

Asthn	0 0						
ASUIII	IId						

# FDA approves drug combination treatment for adults with asthma

- Airsupra (albuterol and budesonide) inhalation aerosol
  - for the as-needed treatment or prevention of bronchoconstriction
  - reduce the risk of asthma attacks in patients with asthma 18 years of age and older
- first combination of an inhaled corticosteroid (ICS) and a short-acting beta-agonist to be approved in the U.S.
- first product containing an ICS to be approved in the U.S. as a reliever treatment (rather than as a controller) for asthma

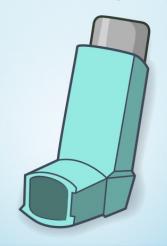
# MANDALA Study

- Reduce the risk of severe asthma attacks in patients with moderate to severe asthma
- randomized, double-blind, multinational, multicenter study
- Airsupra 180 mcg/ 160 mcg or albuterol 180 mcg and instructed to take as needed for asthma symptoms
- Treated for at least 24 weeks
- Primary Endpoint: time to first severe asthma attack (defined as worsening or onset of asthma symptoms that required systemic corticosteroids for at least three days or an emergency room visit that led to the use of systemic corticosteroids for at least three days or a hospitalization for at least 24 hours due to asthma)
- 28% reduction in the risk of a severe asthma attack as assessed by the time to first severe asthma attack

Papi A, Chipps BE, Beasley R, et al. Albuterol-Budesonide Fixed-Dose Combination Rescue Inhaler for Asthma. *N Engl J Med*. 2022;386(22):2071-2083. doi:10.1056/NEJMoa2203163

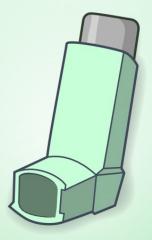
### **Higher-Dose Combination**

Albuterol (180  $\mu$ g) + Budesonide (160  $\mu$ g)



### **Lower-Dose Combination**

Albuterol (180  $\mu$ g) + Budesonide (80  $\mu$ g)



### **Albuterol Alone**

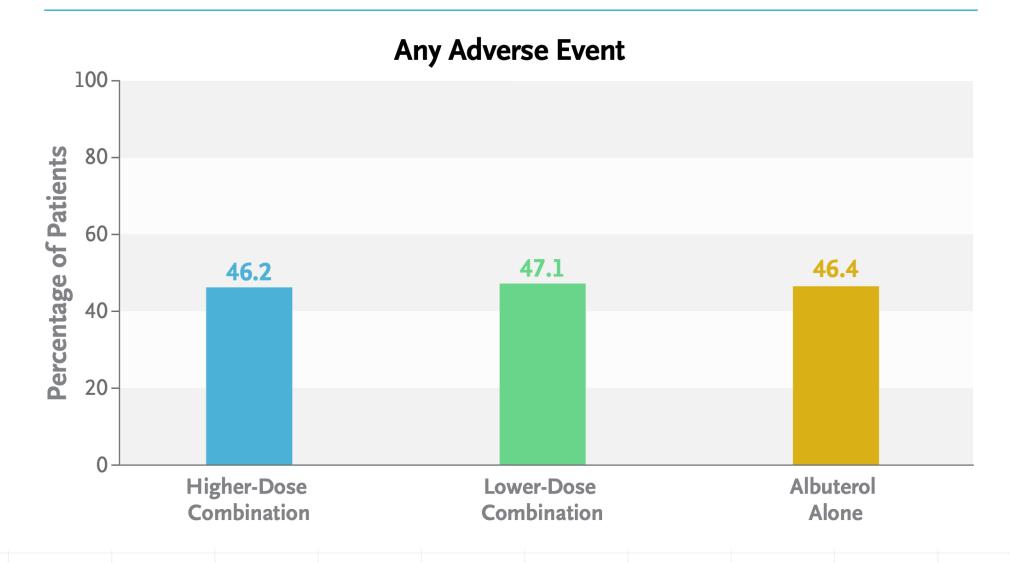
Albuterol (180  $\mu$ g)



Adults and adolescents

Children 4 through 11 years of age

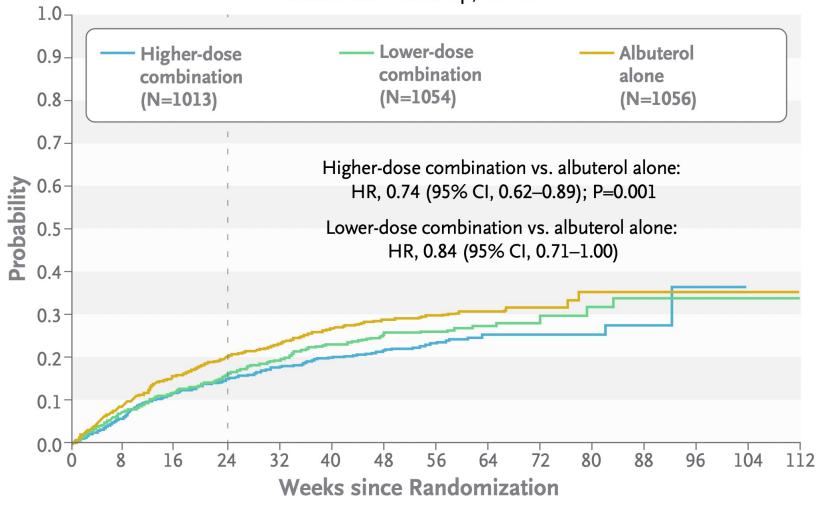
Papi A, Chipps BE, Beasley R, et al. Albuterol-Budesonide Fixed-Dose Combination Rescue Inhaler for Asthma. *N Engl J Med*. 2022;386(22):2071-2083. doi:10.1056/NEJMoa2203163



Papi A, Chipps BE, Beasley R, et al. Albuterol-Budesonide Fixed-Dose Combination Rescue Inhaler for Asthma. *N Engl J Med*. 2022;386(22):2071-2083. doi:10.1056/NEJMoa2203163



Minimum Follow-up, 24 Wk



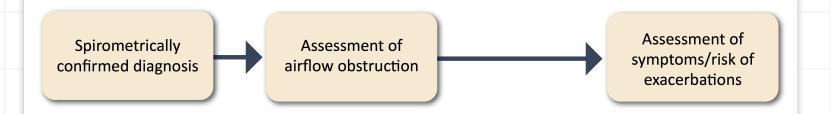
Papi A, Chipps BE, Beasley R, et al. Albuterol-Budesonide Fixed-Dose Combination Rescue Inhaler for Asthma. *N Engl J Med*. 2022;386(22):2071-2083. doi:10.1056/NEJMoa2203163

COPD						
COPD						
					<u>.</u>	



Figure 2.3

2023
Teaching
Slide Set



Post-bronchodilator FEV1/FVC < 0.7

GRADE	<b>FEV1</b> (% predicted)
GOLD 1	≥ 80
GOLD 2	50-79
GOLD 3	30-49
GOLD 4	< 30

### EXACERBATION HISTORY

≥ 2 moderate exacerbations or ≥ 1 leading to hospitalization

0 or 1 moderate exacerbations (not leading to hospitalization) E

В

mMRC 0-1 CAT < 10  $mMRC \ge 2$  $CAT \ge 10$ 

**SYMPTOMS** 



### **Modified MRC Dyspnea Scale**

Table 2.7

# 2023 Teaching Slide Set

#### PLEASE TICK IN THE BOX THAT APPLIES TO YOU | ONE BOX ONLY | Grades 0 - 4

#### mMRC Grade 0

I only get breathless with strenuous exercise

#### mMRC Grade 1

I get short of breath when hurrying on the level or walking up a slight hill

#### mMRC Grade 2

I walk slower than people of the same age on the level because of breathlessness, or I have to stop for breath when walking on my own pace on the level

#### mMRC Grade 3

I stop for breath after walking about 100 meters or after a few minutes on the level

#### mMRC Grade 4

I am too breathless to leave the house or I am breathless when dressing or undressing



Reference: ATS (1982) Am Rev Respir Dis. Nov;126(5):952-6.

For each item below, place a mark (x) in the box that best describes you currently. Be sure to only select one response for each question.

EXAMPLE: I am very happy	0 🗶 2 3 4 5	I am very sad	Score
I never cough	012345	I cough all the time	
I have no phlegm (mucus) in my chest at all	012345	My chest is completely full of phlegm (mucus)	
My chest does not feel tight at all	012345	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	012345	When I walk up a hill or one flight of stairs I am very breathless	
I am not limited doing any activities at home	012345	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	012345	I am not at all confident leaving my home because of my lung condition	
I sleep soundly	012345	I don't sleep soundly because of my lung condition	
I have lots of energy	012345	I have no energy at all	

Reference: Jones et al. ERJ 2009; 34 (3); 648-54.

**TOTAL SCORE:** 



CHRONICORS

### **Initial Pharmacological Treatment**

Figure 4.2

2023
Teaching
Slide Set

≥ 2 moderate exacerbations or ≥ 1 leading to hospitalization **GROUP E** 

LABA + LAMA\*

consider LABA+LAMA+ICS\* if blood eos ≥ 300

0 or 1 moderate exacerbations (not leading to hospital admission) **GROUP A** 

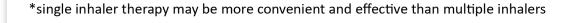
A bronchodilator

**GROUP B** 

LABA + LAMA\*

mMRC 0-1, CAT < 10

 $mMRC \ge 2$ ,  $CAT \ge 10$ 





2023
Teaching
Slide Set

- Influenza vaccination is recommended in people with COPD (Evidence B)
- The WHO and CDC recommends SARS-CoV-2 (COVID-19) vaccination for people with COPD (Evidence B)
- The CDC recommends one dose of 20-valent pneumococcal conjugate vaccine (PCV20); or one dose of 15-valent pneumococcal conjugate vaccine (PCV15) followed by 23-valent pneumococcal polysaccharide vaccine (PPSV23) in people with COPD (Evidence B)
- Pneumococcal vaccination has been shown to reduce the incidence of community-acquired pneumonia and exacerbations in people with COPD (Evidence B)
- The CDC recommends Tdap (dTaP/dTPa) vaccination to protect against pertussis (whooping cough) for people with COPD that were not vaccinated in adolescence (Evidence B), and Zoster vaccine to protect against shingles for people with COPD over 50 years (Evidence B)



\/:							
Vaccii	nes						

# Pneumococcal Vaccine Recommendations

- Use of PCV20 alone or PCV15 in series with PPSV23
  - To reduce pneumococcal disease incidence in adults aged ≥65 years and in those aged 19–64 years with certain underlying conditions.
  - immunogenicity and safety, comparable to PCV13 alone or PCV13 in series with PPSV23
  - Cost-effectiveness studies demonstrated was cost-saving
  - Simplifies adult pneumococcal vaccine recommendations

Kobayashi M, Farrar JL, Gierke R, et al. Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:109–117.

## Pneumococcal Vaccine Timing for Adults

Make sure your patients are up to date with pneumococcal vaccination.

## Adults ≥65 years old Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	PCV20	PCV15 ≥1 year <sup>†</sup> PPSV23
PPSV23 only at any age	≥1 year PCV20	≥1 year PCV15
PCV13 only at any age	≥1 year PCV20	≥1 year <sup>†</sup> PPSV23
PCV13 at any age & PPSV23 at <65 yrs	≥5 years PCV20	≥5 years <sup>§</sup> PPSV23

<sup>\*</sup> Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

#### Shared clinical decision-making for those who already completed the series with PCV13 and PPSV23

Prior vaccines		Shared clinical decision-making option
Complete series: PCV13 at any age & PPSV23 at ≥65 yrs	≥5 years PCV20	Together, with the patient, vaccine providers <b>may choose</b> to administer PCV20 to adults ≥65 years old who have already received PCV13 (but not PCV15 or PCV20) at any age and PPSV23 at or after the age of 65 years old.

https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

<sup>&</sup>lt;sup>†</sup> Consider minimum interval (8 weeks) for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak (CSF) leak

<sup>§</sup> For adults with an immunocompromising condition, cochlear implant, or CSF leak, the minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose; for others, the minimum interval for PPSV23 is ≥1 year since last PCV13 dose and ≥5 years since last PPSV23 dose

# Adults 19–64 years old with specified immunocompromising conditions Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	PCV20	PCV15 ≥8 weeks PPSV23
PPSV23 only	≥1 year PCV20	≥1 year PCV15
PCV13 only	≥1 year PCV20	≥8 weeks PPSV23 ≥5 years PPSV23  Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13 and 1 dose of PPSV23	≥5 years PCV20	≥5 years <sup>†</sup> <b>PPSV23</b> Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
PCV13 and 2 doses of PPSV23	≥5 years PCV20	No vaccines recommended at this time.  Review pneumococcal vaccine recommendations again when your patient turns 65 years old.
Immunocompromising conditions	Chronic renal failure Congenital or acquired asplenia Generalized malignancy HIV infection  Hodgkin disease latrogenic immunosu Leukemia Lymphoma Multiple myeloma	Nephrotic syndrome     Sickle cell disease/other     hemoglobinopathies     Solid organ transplant

<sup>\*</sup> Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

<sup>&</sup>lt;sup>†</sup> The minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose

<sup>§</sup> Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)

<sup>1</sup> Includes diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy

# Adults 19–64 years old with a cochlear implant or cerebrospinal fluid leak Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B			
None*	PCV20	PCV15 ≥8 weeks PPSV23			
PPSV23 only	≥1 year PCV20	≥1 year PCV15			
PCV13 only	≥1 year PCV20	≥8 weeks PPSV23  Review pneumococcal vaccine recommendations again when your patient turns 65 years old.			
PCV13 and 1 dose of PPSV23	≥5 years PCV20	No vaccines recommended at this time.  Review pneumococcal vaccine recommendations again when your patient turns 65 years old.			

<sup>\*</sup> Also applies to people who received PCV7 at any age and no other pneumococcal vaccines

https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf

#### **Abbreviations**

- PCV or PCV13 =
   Pneumococcal conjugate
   vaccine
- PPSV or PPSV23 =
   Pneumococcal
   polysaccharide vaccine



The PneumoRecs VaxAdvisor Mobile App was updated on February 9, 2023, to reflect CDC's new adult pneumococcal vaccination recommendations including for those who previously received PCV13.

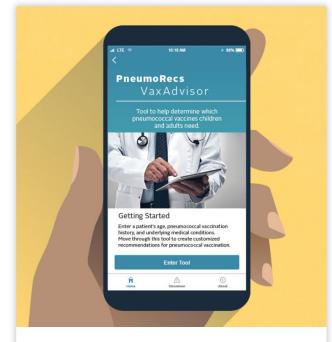
The *PneumoRecs VaxAdvisor* mobile app helps vaccination providers quickly and easily determine which pneumococcal vaccines a patient needs and when. The app incorporates recommendations for all ages so internists, family physicians, pediatricians, and pharmacists alike will find the tool beneficial.

#### Users simply:

- Enter a patient's age.
- Note if the patient has specific underlying medical conditions.
- Answer questions about the patient's pneumococcal vaccination history.

Then the app provides patient-specific guidance consistent with the immunization schedule recommended by the U.S. Advisory Committee on Immunization Practices (ACIP).

# Download the mobile app or use the web version



PneumoRecs VaxAdvisor is available for download on iOS and Android mobile devices.

Download "PneumoRecs VaxAdvisor" free for <u>iOS</u> \( \text{\text{\text{iOS}}} \) and <u>Android</u> \( \text{\text{\text{devices}}} \)



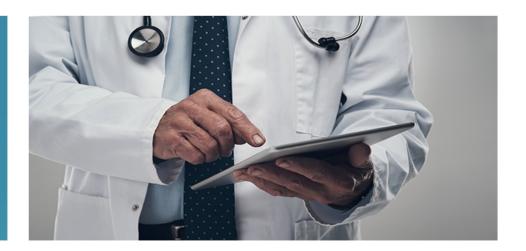
https://www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html

#### Pneumococcal Vaccine Recommendations

PneumoRecs VaxAdvisor

# **PneumoRecs**VaxAdvisor

Tool to help determine which pneumococcal vaccines children and adults need.



Get Started

Enter a patient's age, pneumococcal vaccination history, and underlying medical conditions. Move through this tool to create customized pneumococcal vaccination recommendations.

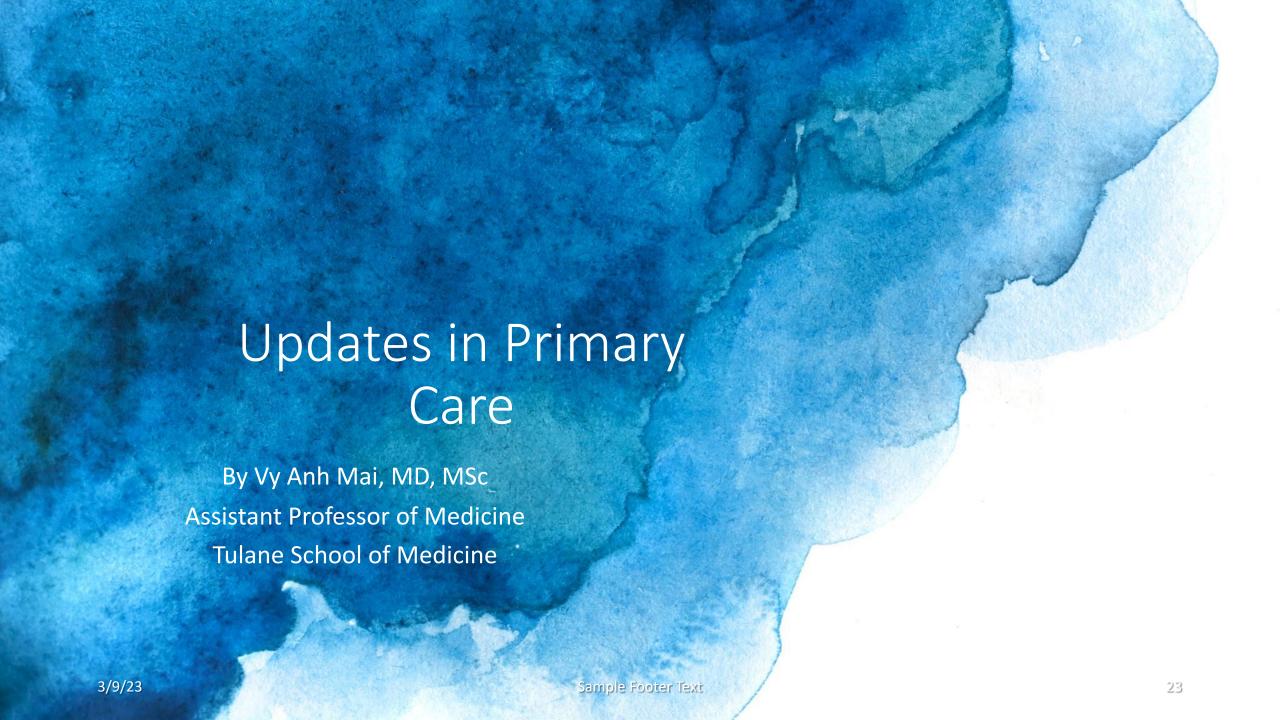
https://www2a.cdc.gov/vaccines/m/pneumo/pneumo.html

# CDC recommends universal Hep B Vaccination 19–59

Vaccination with hepatitis B (HepB) vaccines shows well-established safety and efficacy However, because of risk factor-based approaches of previous vaccination recommendations, coverage among adults has been suboptimal

Universal adult HepB vaccination through age 59 years removes the need for risk factor screening and disclosure and could increase vaccination coverage and decrease hepatitis B cases

- Heplisav-B and PreHevbrio data is currently insufficient to inform vaccine-associated risks in pregnancy
- Vaccinate pregnant women needing HepB vaccination with Engerix-B, Recombivax HB, or Twinrix



# Disclosure of Interest

Nothing to disclose

# Topics

Type 2 Diabetes

Weight Loss Management Buprenorphine Prescribing

## Learning Objectives for Type 2 Diabetes Mellitus



Acknowledge providerrelated barriers leading to poor diabetes control 2

Review new screening guidelines

3

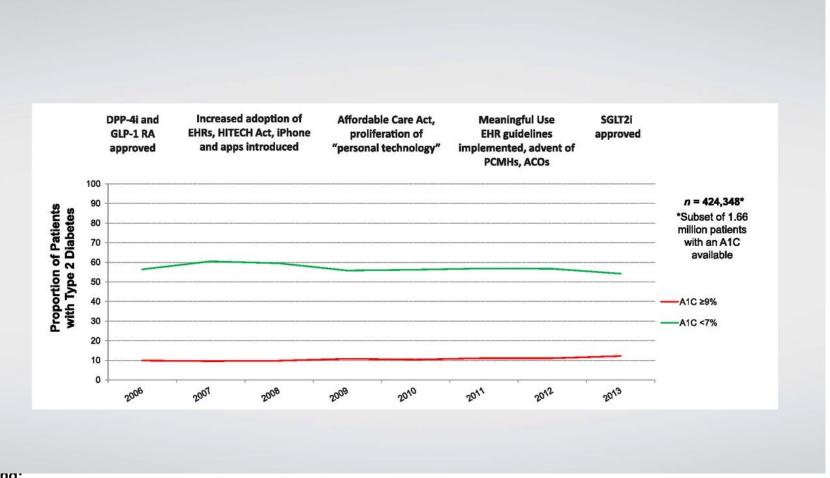
Review algorithms and medication profiles per American Diabetes Association (ADA) and American Association of Clinical Endocrinology (AACE) 4

Review updates in insulin affordability



From: Addressing Therapeutic Inertia in 2020 and Beyond: A 3-Year Initiative of the American Diabetes Association

Clin Diabetes. 2020;38(4):371-381. doi:10.2337/cd20-0053

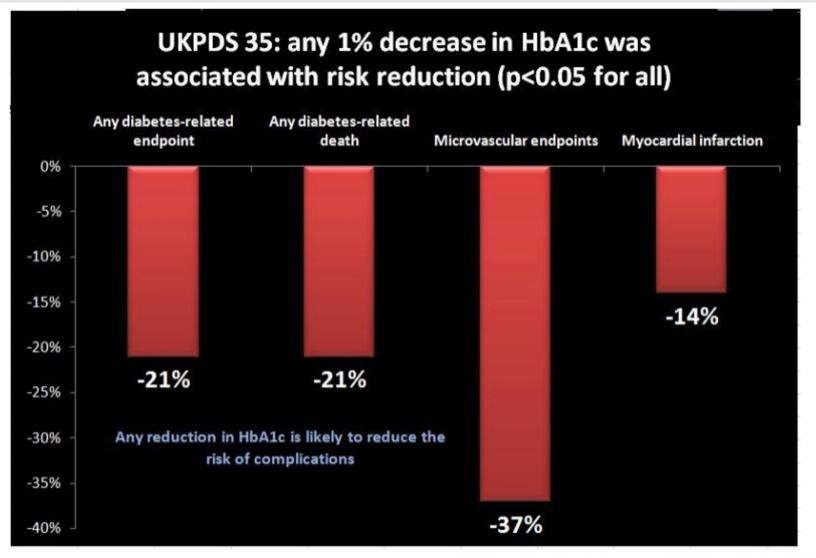


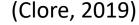
#### Figure Legena:

Type 2 diabetes trends in the United States, 2006–2013. Advances in health technologies, drug therapies, and public policy have not translated to improvements in diabetes care quality. ACO, accountable care organization; DPP-4i, dipeptidyl peptidase 4 inhibitor; GLP-1RA, glucagon-like peptide 1 receptor agonist; HITECH, Health Information Technology for Economic and Clinical Health; PCMH, patient-centered medical home; SGLT2i, sodium–glucose cotransporter 2 inhibitor. Adapted from ref. 24.

### Barrier to Care – Clinical Inertia

- Most often time we focus a lot on medical nonadherence and blame poor control due to limitations of our patients.
- It's also important to recognize our role in poor control of diabetes as well.
- Failure of healthcare providers to initiate or intensify therapy can be due to lack of education, training or having programs or clinical practices aimed at achieving therapeutic goals (Gabbay, 2020).
- Therapeutic inertia is common affecting as many as 50% of patients with type 2 diabetes (McCoy, 2021).
  - Driven by wide range of barriers (Rattelman, 2021).
    - Clinician
    - Patient
    - Health system levels



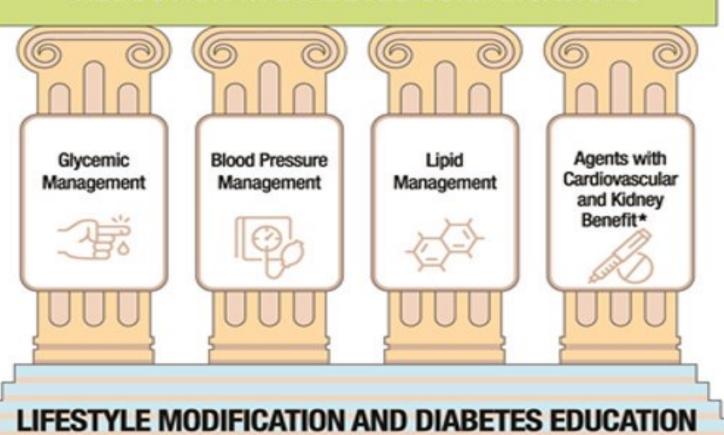


### When to Screen

- New guidelines include screening adults without diabetes symptoms for both prediabetes and diabetes at the age of 35 (Kenney, 2022).
- Any individual who is overweight or obese (BMI ≥25 kg/m² or ≥23 kg/m² in Asian American individuals) who have one or more of the following risk factors:
  - 1<sup>st</sup> degree relative with diabetes
  - High risk race/ethnicity
  - History of CVD
  - HTN (≥130/80 mmHg or on therapy for hypertension)
  - HDL cholesterol level <35 mg/dL (0.90 mmol/L) and/or a triglyceride level >250 mg/dL (2.82 mmol/L)
  - Individuals with polycystic ovary syndrome
  - Physical inactivity
  - Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)
- Individuals with HIV
- People with prediabetes should be tested yearly
- People diagnosed with gestational diabetes should have lifelong testing every 3 years
- If results are normal, testing should be repeated at minimum of 3-year intervals with consideration to the patients' risk factors and exam findings

### REDUCTION IN DIABETES COMPLICATIONS

https://diatribe.org/y our-guide-2022changes-adastandardscare#glucose

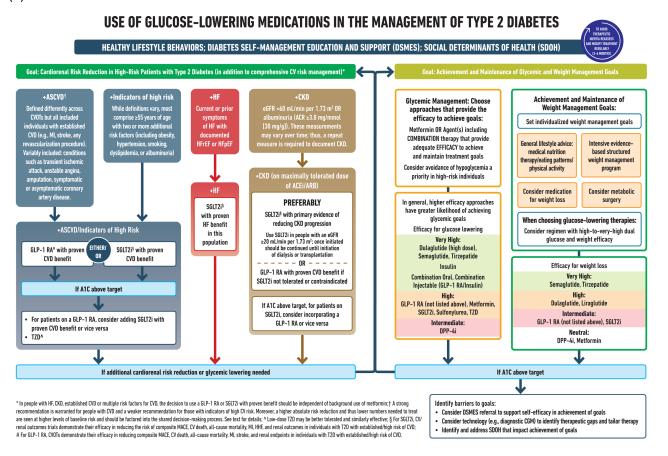


## Foundations of Diabetes Therapy

- Healthy Diet and Exercise
- Metformin is usually still the initial therapy for patients with type 2 diabetes.
  - Recommended dose is 1000 mg twice daily if tolerated
  - Titrate slowly over 1-2 weeks in 500 mg increments
  - Extended-release formulation is highly recommended
  - Medication must be renally dosed and should not be used if GFR less than 30 cc/min (Clore, 2019)
- New guidelines are now recommending an individualized approach at the time of diagnosis.
- From the Chief Science and Medical Officer of American Diabetes Association Robert A. Gabbay, MD, PhD:
  - "We know now that many of these medications that lower cardiovascular [heart] and renal [kidney] disease can be quite effective, often literally life-saving," said Gabbay. "Metformin is still a good drug, but it should not be a deterrent to work quickly and start medications we know will be effective" (Kenney, 2022).

### From: Standards of Care in Diabetes—2023 Abridged for Primary Care Providers

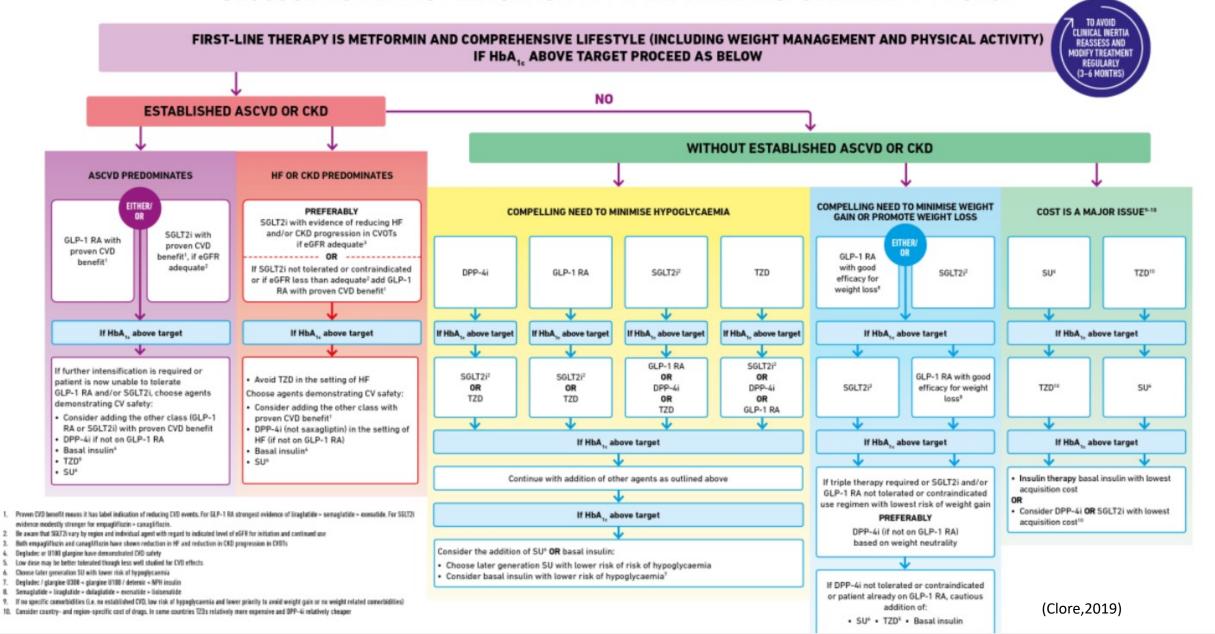
Clin Diabetes. 2022;41(1):4-31. doi:10.2337/cd23-as01



#### Figure Legend:

Use of glucose-lowering medications in the management of type 2 diabetes. ACEi, ACE inhibitor; ACR, albumin-to-creatinine ratio; CVOT, cardiovascular outcomes trial; DPP-4i, dipeptidyl peptidase 4 inhibitor; GLP-1 RA, glucagon-like peptide 1 receptor agonist; HHF, hospitalization for heart failure; SGLT2i, sodium-glucose cotransporter 2 inhibitor; T2D, type 2 diabetes. Adapted from Davies MJ, Aroda VR, Collins BS, et al. Diabetes Care 2022;45:2753–2786.

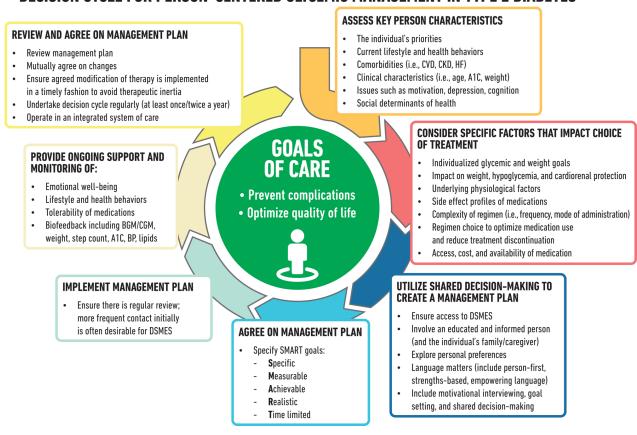
#### GLUCOSE-LOWERING MEDICATION IN TYPE 2 DIABETES: OVERALL APPROACH



From: Standards of Care in Diabetes—2023 Abridged for Primary Care Providers

Clin Diabetes. 2022;41(1):4-31. doi:10.2337/cd23-as01

#### DECISION CYCLE FOR PERSON-CENTERED GLYCEMIC MANAGEMENT IN TYPE 2 DIABETES



#### Figure Legend:

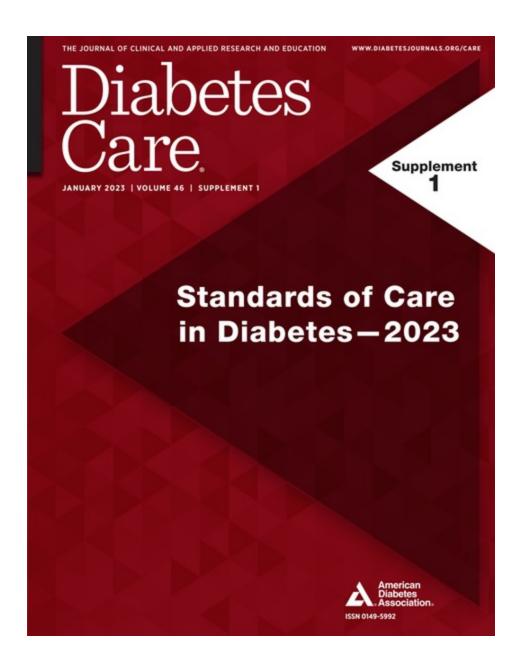
Decision cycle for person-centered glycemic management in type 2 diabetes. Adapted from Davies MJ, Aroda VR, Collins BS, et al. Diabetes Care 2022;45:2753–2786.

# Insulin Affordability!

- Eli Lilly announced on March 1, 2023 that it plans on reducing cost of insulin by 70%
- Automatic cap on out-of-pocket costs of \$35 or less for those with those with private insurance and use of participating pharmacies
- People who don't have insurance can continue to go to <u>InsulinAffordability.com</u> and immediately download the Lilly Insulin Value Program savings card to receive Lilly insulins for \$35 per month.

# Steps Towards Insulin Cost Reductions

- Cutting the list price of its non-branded insulin, Insulin Lispro Injection 100 units/mL, to \$25 a vial. Effective May 1, 2023, it will be the lowest list-priced mealtime insulin available, and less than the price of a Humalog® vial in 1999.
- Cutting the list price of Humalog® (insulin lispro injection) 100 units/mL¹, Lilly's most commonly prescribed insulin, and Humulin® (insulin human) injection 100 units/mL² by 70%, effective in Q4 2023.
- Launching Rezvoglar<sup>™</sup> (insulin glargine-aglr) injection, a basal insulin that is biosimilar to, and interchangeable with, Lantus<sup>®</sup> (insulin glargine) injection, for \$92 per five pack of KwikPens<sup>®</sup>, a 78% discount to Lantus, effective April 1, 2023.



#### (Garber 2020)

#### PROFILES OF ANTIHYPERGLYCEMIC MEDICATIONS

	MET	GLP1-RA	SGLT2i	DPP4i	AGi	TZD (moderate dose)	SU	COLSVL	BCR-QR	INSULIN	PRAML
НҮРО	Neutral	Neutral	Neutral	Neutral	Neutral	Neutral	Moderate/ Severe Mild	Neutral	Neutral	Moderate to Severe	Neutral
WEIGHT	Slight Loss	Loss	Loss	Neutral	Neutral	Gain	Gain	Neutral	Neutral	Gain	Loss
RENAL / GU	Contra- indicated if eGFR <30 mL/min/ 1.73 m²	Exenatide Not Indicated CrCl <30 Potential Benefit of LA GLP1-RA	Not Indicated for eGFR <45 mL/ min/1.73 m² See #1 Genital Mycotic Infections Potential CKD Benefit; See #1	Dose Adjustment Necessary (Except Linagliptin) Effective in Reducing Albuminuria	Neutral	Neutral	More Hypo Risk	Neutral	Neutral	More Hypo Risk	Neutral
GI Sx	Moderate	Moderate	Neutral	Neutral	Moderate	Neutral	Neutral	Mild	Moderate	Neutral	Moderate
CHF		Neutral	Prevent HF Hospitalization Manage HFrEF; See #2	See #4	Neutral	Moderate	Neutral	Neutral	Neutral	CHF Risk	Neutral
ASCVD	Neutral	Potential Benefit of LA GLP1-RA	See #3			May Reduce Stroke Risk	Possible ASCVD Risk	Lowers LDL-C	Safe	Neutral	
BONE	Neutral	Neutral	Neutral	Neutral	Neutral	Moderate Fracture Risk	Neutral	Neutral	Neutral	Neutral	Neutral
KETOACIDOSIS	Neutral	Neutral	DKA Can Occur in Various Stress Settings	Neutral	Neutral	Neutral	Neutral	Neutral	Neutral	Neutral	Neutral



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Few adverse events or possible benefits

Use with caution

Likelihood of adverse effects

Canagliflozin indicated for eGFR ≥30 mL/min/1.73 m² in patients with CKD 3 + albuminuria.

<sup>2.</sup> Dapagliflozin-potential primary prevention of HF hospitalization & demonstrated efficacy in HFrEF.

<sup>3.</sup> Empagliflozin-FDA approved to reduce CV mortality. Canagliflozin-FDA approved to reduce MACE events.

<sup>4.</sup> Possible increased hospitalizations for heart failure with alogliptin and saxagliptin.



# Learning Objectives for Obesity Medicine

Review data supporting more intense behavioral interventions for weight loss

Discuss available weight loss medications that are FDA approved

## Clinical Trials

## PROPEL (Promoting Successful Weight Loss in Primary Care in Louisiana)

 18 primary care clinics from 5 health systems in Louisiana that served a large percentage of low-income and underserved patient

# REPOWER (Rural Engagement in Primary Care for Optimizing Weight Reduction)

 36 primary care practices from the Midwestern US that predominantly or solely served rural patients

## **PROPEL**

#### PROPEL – In Clinic/Phone

- Received weekly counseling sessions (16 in-person and 6 telephone) in the first 6 months followed by monthly sessions (alternating in person visits and telephone calls) for the remaining 18 months.
- Mostly individual sessions but also could be done in small groups (2-3 patients)
- In person individual sessions were 30 minutes
- In person group sessions were 1 hour
- Phone sessions were 15 20 minutes
- All sessions were done by study-employed health coaches embedded in primary care clinics
- Received counseling on how to set goals and develop individual action plans for diet and exercise with goal to achieve 10% weight loss in 6 months
- Primary care physicians had access to an online obesity science education program that provided education on obesity management, management of co-existing conditions such as Type 2 diabetes and hypertension, minimizing bias and stigma related to obesity, and principles of health literacy

#### PROPEL – Usual Care

- Routine care with primary care team training included a presentation and brochure on obesity management guidelines and CMS reimbursement.
- Received 6 newsletters covering topics related to sitting and health, goal setting, staying safe in the heat, memory health, self-care, sleepy hygiene and smoking cessation

(Katzmarzyk et al., 2021)

## REPOWER

#### REPOWER-clinic-individual

- 15-minute face-to-face individual counseling visits from practice-employed clinicians that occurred weekly for 1 month, every other week for months 2 to 6, and monthly thereafter.
- Each practice selected 1 to 2 counselors, most commonly were clinic-employed nurses
- The counselors participated in a single, 3-hour training session focused on dietary and physical activity recommendations, behavioral strategies, and motivational interviewing..

### REPOWER-clinic-group

- Led by practice-employed clinicians
- Visits were 60 minutes and occurred weekly for the first 3 months and every other week for months 4-6 and monthly thereafter.
- First 14 sessions were face to face. Afterwards practices had the option to switch to group telephone conference calls
  - All but one practice opted to continue face to face visits.
- Each clinic selected between 1 and 3 counselors (predominantly nurses) to deliver intervention.

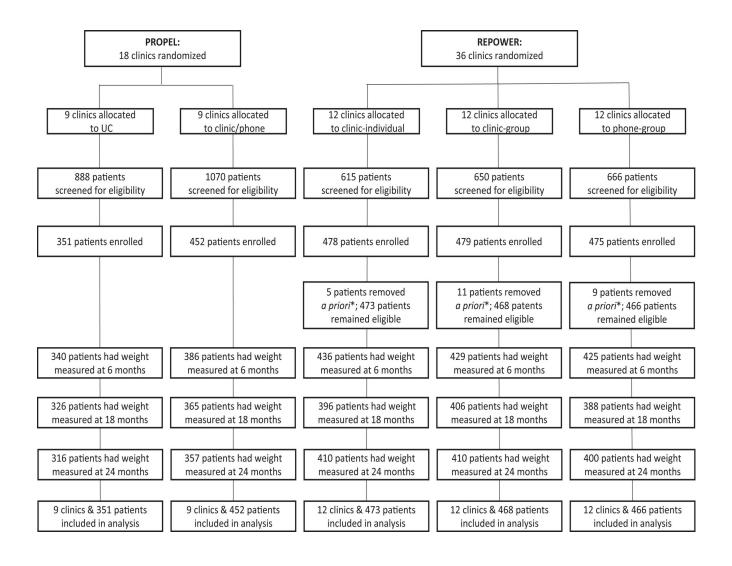
(Katzmarzyk et al., 2021)

## REPOWER

# REPOWER-phone-group

- Received same group-based intervention as REPOWER clinic-group but sessions were delivered via telephone conference calls by centralized study staff
  - Staff employed by research team with graduate degrees in relevant fields (ex: psychology, nutrition, exercise science).

    (Katzmarzyk et al., 2021)



Obesity, Volume: 29, Issue: 12, Pages: 2044-2054, First published: 29 October 2021, DOI: (10.1002/oby.23292)

## Conclusion

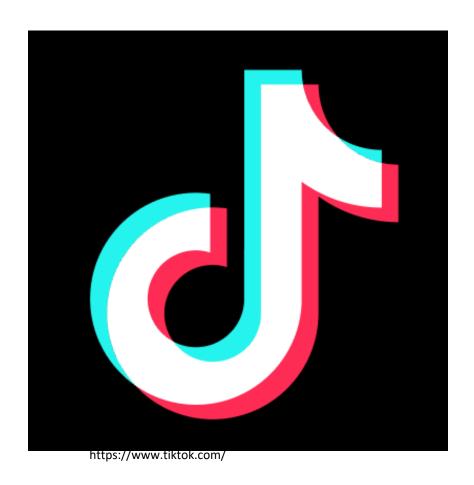
High-Intensity behavioral counseling in primary care settings when delivered in person, by phone or electronically produce clinical significant weight loss (4-7 kg) compared to low and moderate intensity counseling which only produces modest weight loss (1-2kg)

(Katzmarzyk et al., 2021)

# Ozempic Shortage



https://www.daytondailynews.com/local/ozempic-shortage-diabetes-drug-in-demand-due-to-side-effect-of-weight-loss/RNT45DHLJBCVXILHDL5DBHK5MA/



# Weight Loss – FDA approved

#### GLP-1s

Semaglutide (Wegovy) and Liraglutide (Saxenda)

### Other weight loss medications for long term use:

- Bupropion-naltrexone (Contrave)
- Orlistat (Xenical, Alli)
- Phentermine-topiramate (Qsymia)
- Setmelanotide (Imcivree)

### Tirzepatide (Mounjaro)

- Glucose dependent insulinotropic polypeptide and glucagon like peptide-1 receptor agonist
- Only approved for adults with type 2 diabetes
- First and only FDA approved GIP and GLP-1 receptor agonist

(Mayo Clinic Staff, 2022)

#### RESEARCH SUMMARY

#### Tirzepatide Once Weekly for the Treatment of Obesity

Jastreboff AM et al. DOI: 10.1056/NEJMoa2206038

#### CLINICAL PROBLEM

Several clinical guidelines recommend pharmacotherapy for obesity. Tirzepatide — a dual glucose-dependent insulinotropic polypeptide and glucagon-like peptide-1 receptor agonist recently approved in the United States to treat type 2 diabetes — induced clinically relevant weight reduction in phase 2 studies of people with diabetes. However, its efficacy for weight reduction in those without diabetes is unknown.

#### CLINICAL TRIAL

Design: An international, phase 3, double-blind, randomized, placebo-controlled trial examined the efficacy and safety of tirzepatide in adults with obesity or overweight who did not have diabetes.

Intervention: 2539 adults with a body-mass index of 30 or higher, or 27 or higher with at least one weight-related complication, were assigned to once-weekly subcutaneous tirzepatide at one of three doses (5 mg, 10 mg, or 15 mg) or placebo, in addition to lifestyle intervention. Treatment included a dose-escalation phase and lasted for 72 weeks. The coprimary end points were the percentage change in weight from baseline to week 72 and weight reduction of at least 5% by week 72.

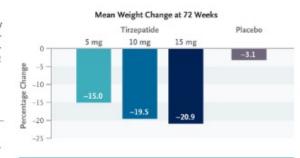
#### RESULTS

Efficacy: Both the percentage change in weight and the percentage of participants with at least 5% weight reduction were significantly greater with all three doses of tirzepatide than with placebo.

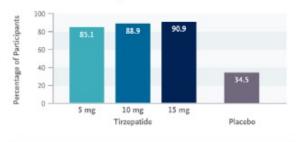
Safety: Gastrointestinal events, including nausea, diarrhea, and constipation, were the most common adverse events seen with tirzepatide; the majority of events were transient and mild to moderate in severity.

#### LIMITATIONS AND REMAINING QUESTIONS

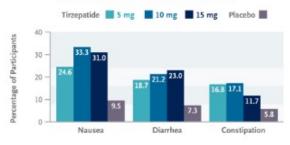
- Enrolled participants may have been more committed to weight management than many people with obesity.
- Cardiometabolic variables (e.g., blood pressure and lipid levels) were relatively normal at baseline, so the ability to show a potential improvement within the time frame of this study was limited.
- The number of participants with overweight plus at least one weight-related complication was small (140 of the 2539 participants; 5.5%), which prevented definitive conclusions in this subgroup.



#### ≥5% Weight Reduction at 72 Weeks



#### Adverse Events Occurring in ≥5% of Participants



#### CONCLUSIONS

All three doses of once-weekly subcutaneous tirzepatide led to clinically meaningful and sustained weight reduction in obese adults who did not have diabetes.

# Buprenorphine Subscribing Update

# Opioid Use Disorder Impact

- Drug overdose deaths have risen fivefold over the past 2 decades
- According to the CDC more than 107,000
   Americans died from drug overdoses in 2021,
   an increase of more than 15 percent from 2020

## DEA Update

- DATA-Waiver for Buprenorphine Eliminated when the Consolidated Appropriations Act (the Act) of 2023 was signed on December 29,2022
- All prescriptions for buprenorphine only require a standard DEA registration number
- There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine
- The Act doesn't impact existing state laws or regulations that may be applicable

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# Questions?

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