



Segal Webinar

New Drugs to Treat Obesity: What Plan Sponsors Need to Know

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Today's Presenters



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Agenda

Diabetes Landscape

- GLP-1 Medication Review, Costs and Concerns

Obesity and the GLP-1 Effect

- Anti-obesity Medication Review and Coverage Cost Implications

Bigger Picture for Managing Obesity and Wellness Programs

Compliance Considerations

Diabetes Landscape

Diabetes Prevalence

11.3% of total US population have diabetes.

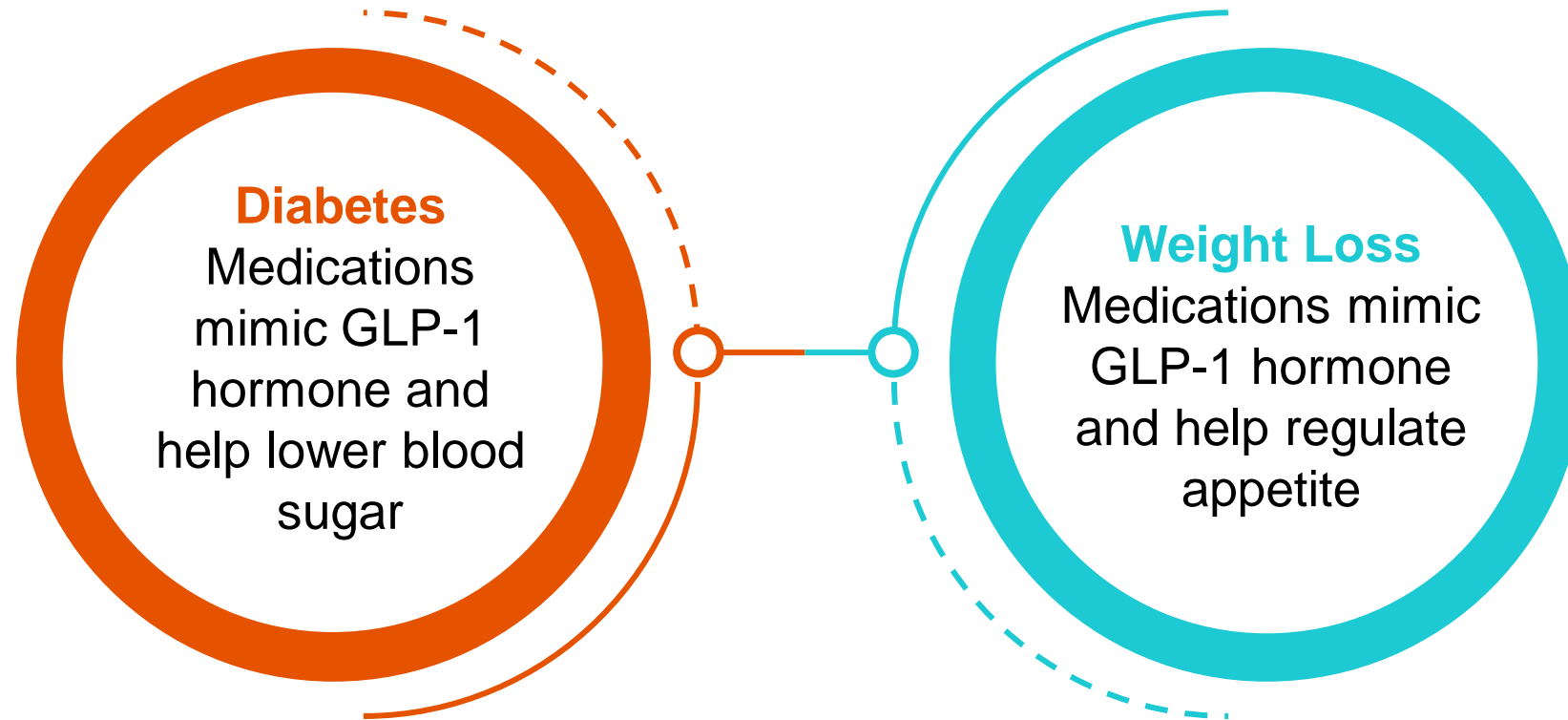
Losing 5-7% of their body weight and added 150 minutes of exercise per week can reduce risk of developing diabetes by up to 58%



Potential market for new drugs is significant

What are GLP-1 Medications?

GLP-1 is a hormone found naturally in our bodies that targets the area of the brain that regulates appetite and is insufficient in people who have type 2 diabetes.



GLP-1s were originally developed to treat type 2 diabetes but now treat for both type 2 diabetes and obesity

What Names do we Know for GLP-1 Agonists?

- Diabetes drugs in the GLP-1 agonists class are generally taken by a shot (injection) given daily or weekly and include:
 - Dulaglutide (Trulicity) (Eli Lilly)
 - Exenatide (Bydureon BCise and Byetta) (AstraZeneca)
 - Semaglutide (Ozempic, Rybelsus oral) (Novo Nordisk)
 - Liraglutide (Victoza) (Novo Nordisk)
 - Lixisenatide (Adlyxin) (Sanofi)
 - Tirzepatide (Mounjaro*) (Eli Lilly)
- Pharma developing more medications based on the success of these medications in treating diabetes

* Mounjaro is the only FDA-approved GIP and GLP-1 receptor agonist

History of GLP-1 Medications

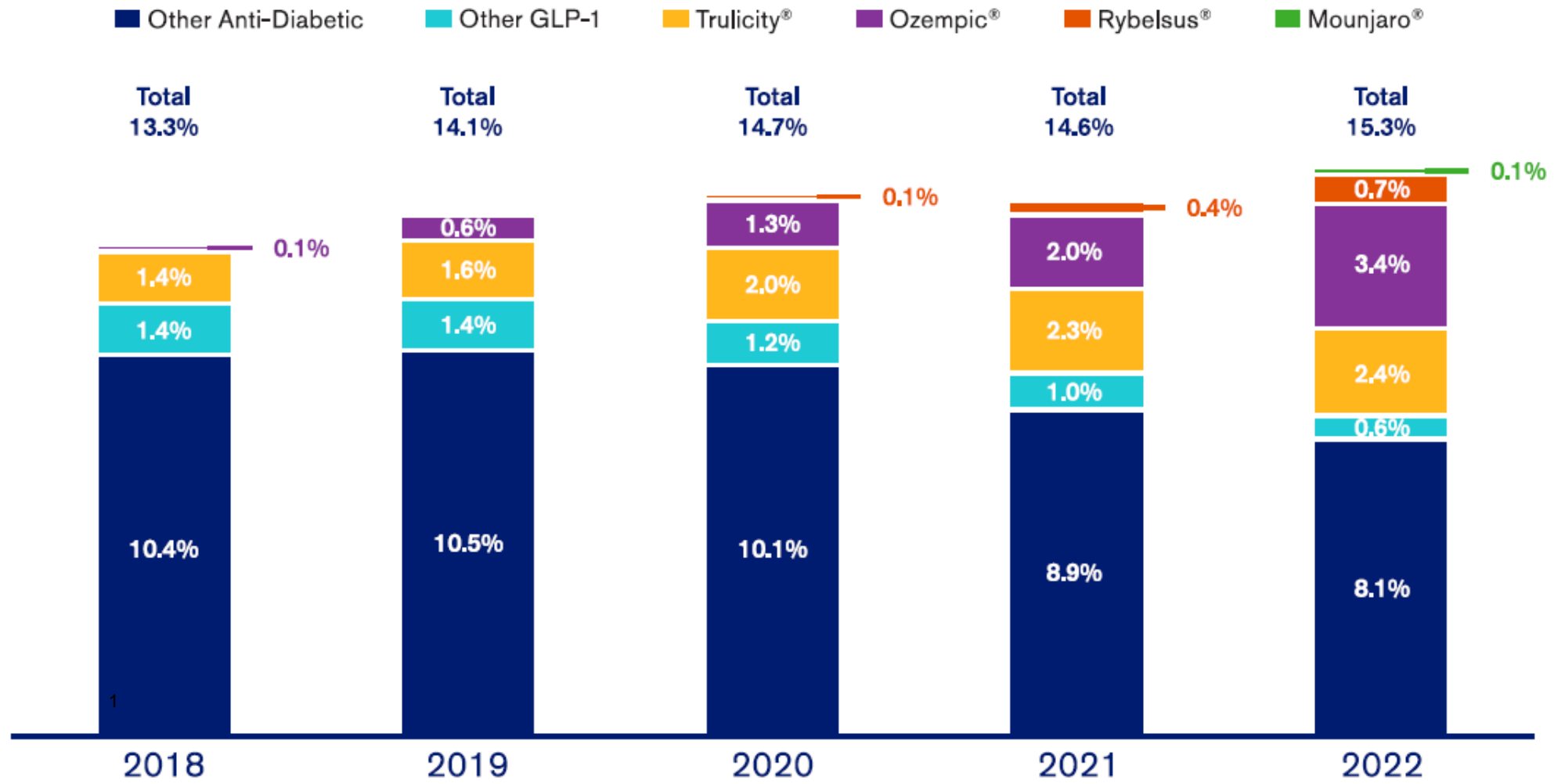
Until recently
GLP-1's used to
treat diabetes

2021, ADA*
recommends prescribing
GLP-1s to reduce health
complications regardless
of A1C or metformin use

2023 ADA guidelines
emphasizes both
supporting higher weight
loss and focusing on
obesity as chronic disease

Led to increased utilization of GLP-1s for diabetes AND weight loss

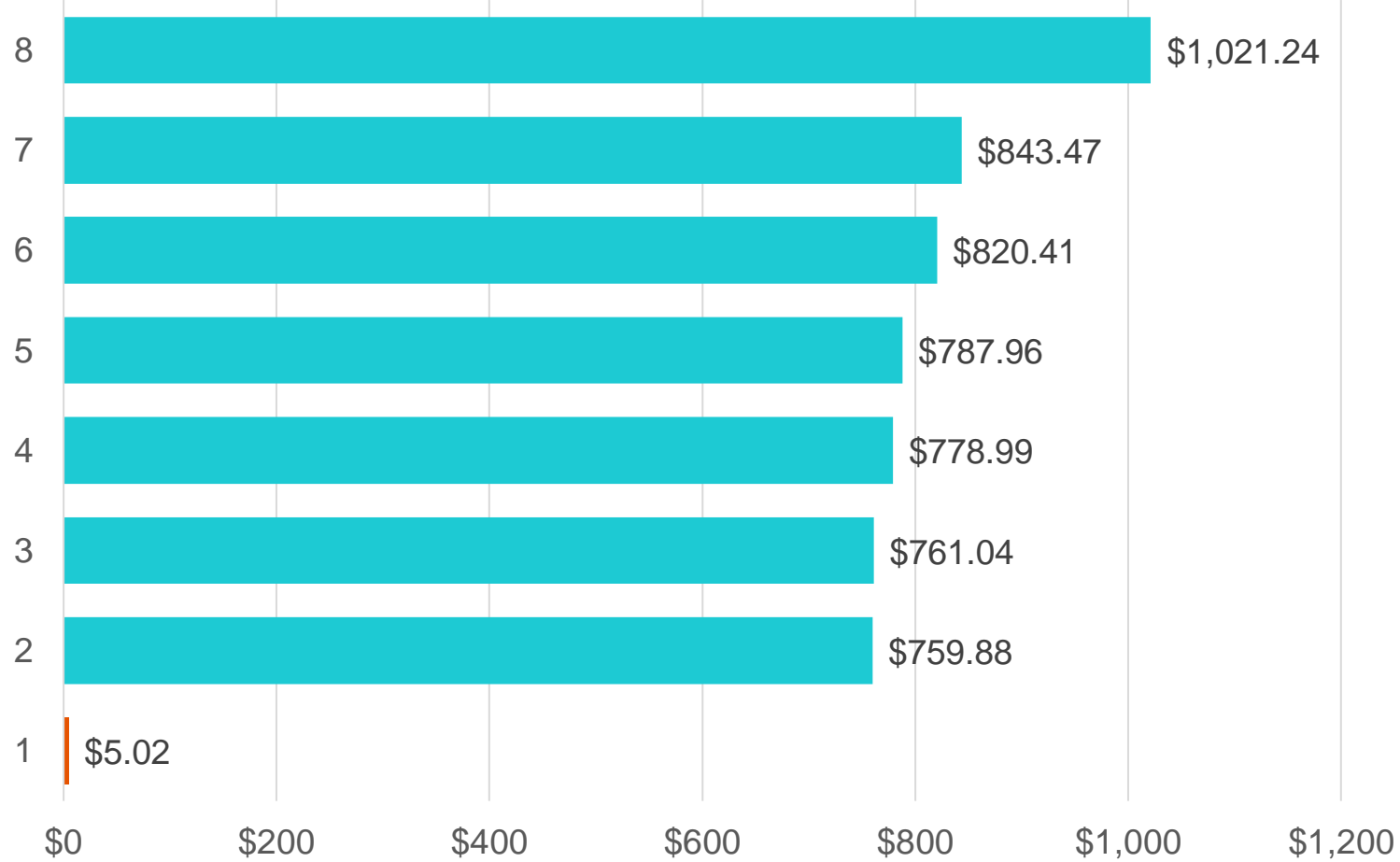
Plan Spending on Diabetic GLP-1s is Rising Steadily



Source: Segal SHAPE, Segal's data warehouse, 2018 to 2022

Diabetic GLP-1 Medication Costs Compared to Metformin

30-day Rx Cost [2023 YTD]



Note that prices listed are mean charges after PBM discounts but before rebate offsets

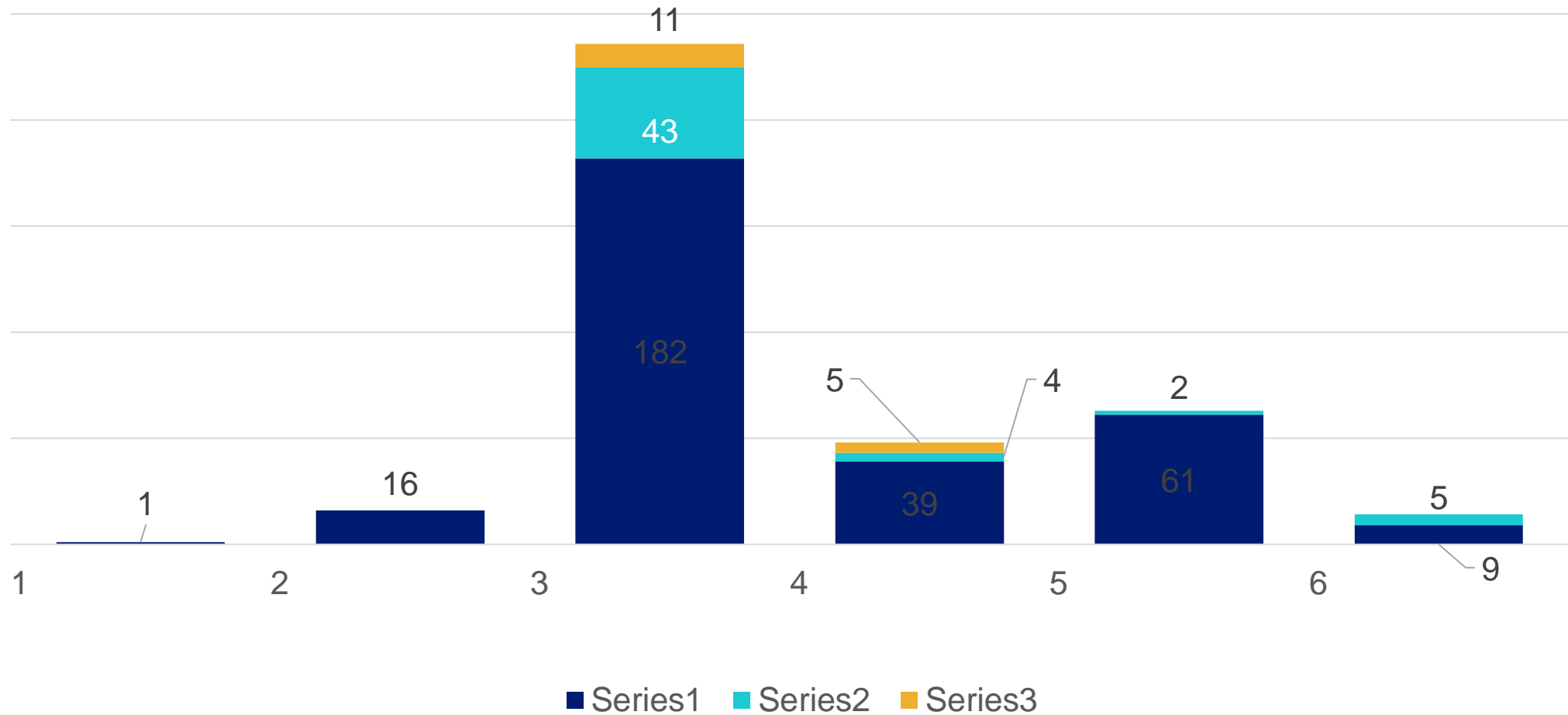
Utilization Concerns

- Off label use of diabetes GLP-1 therapies (i.e. Ozempic) for weight loss
- Social media has been a big contributor to using Ozempic for weight loss which, in turn, has caused drug shortages.
- PBMs are offering utilization management programs to curb off-label spend for the GLP-1 medications.
- GLP-1s are likely to become the number one drug cost therapy for many plan sponsors by 2024.



Off-Label Weight-Loss Drug Usage

2021 – 2022 GLP-1 Utilizer History¹



1. Historical lookback began with date of first GLP-1 medication fill, members may have utilization of more than 1 medication in this class subsequently

Obesity and the GLP-1 Effect

Obesity Prevalence

42% of US
adults are obese

Obesity is
recognized as a
chronic disease
since 2013.

Potential market for new drugs is significant

Are Plans Covering Anti-obesity medications?

- Employers Health, a large group-purchasing organization for pharmacy benefits for 2021 reported 60% of clients exclude obesity drugs and 25% cover them with a PA.
- The IFEBP 2022 Employee Benefits Survey found that 22% of plans covered prescription drugs for weight loss.



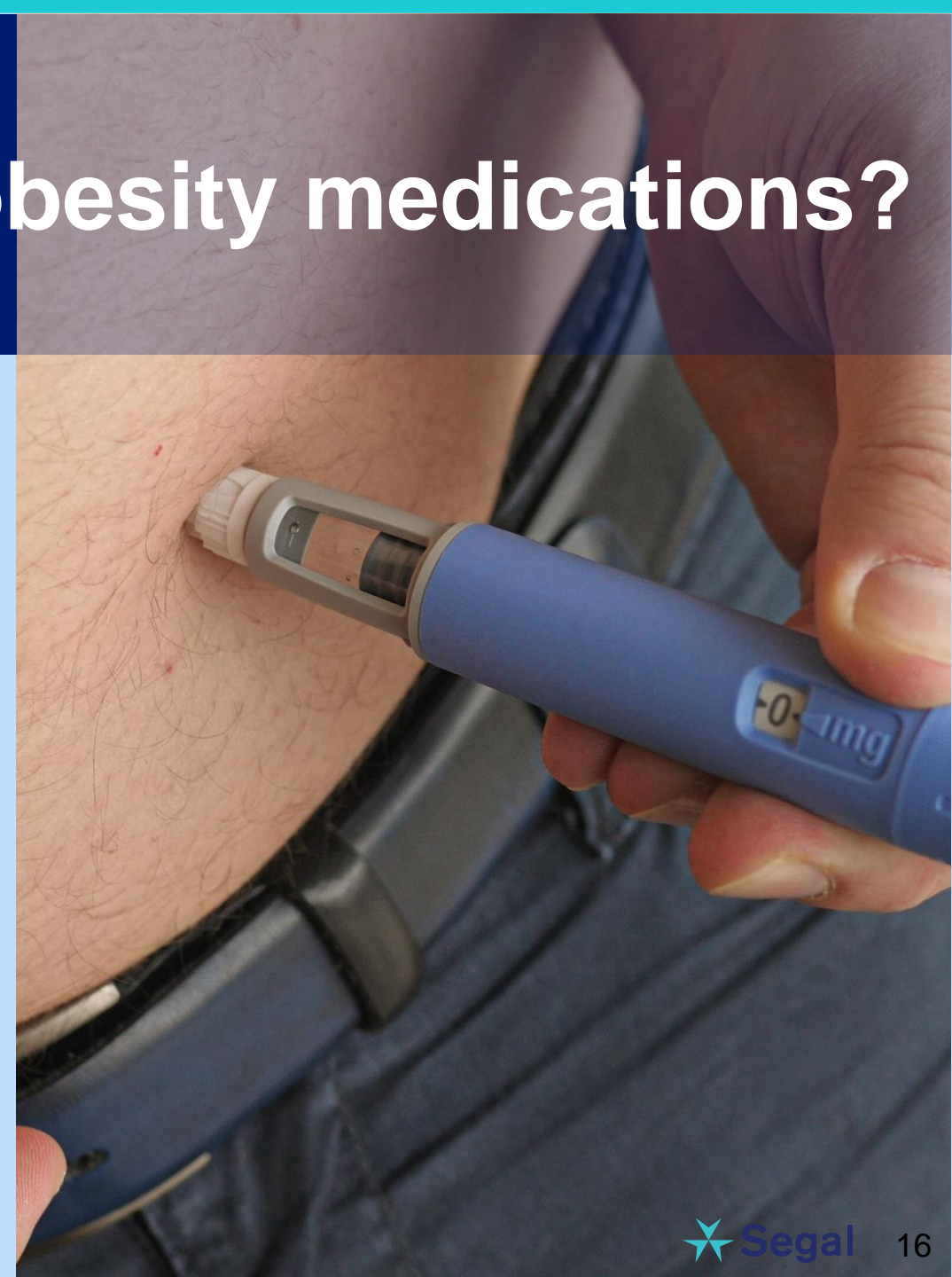
Polling Question 1:

Does your plan cover anti-obesity medications?

Yes

No

No, but plan to cover anti-obesity medications within the next 12 months



What Drugs are the FDA Approved Anti-Obesity Medications?

FDA approved anti-obesity medications include the following:

- Older Anti-obesity Medications (AOMs)
 - Phentermine (Adipex, Lomaira) (Teva Pharmaceuticals, KVK Tech)
 - Phentermine/ topiramate ER (Qsymia) (Vivus)
 - Naltrexone/bupropion HCL (Contrave) (Curax Pharmaceuticals)
 - Orlistat (Xenical, Alli – otc) (CHEPLAPHARM, GlaxoSmithKline)
- Newer Anti-obesity Medications (AOMs)
 - Semaglutide (Wegovy) (Novo Nordisk)
 - Liraglutide (Saxenda) (Novo Nordisk)
 - Imcivree (setmelanotide) (Rhythm Pharmaceuticals and Genpharm)

Anti-obesity Medication Coverage Costs Implications

Wegovy is about 1.5 to two times more effective in losing body weight compared to the older AOMs currently in market.*

Due to success of GLP-1s, plan sponsors that cover anti-obesity medications have seen a dramatic increase in spending on those drugs in the recent years.

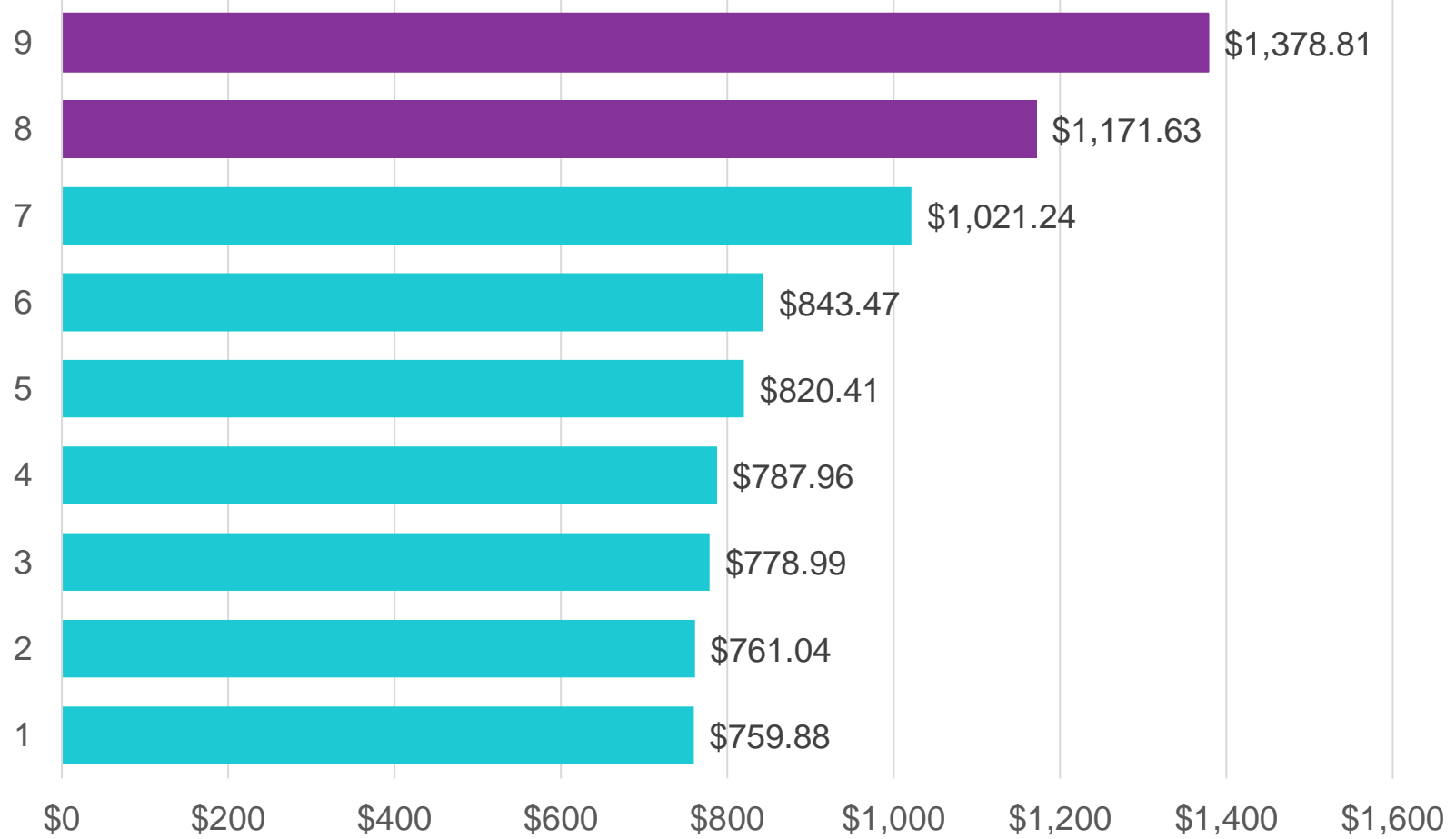
In 2018, the average cost for Segal clients who cover anti-obesity medications (which include the older AOMs and the newer GLP-1 AOMs) was \$0.50 PMPM and by 2022, it was \$2.21 PMPM.

* Source: <https://news.northwestern.edu/stories/2021/02/anti-obesity-medication/>



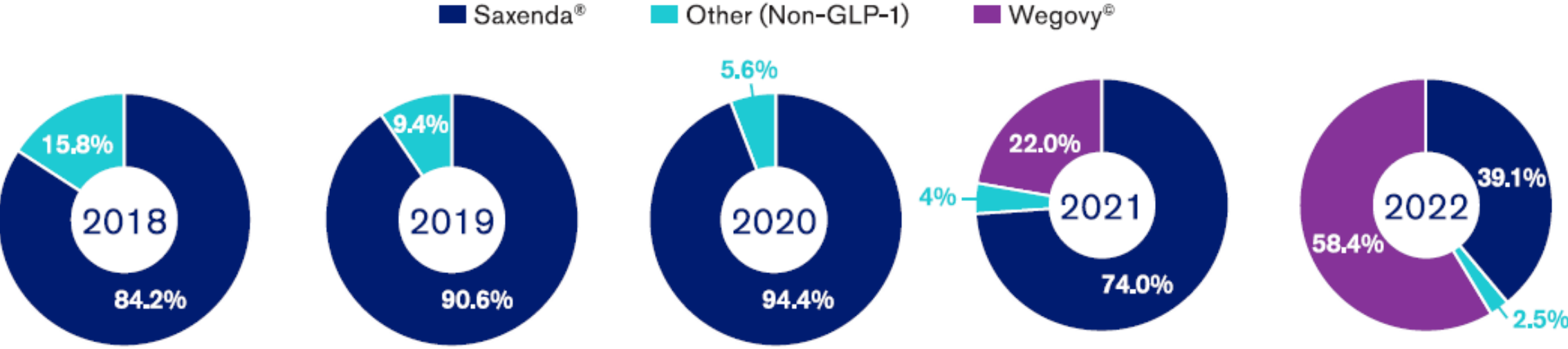
Obesity GLP-1 Medication Costs Compared to Diabetes GLP-1 Medications

30-day Rx Cost [2023 YTD]



Note that prices listed are mean charges after PBM discounts but before rebate offsets

Plan Spending on Anti-obesity Medication Continues to Shift Towards GLP-1s



Source: Segal SHAPE, Segal's data warehouse, 2018 to 2022

Potential Long-Term Benefits of GLP-1 Drug Therapies

There are no long-term studies on Wegovy and Saxenda.

GLP-1 receptor agonists have been used for more than a decade to treat Type 2 diabetes.

Those who are overweight or obese may have or are at greater risk of developing serious health conditions like heart disease and type 2 diabetes.*

Potential long-term benefits may include decreased hospitalizations associated with cardiac events, reduction in other drug therapies as they replace other forms of treatment, reduction in bariatric surgery, etc.

Medicare Coverage

Medicare does not cover obesity drugs, but does cover bariatric surgery and intensive behavioral therapy

The Part D program excludes coverage for obesity medication, but legislation has been proposed to change coverage rules

Supporters of expanding coverage include the NAACP, cancer patient advocacy groups, as well as manufacturers

Coverage is a health equity issue, as obesity is disproportionately prevalent among Black and Hispanic adults

Integrating GLP-1 Coverage with your current Wellness Strategy

What is the plan's current wellness strategy?

How does the plan support diabetes patients?

How does the plan support weight loss?

The Bigger Picture for Managing Obesity

- Assess and reevaluate current obesity treatments under the medical benefit.
- Update patient education and access to lifestyle weight-loss programs
- Offer access to low-cost fitness programs
- Implement UM guidelines for all AOMs
- Require patients to be in a behavioral health management program



The Bigger Picture for Managing Obesity

- Negotiate lowest-net-cost PBM formulary changes
- Provide educational support for appropriate and safe exercising.
- Offer access to virtual coaching
- Implement accountability check-ins with patients
- Consider implementing stricter coverage to target smaller group of plan participants
- Seek outcomes-based performance guarantees with PBMs when adding coverage of these high-cost anti-obesity meds tied to achieving minimum average weight loss amounts (e.g. at least 10% weight loss after 6 months use).

Need for Health Coaching

Needs whole person care, not just medication access

- Health coaching is of paramount importance in order to:
 - Build ongoing, trusted relationship with the recipient of the medication
 - Monitor the medication side effects and interactions
 - Address the medication goal areas and adherence
 - Discuss dosages, interactions, side effects and concerns related to the medication
 - Can advocate, speak directly with Physician or pharmacy
 - Monitor and help manage medication tolerance and contraindications

Goal: Sustainable Weight Loss

- Continued behavior change coaching for 1-2 years post treatment
- Build and activate ongoing support network for each participant
- Learned and lasting behavior change
 - Weight management
 - Nutrition advice
 - Exercise advice
 - Medication adherence
 - Stress, sleep, other disease state management
- Importance of physical health and wellbeing is established
- Relapse prevention

Compliance Considerations

What Does the Plan Currently Cover?

Does the SPD currently cover or exclude weight loss medications?

Check with the PBM to determine whether administration is consistent with the SPD.

Are there any current rules about coverage of eating disorders, weight loss drugs, or bariatric surgery that may impact weight loss drug benefits or services included as part of a weight loss program?

Are weight loss drugs covered in every instance of medically necessity or only for diabetes?

Make plan changes that are needed.

The Evolving Landscape of Weight Loss Drugs

- Plan sponsors will need to continue to watch the evolution of clinical indications and prescribing practices and review and update plan terms as needed, to any extent new trends implicate coverage considerations.
- Plan sponsors should always consider generally applicable rules such as the HIPAA nondiscrimination rules, the HIPAA and ACA wellness program rules, the Mental Health Parity and Addiction Equity Act (MHPAEA), the Americans with Disabilities Act (ADA) and the HIPAA Privacy rules.

Compliance Considerations

- If my plan covers all FDA approved drugs will these weight loss drugs be covered?
- Does the exclusion of ALL weight loss drugs currently raise compliance concerns?
- Does the application of prior authorization of weight loss drugs raise compliance concerns?

Compliance Considerations

Wellness

The HIPAA Nondiscrimination rules generally prohibit discrimination in group health plan benefits and premium and contribution rates based on a health factor.

HIPAA and the Affordable Care Act (ACA) include special rules related to group health plan wellness programs. EEOC wellness program rules in flux.



Compliance Considerations

Wellness

- **Ignore the label!** Many programs implicate the wellness program rules, regardless of how the program is named.
- Presently many plans exclude coverage of weight loss drugs except for the treatment of diabetes.
- Consider if the benefits are offered in conjunction with a program of health promotion or disease prevention
 - Participatory Wellness Programs
 - Health Contingent Wellness Programs (which include limits on the size of the reward)
 - Benign Discrimination
 - Notice

Compliance Considerations

Mental Health Parity

- Presently most weight loss drugs are only clinically indicated for the treatment of diabetes. However, Wegovy is indicated for high BMI and more drugs focused on weight loss, absent a diabetes diagnosis are expected.
- While individuals with a mental health condition, such as an eating disorder may benefit from a weight loss drug, the primary diagnosis for prescribing these is expected to be the medical condition of obesity.
- However, plans should ensure that as plan terms evolve parity in MH/SUD benefits remain considered.
- Continued consistency in the approach to prior authorization for Med/Surg and MH/SUD Rx must be considered.

Compliance Considerations

Mental Health Parity

Expanded access to mental health and/or nutrition counseling in connection with eating disorders as part of a weight loss program designed around best practices for the use of weight loss drugs may raise compliance considerations.



Thank You

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