GLP-1 Medications for Weight Loss

Board of Trustees Meeting

January 25, 2024

North Carolina State Health Plan
FOR TEACHERS AND STATE EMPLOYEES
A Division of the Department of State Treasurer

Dale R. Folwell, CPA
State Treasurer of North Carolina

GLP-1 Medications for Weight Loss Coverage Exclusion

At the October 26, 2023, board meeting, the board voted on and enacted the following moratorium:

- Effective January 1, 2024, GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities when used for the purpose of weight loss will be excluded from State Health Plan coverage for any member that has not obtained the medication prior to Jan. 1, 2024.
- Therefore, if a member was already taking Saxenda, Wegovy or Zepbound, they are grandfathered in and can continue to take it.
- This did not impact members taking GLP-1 and GIP-GLP-1 agonists medications FDA approved to manage diabetes.

- The board asked Plan staff to research other options or alternatives for utilization management opportunities.

3 Levers

Lower the Cost of Medication

Increase Rebates

Reduce Utilization

Background

- Since January 2015, the State Health Plan (Plan) has covered the GLP-1 classification of drugs for weight loss. This includes Saxenda, with Wegovy being added in October 2021.
- **Over the last three years, the Plan has seen an unprecedented growth in usage of these medications.**
- The cost to the Plan for GLP-1s prescribed for weight loss has increased from approximately $3 million per month, three years ago, to over $14 million per month in 2023 (before manufacturer rebates).
- The Plan expects these costs to continue to increase. These drugs are projected to exceed $600 million annually before rebates within the next five years, absent significant price concessions.
- By 2025, State Health Plan premiums would have to increase by $48.50 per subscriber per month for all members – not just users of these drugs – to cover the projected net cost of GLP-1s being used for weight loss.

2023 Total Plan Cost of GLP-1 Weight Loss Medications

Drug Brand Name	Utilizers	Prescriptions	Plan Cost Before Rebates	Approximate Net Plan Cost
Wegovy	20,400	109,100	$144,800,000	$86,900,000
Saxenda	6,600	19,800	$25,200,000	$15,100,000
Zepbound	450	500	$200,000	$200,000
Total	***24,750**	**129,400**	**$170,000,000**	**$102,200,000**

* After the board action in October, approximately 2,000 new utilizers filled prescriptions.

Rebates

- The State Health Plan uses a PBM, currently CVS Caremark, to manage and administer prescription drug benefits. The Plan uses a “pass-through” model for the PBM contract.
- Pass-through PBMs offer the most transparency among PBM models. They pass 100% of all rebates and discounts back to the plan sponsor. Pass-through PBMs can do this since their only source of revenue is an administration fee.
- They typically provide full financial and operational disclosure and offer full audit rights down to the claim and invoice level so plan sponsors can verify the transactions.
- When it works correctly, this model incentivizes the PBM to focus on lowering overall drug spending with the right drug mix and selective rebates. This also helps plan sponsors achieve a better prescription drug financial trend and maintain a low Per Member Per Month (PMPM) cost.
- CVS Caremark must provide quarterly rebate payments equal to one hundred percent (100%) of pass-through actual rebates.

CVS Statement Regarding Impact on Rebates

During the last Board meeting we discussed that the following would result in loss of rebates.

- Benefit Exclusion of GLP-1 Weight Loss Medications
- Utilization Management Update of Prior Authorization

Since the last meeting the Plan has received additional information from CVS Caremark:

Possible Program Options

> *"At this time CVS Caremark believes this program would not earn any rebates. The reason being is that it requires completion of this program before dispensing and does not follow label. Saxenda and Wegovy are indicated as an adjunct to diet and exercise, not as a follow-up after diet and exercise failed, which is why we believe requiring diet and exercise programs first to not be to label."*

Emailed 11.28.23.

Grandfathered Members

If we do not restart the GLP-1s for weight loss, what will the rebate impact be for the members grandfathered in under the moratorium?

> *"With your planned plan exclusions in 2024, we do not believe grandfathered/PUE members would be rebate eligible."*

Emailed 12.1.23.

Projected 2024 Cost of Grandfathered Participants

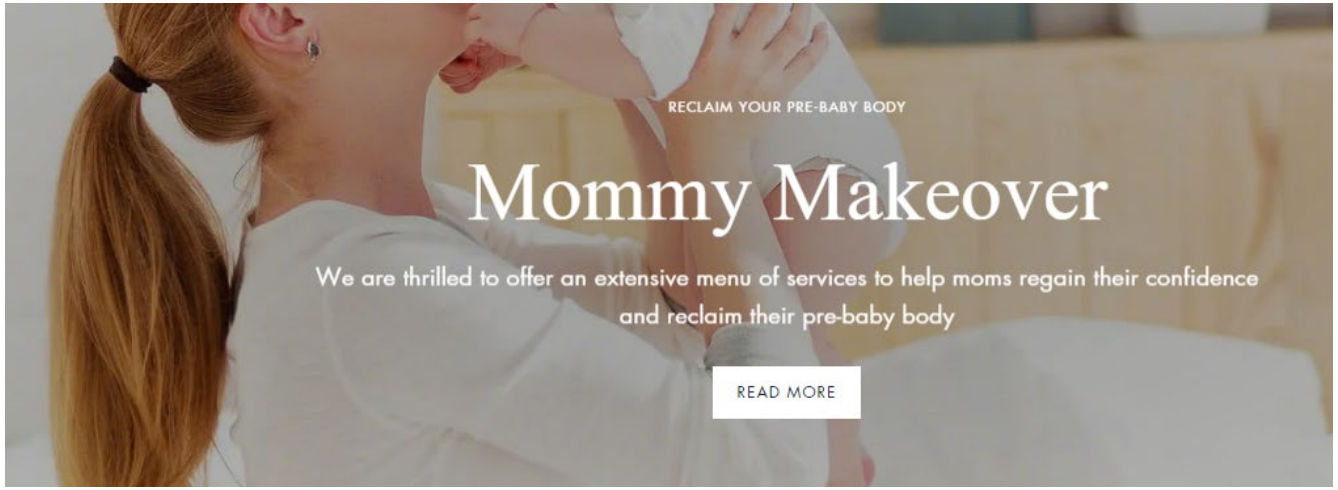
Grandfathered Participants from 2023
24,749

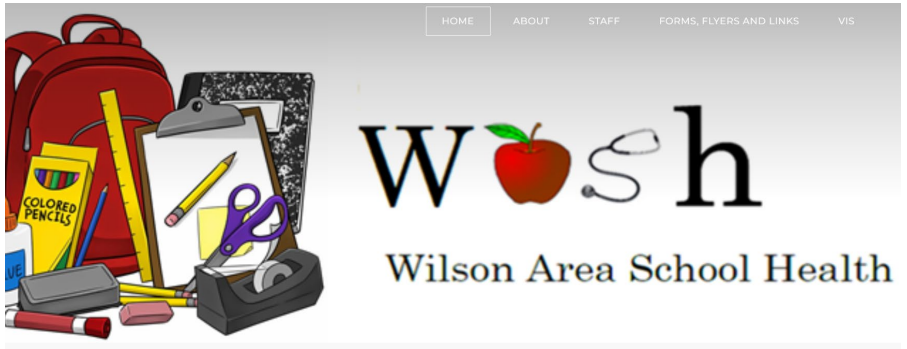
2024 Projected Cost
$139M

Projected net costs to the Plan in 2024 if the board had not excluded new users in October 2023	**$170M**
Cost of Grandfathered Class if Rebate Remained at 2023 Level	**$85M**
Cost of Covering Grandfathered Class After Rebate Loss	**$139M**
Difference Due to Rebate Loss	**$54M**

Top 25 Prescribers of GLP-1 Medications

- In 2023, about 6,200 providers wrote prescriptions for weight-loss GLP-1s to Plan members.
- The top 25 prescribers accounted for more than 8% of the Plan's pharmacy cost for GLP-1 weight loss drugs.
- For some prescribers, there were no medical claims submitted that are associated with these prescriptions.





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Obesity Management Certificate Programs, Some Funded by Novo Nordisk

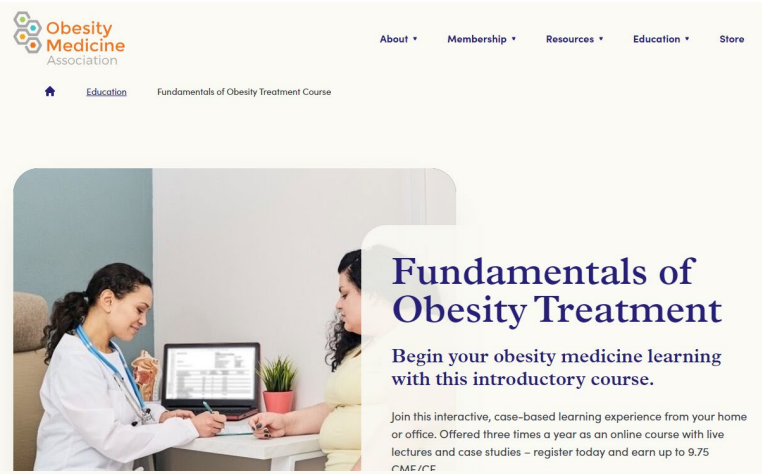
- Novo Nordisk is providing grants to fund obesity medicine certifications for prescribers.
- Some of the physicians involved in developing treatment guidelines for obesity medicine are paid by Novo Nordisk.
- Novo Nordisk has paid U.S. medical professionals at least $25.8 million over a decade in fees and expenses related to Saxenda and Wegovy.

A REUTERS SPECIAL REPORT

Maker of Wegovy, Ozempic showers money on U.S. obesity doctors

Drugmaker Novo Nordisk paid U.S. medical professionals at least $25.8 million over a decade in fees and expenses related to its weight-loss drugs, a Reuters analysis found. It concentrated that money on an elite group of obesity specialists who advocate giving its powerful and expensive drugs to tens of millions of Americans.

By CHAD TERHUNE and ROBIN RESPAUT | Filed Dec. 1, 2023, 11 a.m. GMT



Accreditation for the Fundamentals of Obesity Treatment Course

The Obesity Medicine Association (OMA) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

- The Obesity Medicine Association designates this live activity for a maximum of 9.75 *AMA PRA Category 1* CreditsTM. Physicians should claim only the credit commensurate with the extent of their participation in the activity.
- Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 9.5 Medical Knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Education Support

This education activity has received support through an independent educational grant from Novo Nordisk, Inc.

"Supported by an independent medical education grant from Novo Nordisk."

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Utilization Management Options

Prior Authorization Options	Rebate Impact
Change BMI criteria for GLP-1 anti-obesity agents a. BMI of at least 40 kg/m2 or b. BMI of at least 35 kg/m2 and 1 or more weight related comorbid condition (hypertension, type 2 diabetes mellitus, or dyslipidemia) State of California utilizes this with CVS.	100% rebate loss
Add additional criteria to Prior Authorization Qset for GLP-1 anti-obesity agents. a. Include manufacturer black box warning on risk of Thyroid C-Cell Tumors. i. Wegovy and Saxenda are contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). b. List current therapy for all medical conditions (including obesity), identifying specific treatments including medications c. Does the patient have type 2 diabetes? i. If yes, they must use the formulation indicated for diabetes. d. Provide documentation of current height and weight measurements (within 30 days of the form) e. Is the patient currently pregnant and/or lactating? f. Does the patient have a history of malabsorption syndromes or cholestasis? g. Does the patient have a history of an eating disorder?	100% rebate loss

Utilization Management Options

Prior Authorization Options	Rebate Impact
Patient must have lost ≥3% weight (2% BMI for adolescents) from baseline from at least three months of lifestyle modification prior to initiating GLP-1 anti-obesity agents.	100% rebate loss Anything that deviates from the FDA labeling and changes utilization patterns.
$20,000 lifetime maximum coverage of GLP-1 anti-obesity agents.	
Limited provider network: Require American Board of Obesity Medicine (ABOM) certified providers to prescribe GLP-1 anti-obesity agents.	

Utilization Management Options

Prior Authorization Options	Rebate Impact
Step therapy a. Require that patients try and fail a non-GLP-1 anti-obesity agent in the previous 6 months before approval of GLP-1 anti-obesity agent.	100% rebate loss Anything that deviates from the FDA labeling and changes utilization patterns.
Duration of therapy limit: Via criteria handled by the medical plan (such as reduced A1C, reduced LDL, etc.). If member is not meeting clinical endpoints, can determine whether to allow continued coverage of GLP-1 anti-obesity agents.	

Possible Utilization Management Program Options

Program	Cost	Rebate Impact
Required Nutrition Visits Require members to complete “x” number of visits with an in-network nutritionist prior to access to GLP-1 anti-obesity agent.	Member cost ($0.00) Plan cost for visit (Avg. $80)	100% loss of rebates
Wellframe Weight Loss Program Would customize. Members would be required to complete program before access to GLP-1 anti-obesity agents.	Quote not provided at this point. Notified this is the most expensive out of ESMMWL, Wellframe and Nutrition Visits options.	100% loss of rebates
Eat Smart, Move More, Weigh Less (ESMMWL) Require all members to utilize program for 15 weeks prior to initiation of GLP-1 anti-obesity agents.	$215.00 per utilizer per year	100% loss of rebates
Flyte Program (Connecticut) Medically supervised weight loss / weight management program. Requirements: must be 18 years old or older, having a BMI of 30 or higher, or a BMI of 27 with one weight-related condition (diabetes, heart disease, sleep apnea, etc.).	$100 per member per month	100% loss of rebates
CVS Weight Loss Program 12-month program in conjunction with GLP-1 anti-obesity agent use.	$138.00 per utilizer per month	Opportunity to earn and keep rebates; Details would have to be worked out.

Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes Clinical Trial

(SELECT (CVOT)-Lincoff AM et al. New England Journal of Medicine, 2023)

Clinical Trial Demographics

- 17,604 adults
- Mean age of 61.6 (+/- 8.9)
- 72.2% male
- Pre-existing cardiovascular disease
  - > ¾ had a previous Myocardial Infarction
  - ¼ chronic heart failure
- Medical Therapies
  - 90.1% were receiving lipid-lowering medications
  - 86.2% were receiving platelet-aggregation inhibitors
  - 70.2% taking beta-blockers
  - 45% taking ACE-Inhibitors and 29.5% taking ARBs
- Mean BMI was 33.3 +/- 5.0
  - 71.5% obese (>30)
- No history of diabetes
  - 66.4% met A1C criteria for pre-diabetes (5.7-6.4%)

Clinical Trial Results

- 20% relative reduction in risk of major adverse cardiovascular event with semaglutide versus placebo on top of standard care.
- **1.5% absolute reduction** from 8.0% in placebo-treated patients to 6.5% in those taking semaglutide.

The benefits of this study do not correlate to the Plan members currently utilizing GLP-1s for weight loss.

Decision Point

Below are four options, three of which would require a motion by the board.

Enact a full exclusion, end grandfathering that was approved at the October 26, 2023, Board meeting and take no further action.

- Vote to exclude coverage of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities when used for the purpose of weight loss from State Health Plan coverage for any member effective April 1, 2024.
- Potentially saves approximately $100M for calendar year 2024.

Enact a full exclusion, end grandfathering, and direct Plan staff to continue exploring options with the PBM and the manufacturers.

- Vote to exclude coverage of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities when used for the purpose of weight loss from State Health Plan coverage for any member effective April 1, 2024.
- Potentially saves approximately $100M for calendar year 2024.

Maintain status quo and direct Plan staff to continue exploring options with the PBM and the manufacturers.

- Move to direct Plan staff to continue negotiations with CVS Caremark and manufacturers of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities when used for the purposes of weight loss.

Maintain status quo and give Plan staff no further direction.

- Keep grandfathering as approved during the October 26, 2023, meeting and not pursue any other options. This would not require a motion.