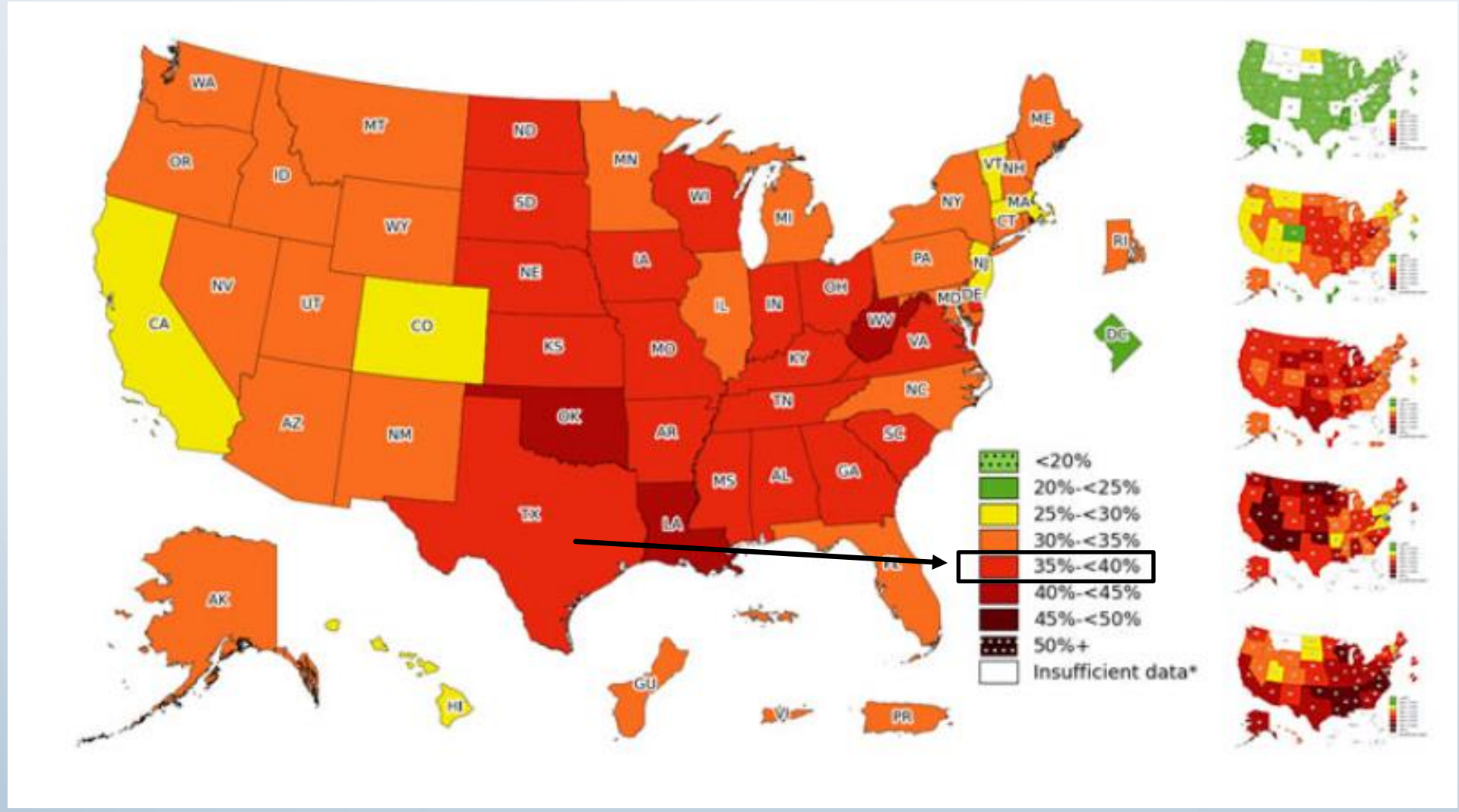
**Texas Diabetes Council Recommendations**

- Update the document required by the Texas Health and Safety Code, Section 168.005, that explains how to train school professionals who are not diabetes professionals
- Encourage Texas Medicaid to add all FDA-approved weight and obesity medications to the Medicaid formulary
- Promote the utilization of pharmacists as healthcare providers who help manage chronic disease and deliver patient care services, as well as support increased access to medications and improve medication adherence
  - Evaluate existing education materials for healthcare providers and PWD on the role of the pharmacist to improve medication use and adherence; explore opportunities to create an educational campaign if existing materials prove insufficient
  - Create a gold standard for pharmacist patient care services and medication access
- Encourage HHSC to amend 26 TAC Section 557.105 so that diabetes medications requiring injections can be given by medication aides for those who need additional assistance

# More from TDC 2023 Report

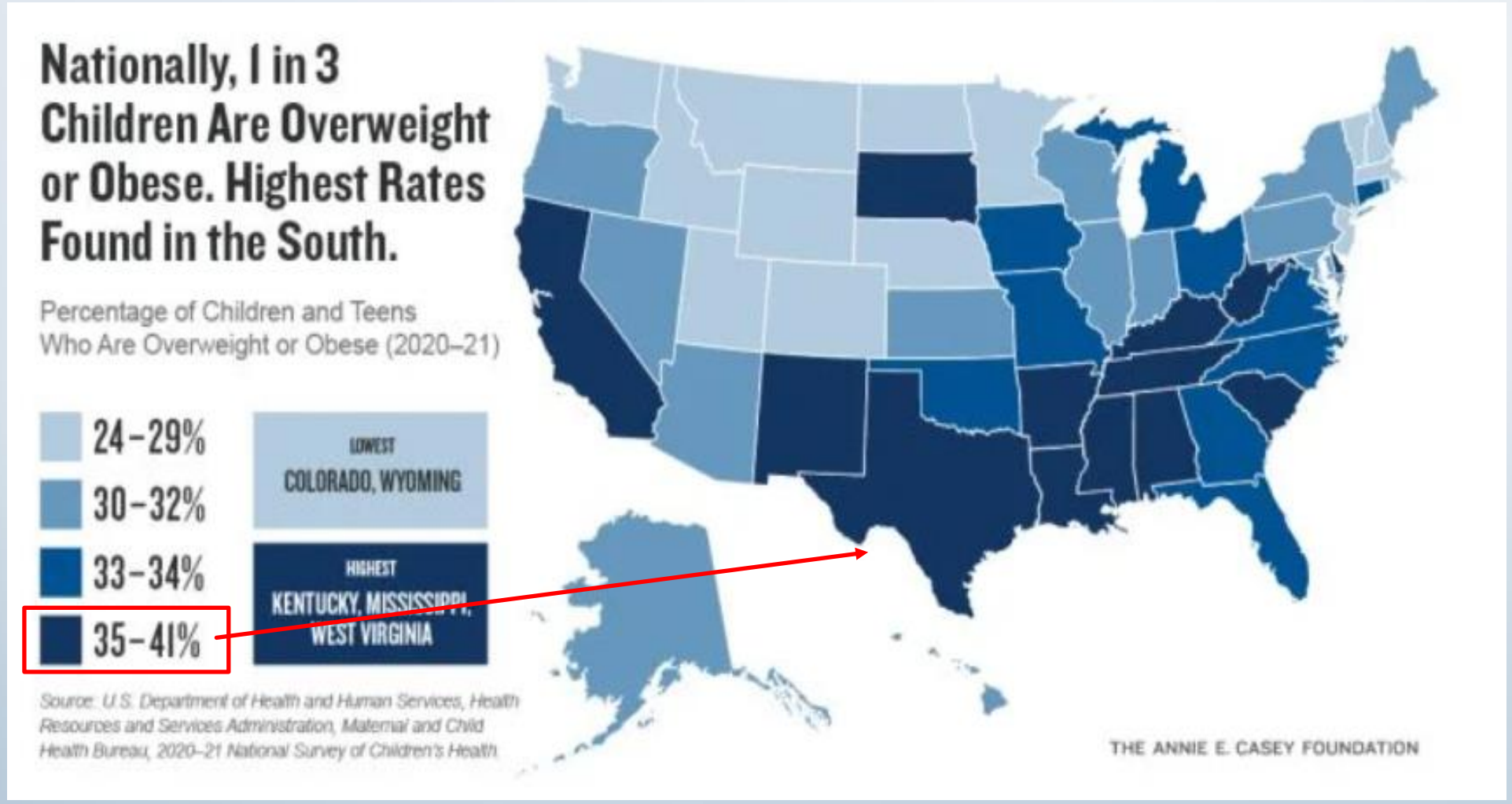
- On pg. 21 of the report, TDC states: "Currently, there are **no known statutes or regulations to preclude states from covering treatment for obesity through Medicaid or private insurance.**"
- **In 2004**, the Centers for Medicare and Medicaid Services **removed language** from the Medicare Coverage Issues Manual that state that ***obesity was not an illness***."
- We also know that **Texas Medicaid has already gotten an approval to remove the CMS exclusion** around **"selected agents when used for anorexia, weight loss, weight gain"**: 23-0009.pdf (texas.gov) effective June 23, 2023

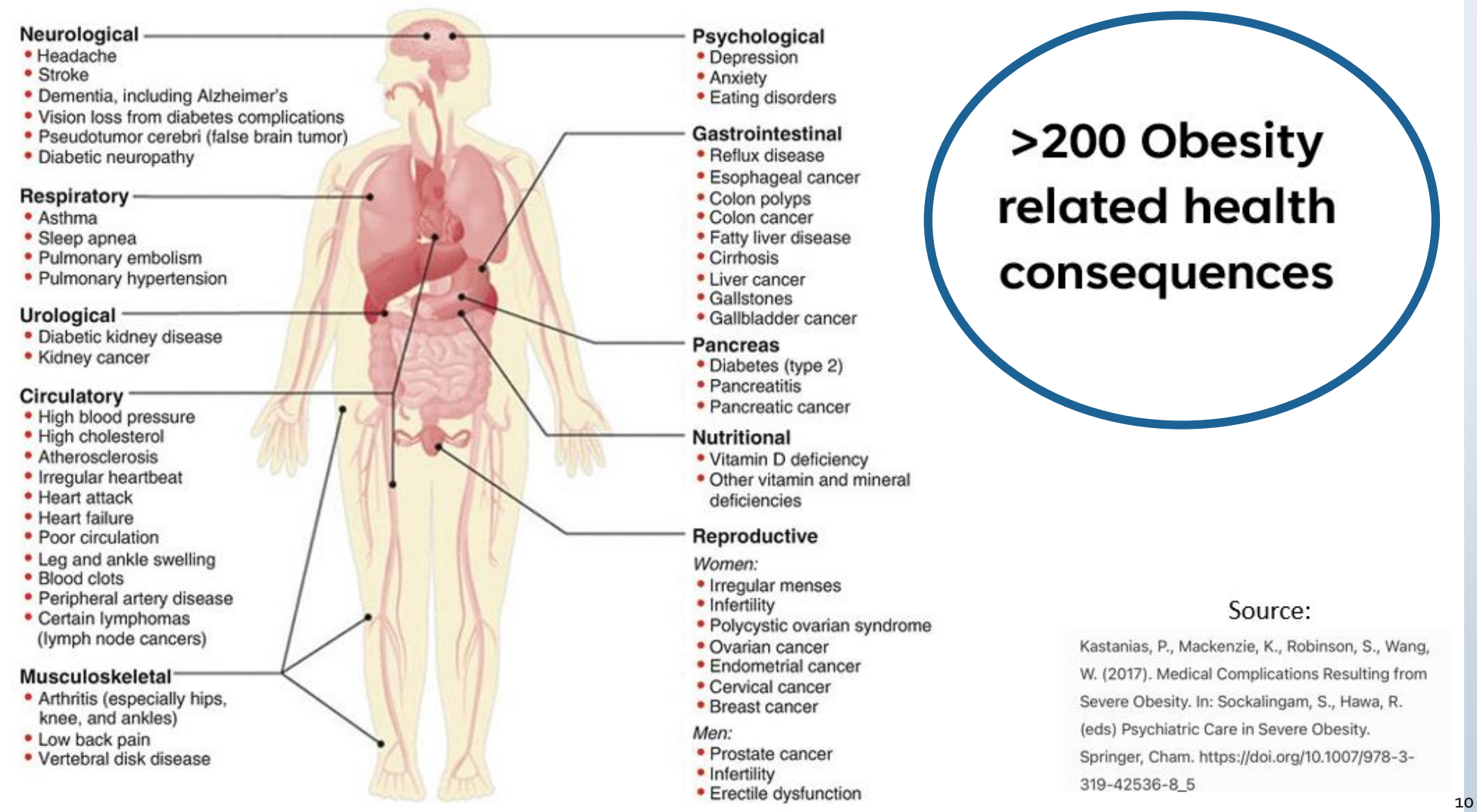
# Adult Obesity Prevalence: as of Sept 2023




CDC. *Adult Obesity Prevalence Maps*. https://www.cdc.gov/obesity/data/prevalence-maps.html#print

# Pediatric Obesity Prevalence-2021






**>200 Obesity related health consequences**

Source:

Kastanias, P., Mackenzie, K., Robinson, S., Wang, W. (2017). Medical Complications Resulting from Severe Obesity. In: Sockalingam, S., Hawa, R. (eds) Psychiatric Care in Severe Obesity. Springer, Cham. https://doi.org/10.1007/978-3-319-42536-8_5

# OBESITY RELATED CANCERS

accounted for about 40 percent of all cancers diagnosed in the United States

**Overall, cancer rates have decreased by 13% but obesity related cancer rates have increased by 7%**

- Meningioma
- Multiple myeloma
- Adenocarcinoma of the esophagus
- Cancers of the thyroid
- Postmenopausal breast
- Gallbladder
- Stomach
- Liver
- Pancreas
- Kidney
- Ovaries
- Uterus
- Colon/Rectum (colorectal)


*Source: Centers for Disease Control and Prevention*

10

11

Division of Cancer Prevention and Control. CDC. Obesity and Cancer. https://www.cdc.gov/cancer/obesity/index.htm

# We readily treat ***ALL*** of these diseases…

## Why is obesity treatment any different?

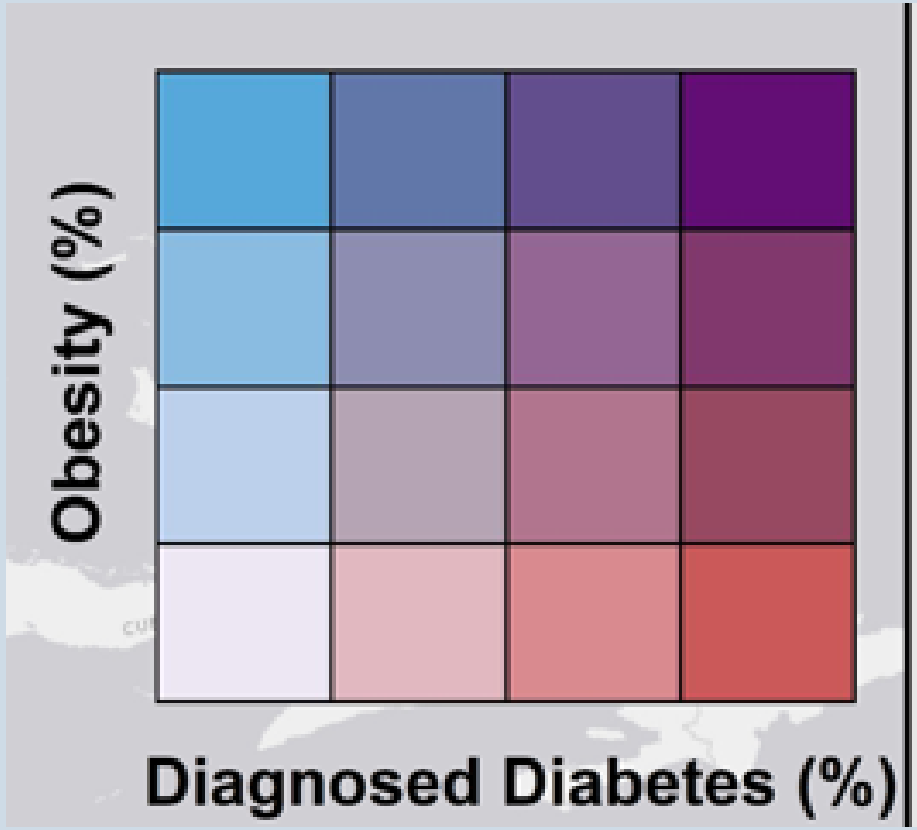
- Negative bias and stigma
- **Many** still believe it is a disease of choice, lack of will power, due to a character flaw
- Cost concerns are valid…but let's look at the data
- It's the **ONLY** chronic medical disease that can be excluded in federal/state/commercial based insurance programs

**THIS IS WEIGHT BASED DISCRIMINATION!!!**

- Obesity affects all socioeconomic groups→those of **lower income** and **people of color** being hit the hardest

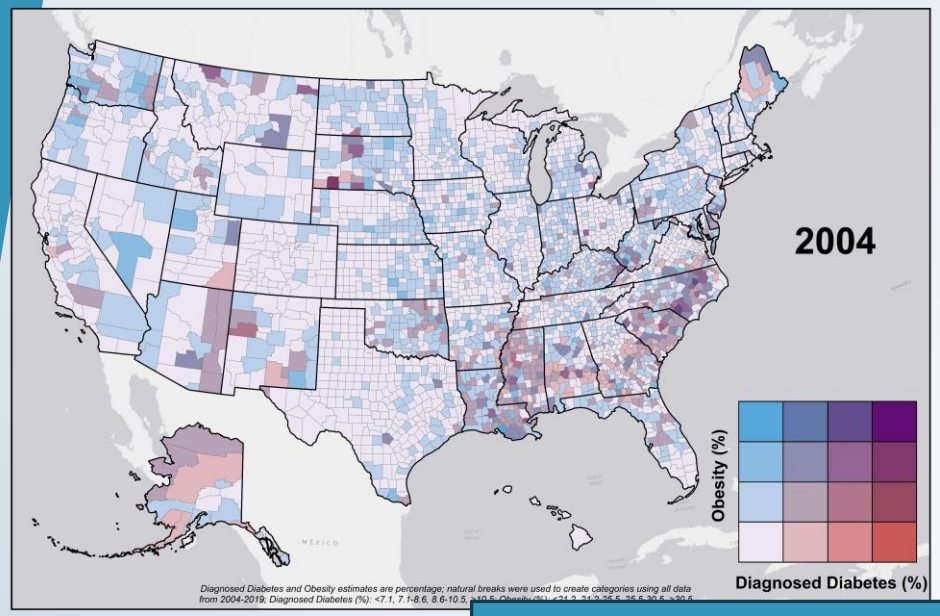
# Map of diagnosed diabetes vs obesity by county among US adults, 2019

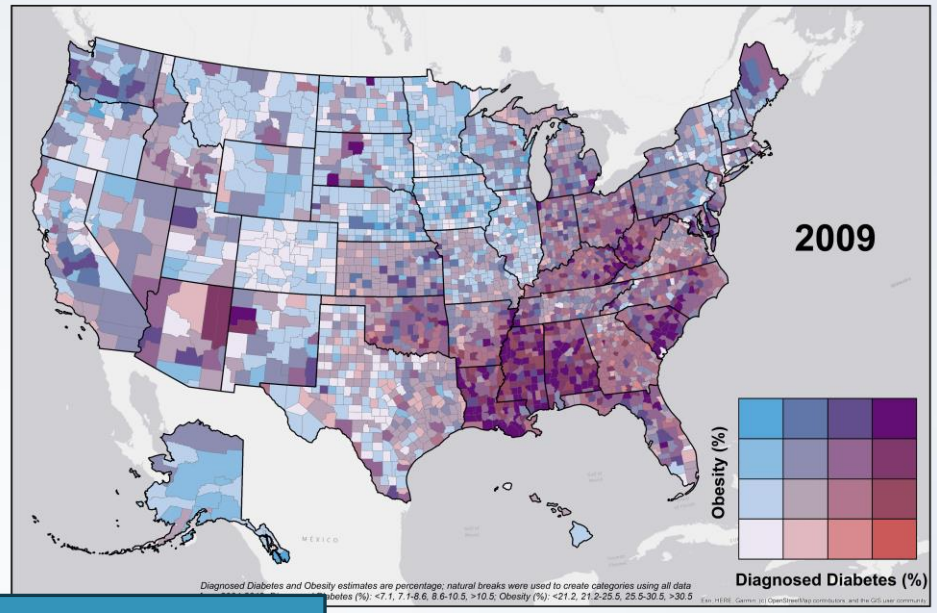
## Age-Adjusted Prevalence of Diagnosed Diabetes and Obesity Among Adults, by County, United States (2004, 2009, 2014, 2019)

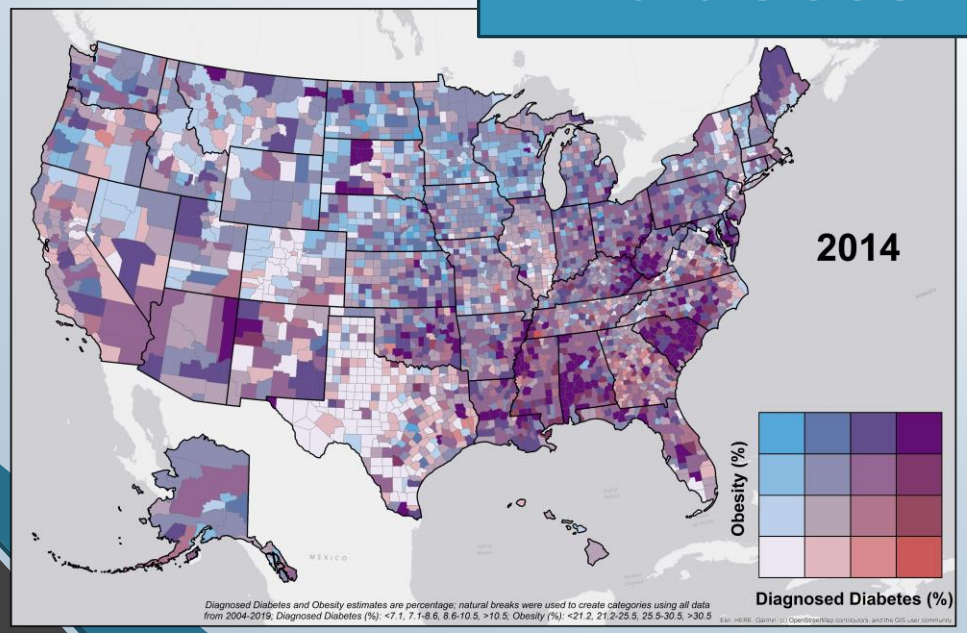


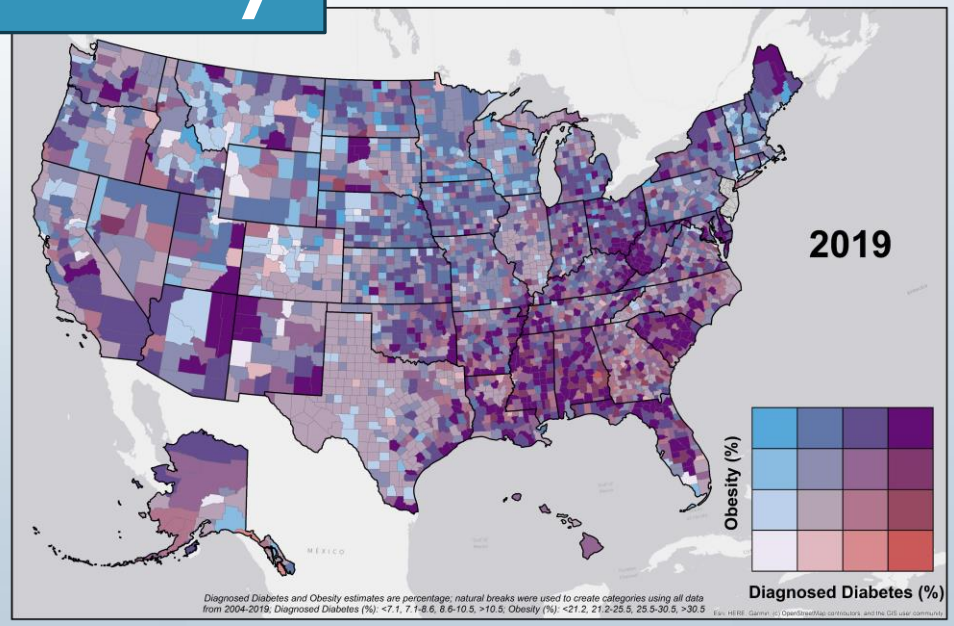

CDC. Diabetes and Obesity Maps. https://www.cdc.gov/diabetes/data/center/slides.html

# Diabetes & Obesity






CDC. Diabetes and Obesity Maps. https://www.cdc.gov/diabetes/data/center/slides.html

# US Adult Diabetes Prevalence

## Fast Facts on Diabetes

### Diabetes

- **Total:** 38.4 million people have diabetes (11.6% of the US population)
- **Diagnosed:** 29.7 million people, including 29.4 million adults
- **Undiagnosed:** 8.7 million people (22.8% of adults are undiagnosed)

### Prediabetes

- **Total:** 97.6 million people aged 18 years or older have prediabetes (38.0% of the adult US population)
- **65 years or older:** 27.2 million people aged 65 years or older (48.8%) have prediabetes

11.6
+22.8
+38.0
---
=72.4%

% of US Citizens w/Pre-Diabetes And Diabetes



CDC. *National Diabetes Statistics Report*. https://www.cdc.gov/diabetes/data/statistics-report/index.html

# Texas Diabesity: Diabetes & Obesity

**Obesity**

- 70% of Texans are overweight*
- Of these, 50% meet criteria for obesity*
- Childhood obesity has tripled in the past 40 years (US data)***

*2022 Texas Behavioral Risk Factor Surveillance System (BRFSS), Public Use Data File, Center for Health Statistics, Texas Department of State Health Services

***NCHS, National Health Examination Surveys II (ages 6-11) and III (ages 12-17), ad NHANES 1999-2000, 2001-2002, 2003-2004, 2005-2006, 2007-2008, 2009-2010, 2011-2012, 2013-2014, 2015-2016

CDC

**Diabetes**

- 14% of adult Texans have T2 DM*
- 11% have Pre-Diabetes (most don't know it)**
- **90% of Texan adults with T2DM or prediabetes are overweight or have obesity****

**2021 Texas Behavioral Risk Factor Surveillance System (BRFSS), Public Use Data File, Center for Health Statistics, Texas Department of State Health Services CDC



2022 Texas Behavioral Risk Factor Surveillance System (BRFSS) Public Use Data File, Center for Health Statistics, Texas Department of State Health Services

# With such overwhelming data, **WHY** are we **STILL** not treating obesity?

## CLINICAL PRACTICE GUIDELINES

- American College of Cardiology
- American Heart Association
- American Diabetes Association (ADA)
- American Academy of Pediatrics
- American Association of Clinical Endocrinologists and American College of Endocrinology
- Endocrine Society
- American Gastroenterological Association
- The Obesity Society
- Obesity Medicine Association
- VA/DoD

**All say to treat obesity with comprehensive treatment plans including medication**

# Americans Now Have an Obesity Bill of Rights

NEWS PROVIDED BY
National Council on Aging →
31 Jan, 2024, 09:30 ET

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(PRNewsfoto/National Council on Aging)


National Consumers League logo

1. **The Right to Accurate, Clear, Trusted, and Accessible Information** on obesity as a treatable chronic disease
2. **The Right to Respect** by all members of the integrated care team when screening, counseling, and providing treatment
3. **The Right to Make Treatment Decisions** about one's health goals and obesity care in consultation with the individual's health providers
4. **The Right to Treatment from Qualified Health Providers** including counseling and ongoing care from health providers with expertise in obesity care
5. **The Right to Person-Centered Care** that is personalized, respects the individual's cultural beliefs, meets their specific health goals, and considers the person's whole health and not just their weight status
6. **The Right to Accessible Obesity Treatment from Health Systems,** so those with severe obesity receive care in settings that allow for privacy, using size and weight-accessible equipment and diagnostic scans
7. **The Right for Older Adults to Receive Quality Obesity Care** that comprises a respectful, comprehensive care approach consistent with their personalized medical needs
8. **The Right to Coverage for Treatment** with access to the full range of treatment options for the person's disease as prescribed by the individual's health provider

# Obesity Treatment Across State Health Plans

Obesity Symposium | Free Access

**Coverage for Obesity Prevention and Treatment Services: Analysis of Medicaid and State Employee Health Insurance Programs**

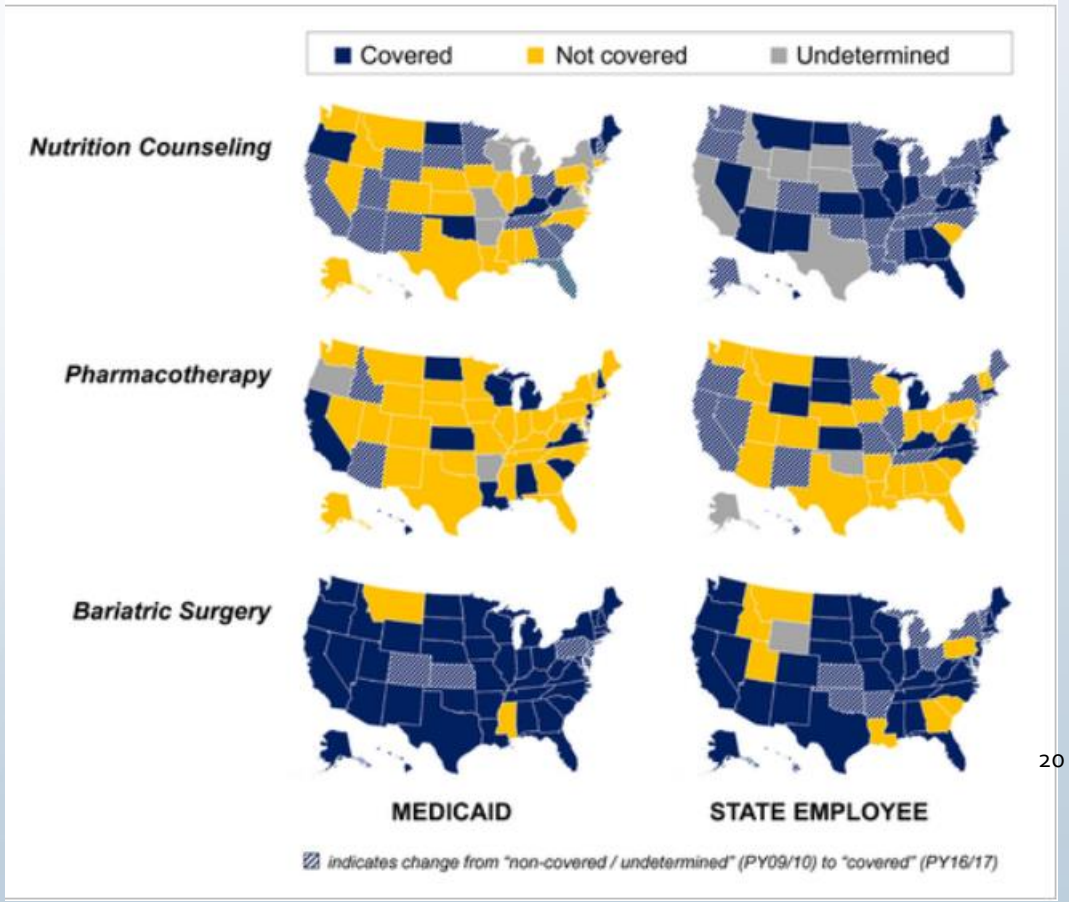
Nichole Jannah, Jeff Hild, Christine Gallagher, William Dietz

First published: 14 November 2018 | https://doi.org/10.1002/oby.22307 | Citations: 46

| Obesity Counseling | Nutrition Counseling | Anti-Obesity Medications | Bariatric Surgery |
|---|---|---|---|
| 41/51 States | 20/51 States | 16/51 States | 49/51 States |

TEXAS MEDICAID: **NO Coverage Anti-Obesity Meds**
TEXAS STATE EMPLOYEES: **Recently DROPPED coverage of Anti-Obesity Meds**

Currently 15 states have proposed legislation requiring AOM coverage



# Federal Employees have better access to Obesity care than Texas Health Plan employees

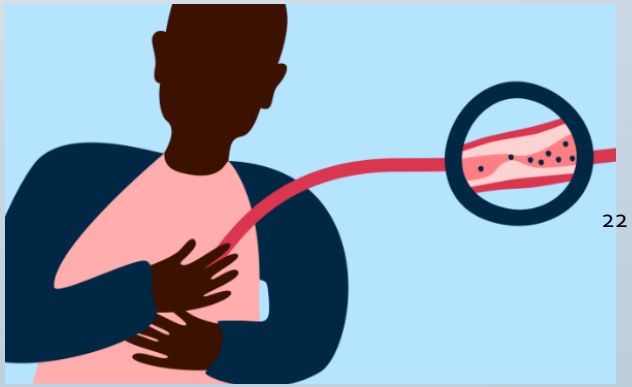
- On the federal level, the Office of Personnel Management (OPM) spelled out specific guidance in 2022 for health insurance carriers that administer Federal Employee Health Benefit (FEHB) plans — clarifying that **"FEHB Carriers are not allowed to exclude anti-obesity medications from coverage based on a benefit exclusion or a carve-out"**… and that
- "FEHB Carriers **must have adequate coverage of FDA approved anti-obesity medications (AOMs)** on the formulary to meet patient needs and must include their exception process within their proposal."

Obesity Care Advocacy Network. *Office of Personnel Management Requires Health Plans Covering Federal Employees to have Adequate Coverage for AOMs starting in 2023*. https://obesitycareadvocacynetwork.com/news/office-of-personnel-management-requires-health-plans-covering-federal-employees-to-have-adequate-coverage-for-ao-ms-starting-in-2023

# Can You Imagine….

- Treating heart disease, high blood pressure, high cholesterol, diabetes, cancer, infection, depression, autoimmune diseases, etc…

**without medications????**



# Now imagine…

There were tools in the toolkit to prevent the progression from overweight to obesity….


That we had tools to decrease weight and reverse the progression of PRE-DIABETES to DIABETES…and ALL of its complications

SELECT TRIAL

Randomized Controlled Trial > N Engl J Med. 2023 Dec 14;389(24):2221-2232.
doi: 10.1056/NEJMoa2307563. Epub 2023 Nov 11.

# Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes

A Michael Lincoff [1], Kirstine Brown-Frandsen [1], Helen M Colhoun [1], John Deanfield [1], Scott S Emerson [1], Sille Esbjerg [1], Søren Hardt-Lindberg [1], G Kees Hovingh [1], Steven E Kahn [1], Robert F Kushner [1], Ildiko Lingvay [1], Tugce K Oral [1], Marie M Michelsen [1], Jorge Plutzky [1], Christoffer W Tornøe [1], Donna H Ryan [1]; SELECT Trial Investigators

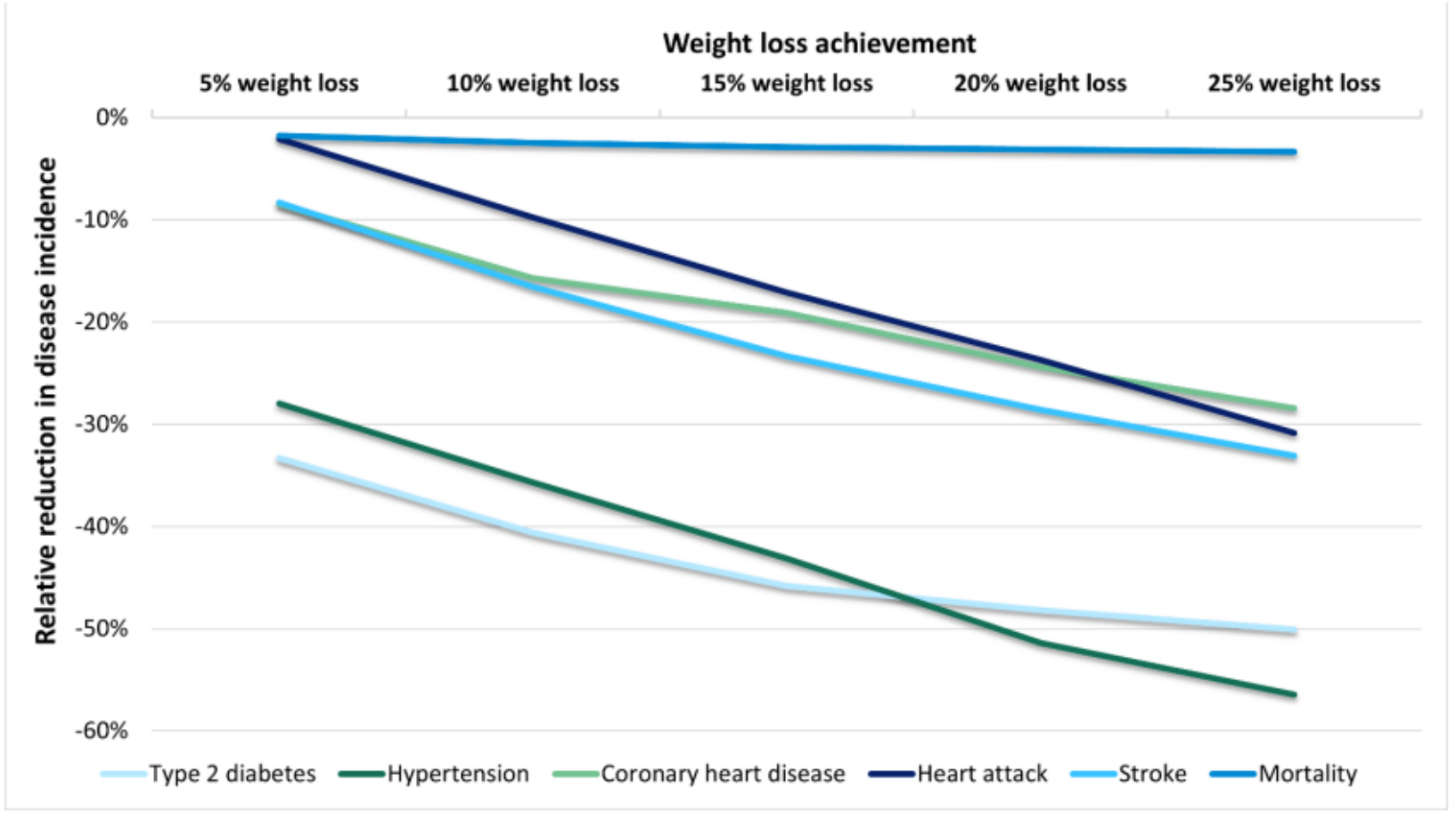
Collaborators, Affiliations + expand

PMID: 37952131 DOI: 10.1056/NEJMoa2307563

- Studied patients with prior heart attack (MI), stroke (CVA), or peripheral vascular disease (PVD)
- Excluded patients w/diabetes
- **20%** Risk Reduction of Major Adverse Cardiovascular Events (MACE)

# Texas: Health Benefits of Treating Obesity

**Exhibit 2. Estimated Clinical Benefits of Weight Loss among Individuals with Obesity**



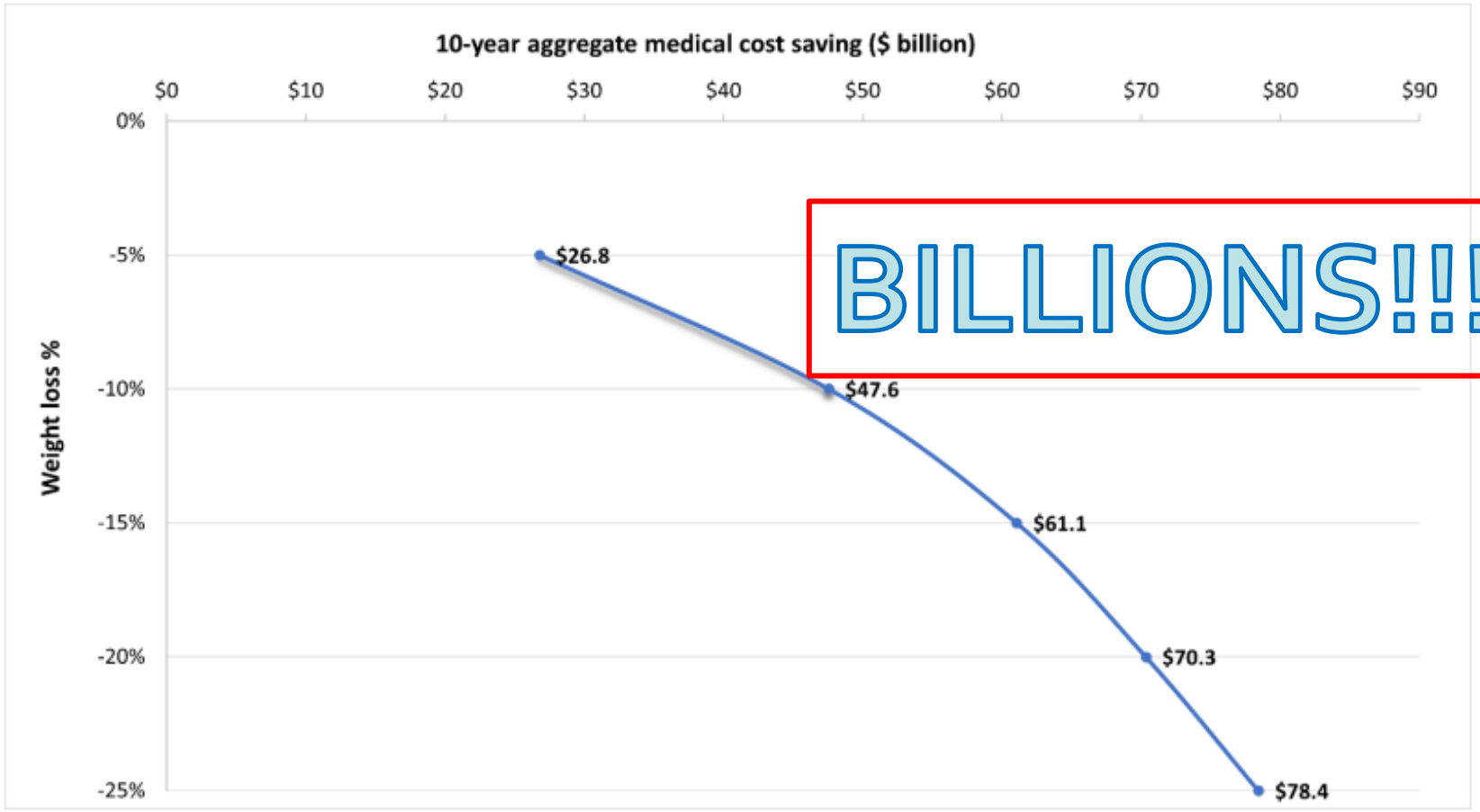

Source: GlobalData



GlobablData. *Obesity's Impact on Texas' Economy and Labor Force*. https://www.globaldata.com/health-economics/US/Texas/Obesity-Impact-on-Texas.pdf

# Texas: Cost Savings of Treating Obesity

**Exhibit 5. Estimated Statewide 10-year Medical Cost Savings by Weight Loss Scenario**




Source: GlobalData

Note: This chart shows the estimated cumulative savings over 10 years if Texas could achieve body weight loss of 5%, 10%, 15%, 20%, or 25% among the current population with obesity.



GlobablData. *Obesity's Impact on Texas' Economy and Labor Force*. https://www.globaldata.com/health-economics/US/Texas/Obesity-Impact-on-Texas.pdf

# *NOT* treating obesity is **EXPENSIVE!!**

***PRESS RELEASE***

## Economic impact of excess weight now exceeds $1.7 trillion, new Milken Institute report reveals

LOS ANGELES, Tuesday, October 30, 2018—The impact of obesity and overweight on the U.S. economy has eclipsed $1.7 trillion, an amount equivalent to 9.3 percent of the nation's gross domestic product, according to a new Milken Institute report on the role excess weight plays in the prevalence and cost of chronic diseases.

The estimate includes $480.7 billion in direct health-care costs and $1.24 trillion in lost productivity, as documented in America's Obesity Crisis: The Health and Economic Impact of Excess Weight. The study draws on research that shows how overweight and obesity elevate the risk of diseases such as breast cancer, heart disease, and osteoarthritis, and estimates the cost of medical treatment and lost productivity for each disease.

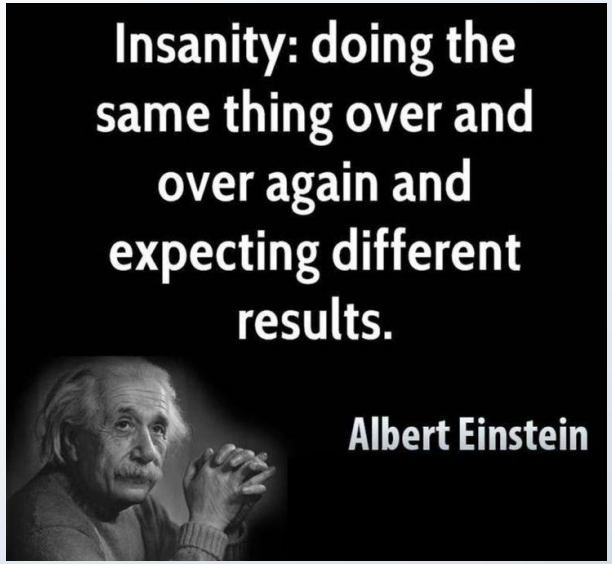
For example, the treatment cost for all type 2 diabetes cases – one of the most prevalent chronic diseases connected to excess weight – was $121 billion and indirect costs were $215 billion. On an individual basis, that comes to $7,109 in treatment costs per patient and $12,633 in productivity costs.

# *NOT* treating obesity is **DANGEROUS!**

**US Diabetes Prevalence Trends[1]:**

- 2014: 22.3 million (9.1%)
- 2030: 39.7 million (13.9%)
- **2060: 60.6 million (17.9%)**

  [For age 65 and up: 9.2→21→35.2!]




**US Obesity Prevalence Trends[2]:**

- **2030: 50%** Americans will have obesity (BMI >30)
- **29** states will have **>50% prevalence**
- 1 in 4 will have severe obesity (BMI >35 kg/m2)*

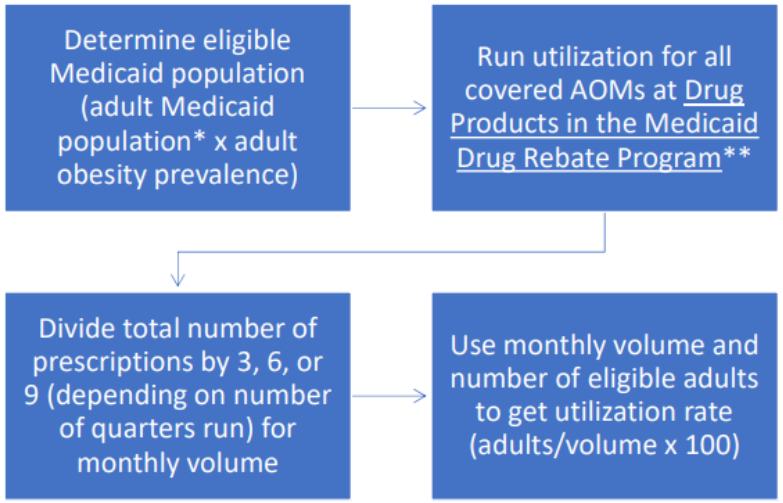


1. National Library of Medicine. *Projection of future diabetes burden in the United States through 2060*. https://pubmed.ncbi.nlm.nih.gov/29903012/
2. National Library of Medicine. *Projected U.S. State-Level Prevalence of Adult Obesity and Severe Obesity*. https://pubmed.ncbi.nlm.nih.gov/31851800/

# Current Medicaid AOM Utilization

## Calculating Anti-Obesity Medication (AOM) Medicaid Utilization

### How to Calculate Utilization




### 2023 Utilization of Anti-Obesity Medications in Medicaid

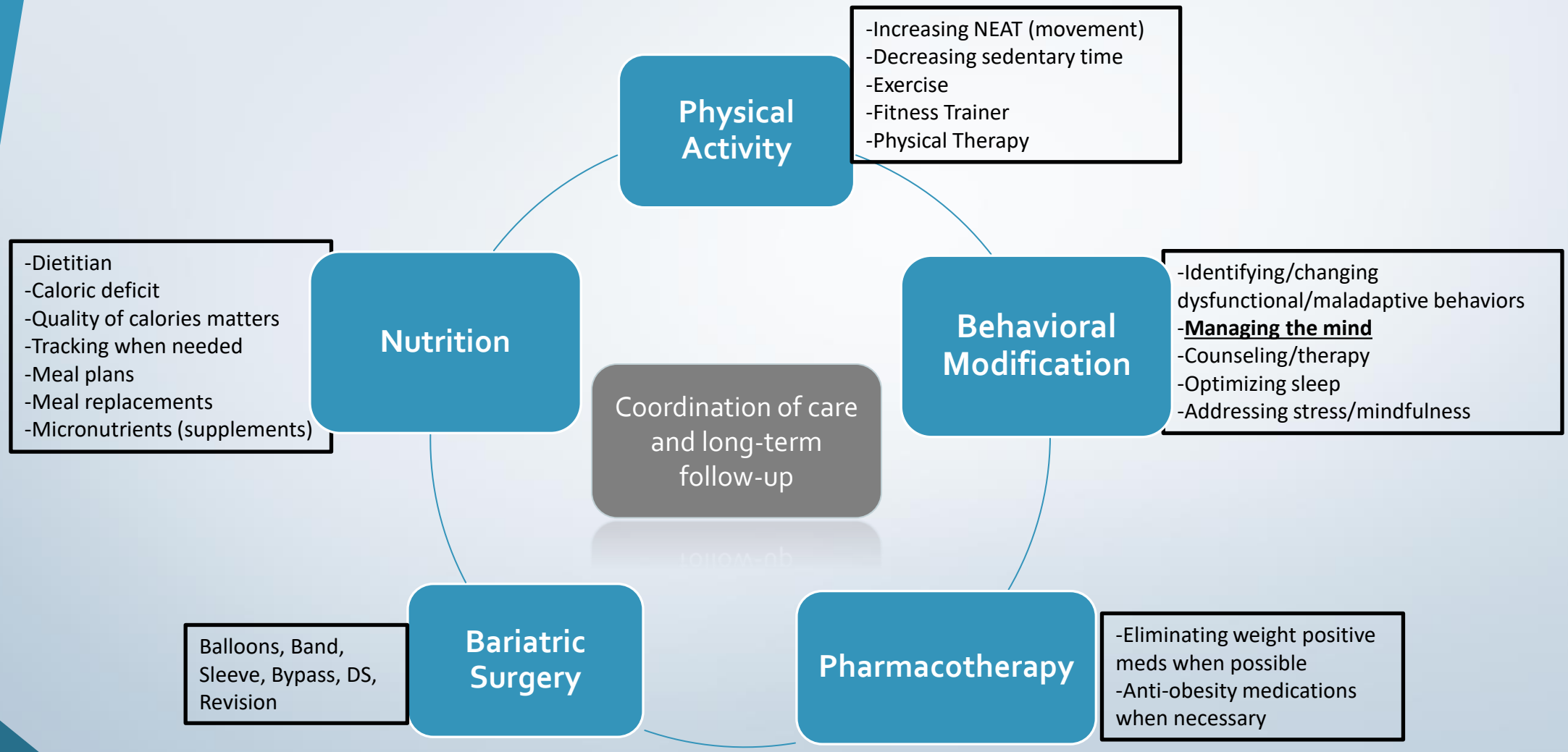
| | | |
|---|---|---|
| **Michigan** *Coverage since 2022* | 1.5% (9mo) | 1.93% Q2 |
| **Kansas** *Coverage since 2013* | 1.88% (6mo) | 1.74% Q2 |
| **Delaware** *Coverage since 2016* | 0.99% (9mo) | 1.31% Q2 |
| **Pennsylvania** *Coverage since Jan 2023* | 1.1% (9mo) | 1.59% Q2 |
| **Wisconsin** *Prior to 2020* | 1.05% (9mo) | 1.39% Q2 |

*Kaiser Family Foundation

**https://data.medicaid.gov/dataset/0ad65fe5-3ad3-5d79-a3f9-7893ded7963a

# What is comprehensive obesity treatment?

# Comprehensive Treatment of Obesity



# Anti-Obesity Medications

## [*NOT* Weight Loss Meds]

| Medication | Year FDA APPROVED | Trial | Total Weight Loss (%) | ≥5% WL | ≥10 WL | ≥15 WL | ≥20% WL |
|---|---|---|---|---|---|---|---|
| Phentermine* | 1959 | LEWIS & ARD | 7.5 | NR | NR | NR | NR |
| Phentermine/Topiramate (Qsymia) | 7/2012 | CONQUER | 10 | 62 | 48 | NR | NR |
| Bupropion/Naltrexone (Contrave) | 9/2014 | COR-1 | 6 | 48 | 25 | 12 | NR |
| Liraglutide (Saxenda) | 12/2014 | SCALE | 8 | 63 | 33 | 14 | NR |
| Semaglutide (Wegovy) | 6/2022 | STEP-1 | 15 | 86 | 69 | 51 | NR |
| Tirzepatide (Zepbound) | 12/2023 | SURMOUNT-1 | 21 | 91 | 84 | 71 | 57 |
| All studies (except phentermine) using 500 kcal/day deficit plus advise for physical activity | | | | | | | |
| *Currently only FDA approved for 12 weeks; data from off label longer term use | | | | | | | |

STANDARDS OF CARE | DECEMBER 16 2021

# 8. Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes: *Standards of Medical Care in Diabetes—2022* FREE

American Diabetes Association Professional Practice Committee

There is strong and consistent evidence that obesity management can delay the progression from prediabetes to type 2 diabetes (1–5) and is highly beneficial in the treatment of type 2 diabetes (6–17). In patients with type 2 diabetes and overweight or obesity, modest weight loss improves glycemic control and reduces the need for glucose-lowering medications (6–8), and more intensive dietary energy restriction can substantially reduce A1C and fasting glucose and promote sustained diabetes remission through at least 2 years (10,18–22). Metabolic surgery strongly improves glycemic control and often leads to remission of diabetes, improved quality of life, improved cardiovascular outcomes, and reduced mortality. The importance of addressing obesity is further

Treatment options for overweight and obesity in type 2 diabetes

| | BMI category (kg/m$^2$) | | |
|---|---|---|---|
| **Treatment** | **25.0–26.9 (or 23.0–24.9*)** | **27.0–29.9 (or 25.0–27.4*)** | **≥30.0 (or ≥27.5*)** |
| Diet, physical activity, and behavioral counseling | ‡ | ‡ | ‡ |
| Pharmacotherapy | | ‡ | ‡ |
| Metabolic surgery | | | ‡ |

* Recommended cutpoints for Asian American individuals (expert opinion).

† Treatment may be indicated for select motivated patients.

# Adult Case-Part 1

45 y/o male with initial BMI of 60.75 (Height: 72 in; Weight: 448 lbs) presents for initial consultation for bariatric surgery. Says he feels hungry often, even just a couple of hours after eating a meal. Tries to make good choices but finds that hard when on the road.

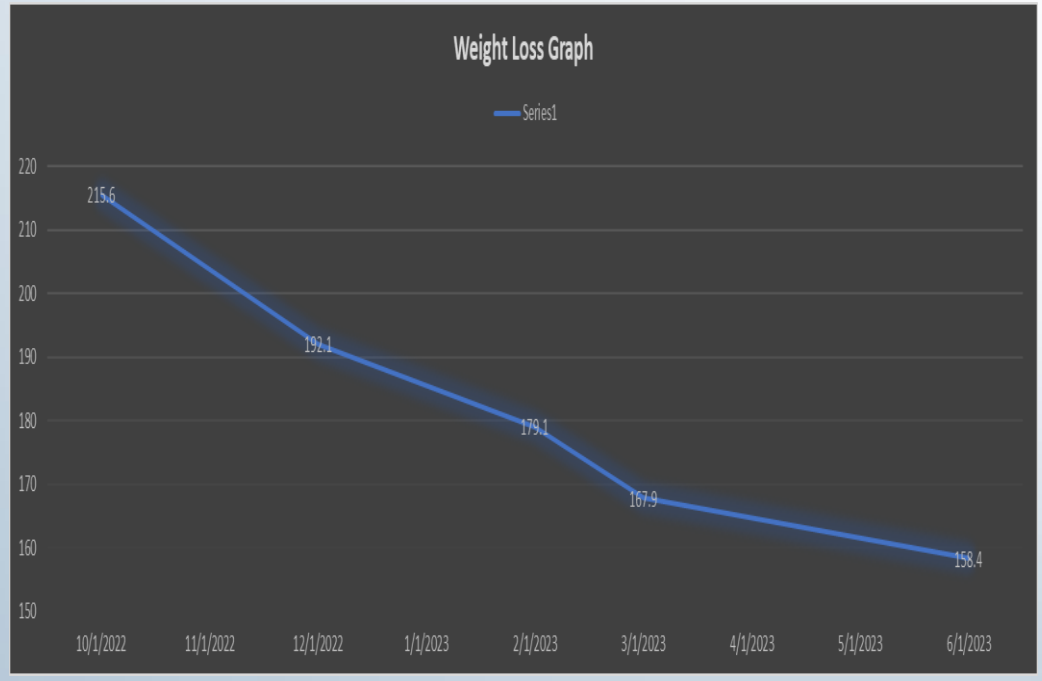
- PMH: High Blood Pressure, Obstructive Sleep Apnea, High Cholesterol, Gastroesophageal Reflux Disease
- Family History: "Everyone is heavy", Cardiac disease
- Social History: Married, 2 kids, Truck Driver; Non-smoker; No alcohol/drugs
- Meds: Metoprolol, Losartan, Multivitamin
- Diet: Eats out daily, sometimes 2x/day-esp on workdays
- Physical Activity: Active with his job but otherwise sedentary

# Adult Obesity Case- Part 2

- No insurance coverage for bariatric surgery
- Insurance DID cover GLP1 medications
- Started on Semaglutide (Ozempic) for his newly diagnosed diabetes
- Over the next 18 months, pt lost 160 lbs!
- Hemoglobin A1C went from 8.4→5.3
- Previously considering disability and now happy with his job, home life
- Lifting weights 2x/week, in addition to his active job

# Pediatric Case

## 17 yo male with obesity, hypothyroidism and delayed puberty




- **Started treatment Oct 2022**
- Tirzepatide 2.5 mg, titrated up each month to 12.5 mg
- Total weight loss of 52 lbs in 8 months
- Off all meds, stabilized and off to college
- Doing well as of Jan 2024

# How Can We Mitigate Costs

- Follow guidelines, utilizing a comprehensive approach
- Consider Step Therapy
- Work with the pharmaceutical industry/PBMs to reduce medication costs
- Streamline the Prior Authorization (PA) process
- Mandate prescribers have obesity-specific CME/ABOM Certification (think about opioid education mandate)
- ALL carriers-government-based and private alike should offer AOMs—such that way even if a patient switches to a new carrier, all will reap the benefits of addressing obesity
- Pass the Treat and Reduce Obesity Act

# On behalf of the 70% of Texans struggling with overweight and obesity, we ask you to support:

- Access to **COMPREHENSIVE OBESITY CARE**, including **ALL FDA APPROVED ANTI-OBESITY MEDICATIONS** –for children and adults
- That these be added to  the state employee health plan **AND** Texas Medicaid
- Increased efforts to break down negative bias and stigma against obesity
- Public awareness campaigns
- Improved partnerships with medical education programs to improve obesity-specific education