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Correspondence Memorandum

Date: July 15, 2024

To: Group Insurance Board

From: Tricia Sieg, Pharmacy Benefits Program Manager

Office of Strategic Health Policy

Subject: Weight-Loss Drugs Analysis and Coverage Considerations

This memo is for informational purposes only. No Board action is required.

Executive Summary

At the May 23, 2024, Group Insurance Board (Board) meeting, the Board asked for updated information regarding weight-loss drugs, also known as anti-obesity medications (AOMs) and glucagon-like peptide 1 (GLP-1) agonist (drugs). The Board requested an update on the cost of AOMs, an overview of coverage of these drugs by other state public employee plans, and the latest available information on these drugs.

The Board's current third-party administration of pharmacy benefits program contract with Navitus Health Solutions (Navitus) specifically excludes pharmacy benefit coverage of any United States Food and Drug Administration (FDA) medications for weight loss. The current contract is set to expire Dec. 31, 2025.

ETF is aware of the continued interest of members in adding weight-loss drug coverage to the pharmacy benefit, as demonstrated in Board Correspondence received over the past three years. The Board has discussed AOMs at several prior meetings.¹

This memo provides the Board with an overview of the history of GLP-1s an update of the ever-changing landscape of AOMs for weight loss and other health benefits, an update on peers in adopting AOMs and initial discussion of approaches to coverage. The legal landscape relative to pharmacy benefits managers (PBMs) and AOMs is further discussed in the "Healthcare Legal Update" memo (Ref. GIB | 08.14.24 | 13A).

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See memos from the following meetings: May 18, 2022 (<u>Ref. GIB | 05.18.22 | 5C</u>), June 30, 2022 (<u>Ref. GIB | 06.30.22 | 4</u>), Nov. 16, 2022 (<u>Ref. GIB | 11.16.22 | 13</u>), May 17, 2023 (<u>Ref. GIB | 05.17.23 | 3C</u>), Feb. 21, 2024 (<u>Ref. GIB | 02.21.24 | 7C</u>), and May 23, 2024 (<u>Ref. GIB | 05.23.24 | 10A</u>).

Plan for Coverage Consideration

ETF will continue to update the Board with any information that becomes available about the utilization, costs, and quality of weight-loss drugs, as well as the possibility of coverage. ETF will provide an operational update regarding AOM utilization, costs, changes in the drug class, legislation, research, and other AOM related topics at the Nov. 13, 2024, Board meeting. Given the Board's interest in considering AOMs for Group Health Insurance Program (GHIP) members and its statutory limitation to add benefits without offsetting savings, ETF plans on providing the board potential short term and long-term options prior to setting 2026 benefit levels.

At the February 2025 Board meeting, the Board is scheduled to award a new Third-Party Administration of Pharmacy Benefits Program contract that will begin on Jan. 1, 2026 (Ref. GIB | 11.15.23 | 12B). Questions regarding AOM coverage were included in the request for proposals (RFP). At the time the RFP results and recommendation are presented, ETF will update the Board on any options that the vendors have presented. However, due to PBM contract negotiations scheduled to begin immediately following the February 2025 Board meeting, options for weight-loss drug coverage for 2026 including possible changes to copays or pilot programs may have to be presented to the Board at the May 2025 Board meeting or possibly in a special meeting prior to the regularly scheduled May meeting.

Historical and New Clinical Indications for GLP-1s

A GLP-1 is a type of peptide hormone that can stimulate the pancreas to produce more insulin, thereby managing a person's blood sugar (also known as glucose) level while slowing the movement of food from the stomach into the small intestine. This slower movement of food helps a person to feel full faster and longer.

In 1984, the first GLP-1 was discovered. The GLP-1 was then researched as a treatment for diabetes. This research led to the first GLP-1 drug, Byetta, being approved by the FDA in 2005, to treat people with type 2 diabetes.²

During clinical trials and in post drug release research on GLP-1 agonists used to treat type 2 diabetes, it was discovered that people taking GLP-1 drugs saw significant weight loss. This led to Novo Nordisk releasing Saxenda in 2014, the first GLP-1 drug intended specifically to treat obesity. Novo Nordisk followed that release with the 2017 release of Ozempic, a GLP-1 drug to treat type 2 diabetes.

In 2021, Novo Nordisk gained FDA approval of Wegovy, a GLP-1 drug, for the treatment of obesity. Ozempic and Wegovy both contain the same active ingredient. Ozempic was only approved by the FDA to treat type 2 diabetes, and until April of 2024, Wegovy was only approved for weight loss. Both drugs are self-injected weekly with the maximum dosage being 2mg for Ozempic and 2.4mg for Wegovy.³

² Cleveland Clinic. GLP-1 Agonists. https://my.clevelandclinic.org/health/treatments/13901-glp-1-agonists

³ Billingsley, Alyssa. "Wegovy vs. Ozempic: Are They the Same? 5 Differences You Should Know About" GoodRx Health. https://www.goodrx.com/classes/glp-1-agonists/wegovy-vs-ozempic

In 2022, Eli Lilly gained FDA approval of Mounjaro, a GLP-1 drug for the treatment of type 2 diabetes. This was followed by Eli Lilly's 2023 introduction of Zepbound, a drug approved for chronic weight management. Both Mounjaro and Zepbound contain the same active ingredient.⁴ Mounjaro and Zepbound are self-injected weekly and have similar dosages, side effects, and drug interactions.⁵

A study released on July 8, 2024, examined electronic health records of more than 18,000 overweight or obese people who were using Ozempic and Mounjaro. The study found that people taking Mounjaro had a higher probability of achieving weight loss at three, six, and 12 months as compared to individuals who were taking Ozempic.⁶ While Mounjaro is the same as Zepbound and Ozempic is the same as Wegovy, the results of those taking Zepbound and Wegovy were not examined in this study.

Table 1: GLP-1 Drugs, Approved Indications, and Current Coverage

Drug	Manufacturer	Approval Year	FDA Approved Indications	Covered by the GHIP
Saxenda	Novo Nordisk	2014	Chronic weight management in adults	No
Ozempic	Novo Nordisk	2017	Lower blood sugar levels in adults with type 2 diabetes	Yes
Wegovy	Novo Nordisk	2021	Chronic weight management in adults and certain children with obesity. Reduces the risk of cardiovascular death, heart attack, and stroke in adults with cardiovascular disease and those who are either obese or overweight.	No
Mounjaro	Elli Lilly	2022	Improve glycemic control in adults with type 2 diabetes	Yes
Zepbound	Elli Lilly	2023	Chronic weight management in adults	No

⁴ Cleveland Clinic. Tirzepatide Injection. https://my.clevelandclinic.org/health/drugs/23789-tirzepatide-injection

Aungst, Christina. "6 Things to Know When Comparing Mounjaro vs. Zepbound" GoodRx Health.
 https://www.goodrx.com/classes/gip-receptor-glp-1-receptor-agonists/mounjaro-vs-zepbound
 Rodriguez PJ, Goodwin Cartwright BM, Gratzl S, et al. "Semaglutide vs Tirzepatide for Weight Loss in Adults

Rodriguez PJ, Goodwin Cartwright BM, Gratzl S, et al. "Semaglutide vs Tirzepatide for Weight Loss in Adults with Overweight or Obesity." *JAMA Intern Med.* Published online July 08, 2024. doi:10.1001/jamainternmed.2024.2525

Table 2: Current Commercial and Employer Group Waiver Plan (EGWP) Utilization for Covered GLP-1 Drugs in the Group Health Insurance Program (GHIP)*

Drug	2021 Utilizing Members	2022 Utilizing Members	2023 Utilizing Members
Ozempic	1,226	2,138	2,774
Mounjaro	-	1,177	1,217

^{*} Mounjaro was not covered under the Board's EGWP formulary until Jan 1, 2024.

New Indications for GLP-1s

Since their approval for treatment of diabetes and obesity, GLP-1s have been approved to treat additional health conditions. On March 8, 2024, the FDA approved Wegovy as a treatment to reduce the risk of cardiovascular death, heart attack, and stroke in adults with cardiovascular disease and either obesity or overweight.⁷ The addition of cardiovascular disease as an approved indication will increase the number of patients with access to these drugs in the GHIP.

Plan sponsors offering Medicare Part D coverage cannot add weight-loss drugs to their formularies due to 42 USC 1395W-102, which prohibits the Center for Medicare and Medicaid Services (CMS) from including such coverage. However, CMS guidance issued on March 20, 2024, allows Medicare Part D sponsors to add coverage for Wegovy with the new indication at the next available opportunity. Coverage under Medicare Part D is restricted to members with the new indications and a Body Mass Index (BMI) of 27 or higher. The drug cannot be used solely for weight loss.⁸

Navitus has not added coverage of Wegovy with the new indications to any of their Medicare Part D formularies or to the Board's commercial formulary. According to Navitus, as of June 24, 2024, they are continuing to evaluate weight-loss drug pricing and are still considering Wegovy's expanded indications.

ETF used the GHIP data warehouse to estimate the potential cost of adding Wegovy with the new cardiovascular indication for both Medicare and non-Medicare members. Members who have a BMI of 27 or greater, a history of cardiovascular disease, and no history of taking a drug to treat type 2 diabetes were found to be the members most likely to take Wegovy with the new indications. Because not every member who fits the criteria will take the drug, the percentage of diabetic patients that take a GLP-1 drug (such as Ozempic, Trulicity, Mounjaro, etc.) was used to estimate how many members may take Wegovy with the new indication.

United States Food and Drug Administration (2024, March 8) FDA approves First Treatment to Reduce Risk of Serious Heart Problems Specifically in Adults with Obesity or Overweight https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-reduce-risk-serious-heart-problems-specifically-adults-obesity-or

Center for Medicare and Medicaid (2024, March 20) Part D Coverage of Anti-Obesity Medications with Medically Accepted Indications https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-wk-4-march-18-22

ETF estimated that 9,823 non-Medicare and 5,574 Medicare members (a total of 14,963 members) may take Wegovy with the new indication. Estimating the drug to cost \$16,200⁹ a year per member (\$1,350 per month)¹⁰ and assuming 27.11% of those that qualify use the drug, it would cost the Board \$65,561,468 annually to cover Wegovy for the cardiovascular indication.

There have been no studies released on what cost savings in the short-term or long-term may be realized for patients or payers when Wegovy is used as a treatment to reduce the risk of cardiovascular death, heart attack, and stroke in adults with cardiovascular disease and those who are either obese or overweight. Navitus and Novo Nordisk are continuing to discuss possible rebate options for instances when Wegovy is prescribed for those with cardiovascular disease.

On June 21, 2024, a new Eli Lilly sponsored study was published in the *New England Journal of Medicine*¹¹ that showed tirzepatide, an ingredient in Zepbound, "significantly improved symptoms of obstructive sleep apnea in people with obesity". ¹² Based on this study, Eli Lilly applied to the FDA for an update of Zepbound indications to include sleep apnea. The FDA is expected to make their decision by the end of the year. ¹³

Novo Nordisk and Eli Lilly are continuing to study their weight-loss drugs for treatment of conditions beyond weight loss. For example, weight loss may alleviate conditions associated with obesity, such as arthritis, high blood pressure, and high cholesterol levels. Currently, no studies have been submitted for FDA approval regarding Wegovy improving kidney function or Zepbound reducing inflammation regardless of BMI.¹⁴

Manufacturer Contracts for GLP-1s

Historically, manufacturers offered very small or no rebates on weight-loss drugs. The rebates that have been offered require strict adherence to the FDA's recommendations for coverage. Eli Lilly has recently begun to offer some rebates on Zepbound that are contingent on compliance with FDA recommendations for coverage. These rebates require a member to have a BMI of 30 or greater, or a BMI of 27 with at least one weight-related comorbidity such as hypertension, cardiovascular disease, type 2

GoodRx, April 12, 2024, "How Much Does Wegovy Cost?" https://www.goodrx.com/wegovy/wegovy-for-weight-loss-cost-coverage

Blum, Dani. "A New Option to Treat Sleep Apnea: Weight-Loss Drugs", June 21, 2024, https://www.nytimes.com/2024/06/21/well/sleep-apnea-weight-loss-drug.html

Kolata, Gina. "Doctors Test the Limits of What Obesity Drugs Can Fix" New York Times, June 18, 2024, https://www.nytimes.com/2024/06/18/health/obesity-first-wegovy-zepbound-doctors.html

Wingrove, Patrick. Roy, Sriparna. "FDA Approves Novo Nordisk's Wegovy for Lowering Heart Risks"
Reuters, March 11, 2024 https://www.reuters.com/business/healthcare-pharmaceuticals/fda-approves-novo-nordisks-wegovy-use-reducing-heart-attack-risks-2024-03-08/

Malhotra Atul, Grunstein Ronald, Fietze Ingo, et al. "Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity." *The New England Journal of Medicine*. Published online June 21, 2024. https://www.nejm.org/doi/abs/10.1056/NEJMoa2404881

Kansteiner, Fraiser. "Amid Duel with Novo's Wegovy, Lilly's Zepbound Homes In On Potential FDA Sleep Apnea Nod" Fierce Pharma, June 24, 2024, https://www.fiercepharma.com/pharma/amid-duel-novos-wegovy-lillys-zepbound-homes-potential-fda-sleep-apnea-nod-year-end

diabetes, or obstructive sleep apnea.¹⁵ Any criteria beyond these FDA guidelines may result in reduced or no rebates from Eli Lilly.

Some public and private sector employers require their members to enroll in weight-loss programs that provide nutritional counseling and/or coaching for weight-loss drugs to be covered. Others implement benefit maximums or create a special tier for weight-loss drug coverage. Eli Lilly does allow payers to require concurrent enrollment in a weight-loss program for coverage of AOMs. All Zepbound rebates are lost if a client establishes a benefit maximum for AOMs or creates a separate AOM drug tier on their drug formulary.

Novo Nordisk's Wegovy current rebate agreements require the FDA's recommendations be followed. Any enrollment requirements in a weight-loss program would result in loss of all rebates from Novo Nordisk for Wegovy. Navitus and Novo Nordisk are continuing to have discussions regarding potential changes to Wegovy's rebate agreements.

Generic Weight-Loss Drugs

As presented to the Board at the May 23, 2024, meeting (Ref. GIB | 05.23.24 | 3), generic drugs are lower in cost than brand name drugs. However, a drug patent is a 20-year period where the federal government allows the manufacturer who developed a drug to exclude others from making or using a drug. Patents allow brand name manufacturers to prevent generic manufacturers from selling other versions of their drugs.

The patent on semaglutide, the key ingredient in Wegovy, is set to expire in 2032 in the United States. ¹⁶ The patents for Zepbound are set to expire in 2039. Saxenda has patents that are expiring in 2025 and 2026, but no launch of a generic has been announced.

Federal Government Action Regarding AOMs

The Treat and Reduce Obesity Act of 2023 would allow for coverage of AOMs by Medicare. Plan sponsors offering Medicare Part D coverage, such as the Board, currently cannot add weight-loss drugs prescribed for weight loss to their formularies due to Federal Statute 42 USC 1395W-102, which prohibits CMS from including such coverage. On June 27, 2024, the Treat and Reduce Obesity Act of 2023 that would allow for coverage of AOMs by Medicare was voted out of the House Ways and Means Committee and into the full House of Representatives.

United States Food and Drug Administration (2023, November 8) FDA Approves New Medication for Chronic Weight Management [Press Release] https://www.fda.gov/news-events/press-announcements/fda-approves-new-medication-chronic-weight-management

Novo Nordisk 2023 Annual Report, issued January 31, 2024 https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2024/novonordisk-annual-report-2023.pdf

Additionally, a meeting of the US Senate Committee on Health, Education, Labor and Pensions (Committee) that will focus on United States prices for Ozempic and Wegovy is scheduled for September 2024. The CEO of Novo Nordisk, the maker of these two drugs, is set to testify at this meeting. Senator Bernie Sanders, who serves as the Committee's chairperson, believes that the September hearing with Novo Nordisk could lead to lower prices for Ozempic and Wegovy. This belief is based on a similar hearing the Committee had with the makers of insulin, resulting in the price of insulin being reduced.¹⁷

Other States' Public Employee Weight-Loss Drug Coverage

States currently covering at least one weight-loss drug for their state employees include Alaska, Connecticut, Delaware, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Massachusetts, Minnesota, Missouri, New Jersey, New Mexico, New York, Michigan, Minnesota, and Tennessee.

In May of 2024, the International Foundation of Employee Benefit Plans (IFEBP) conducted a survey of United States public employers and multiemployer plans regarding coverage and considerations about GLP-1 drugs. ¹⁸ The survey found 63% of respondents covered GLP-1 drugs for diabetes only and 26% cover the drugs for both diabetes and weight loss.

When asked if they were considering offering coverage for GLP-1 drugs for weight-loss 72% of respondence said no, while 15% said yes.

The IFEBP May survey asked what factors were considered of those who offered GLP-1 coverage for obesity care. The top consideration at 86% was long-term costs, followed by obesity as a risk factor for chronic diseases and associated costs at 82%, and GLP-1 label expansion with 68%.

The survey found that some of the cost-control mechanisms in place for GLP-1 drugs for public employers and multiemployer plans include utilization management, step therapy, eligibility requirements, and annual maximums.

Here are specific examples of how surrounding states and others handle weight-loss drug coverage for state employees:

Connecticut

The State of Connecticut started a pilot program on July 1, 2023, for state employees after seeing a 50% year over year increase in spending for GLP-1 drugs. The pilot program requires all prescriptions for weight-loss drugs must be written by Flyte

Aboulenein, Ahmedl "US Senator Sanders Optimistic Novo Nordisk Can Be Pressured to Cut Wegovy, Ozempic Prices" U.S. News and World Report, July 10, 2024. https://www.usnews.com/news/top-news/articles/2024-07-10/us-senator-sanders-optimistic-novo-nordisk-can-be-pressured-to-cut-wegovy-ozempic-prices

Temployee Benefit Plans. https://www.ifebp.org/docs/default-source/pdf/resources---news/pulse-surveys/glp-1-drugs-me-pe-2024.pdf

prescribers. Flyte is a telehealth program created by the medical technology company Intellihealth. Flyte connects patients to doctors, dieticians, and weight-loss experts online. A member must be 18 years or older and meet the FDA recommendations for weight-loss drug coverage. ¹⁹

The Connecticut Comptroller recently announced the pilot program has provided cost-effective access to GLP-1 drugs and that the state intends to make the program permanent, as well as expand eligibility to those in Connecticut's Medicare Advantage plan.²⁰

Delaware

Delaware currently covers weight-loss drugs for its state employees if the prescription is filled at a participating retail pharmacy. Delaware's PBM's mail order pharmacy no longer has enough inventory to be able to fill these prescriptions.

In 2023, the Delaware State Employee Benefits Committee (SEBC) found that its Group Health Insurance Plan had a \$15 million deficit in funding. During a November 2023 meeting about the deficit the SEBC was told that part of the deficit was due to the SEBC's PBM projecting that the pharmacy spend would be "just shy of \$2 million, and instead it's well over \$7 million." This difference was attributed to weight-loss drug coverage for state employees. ²¹

Illinois

During 2023, the Illinois Fiscal Year 2024 budget included \$210 million to add coverage of injectable weight-loss drugs for the State Employee Group Health Insurance Program. On June 7, 2023, Illinois Governor Pritzker signed the Fiscal Year 2024 budget into law and created 5 III. Comp Stat. 375/6.11C (2024). This new statute, which went into effect on July 1, 2024, requires the State Employee Group Insurance Program to cover all types of medically necessary "injectable medicines prescribed on-label or off-label to improve glucose or weight loss for use by adults diagnosed or previously diagnosed with prediabetes, gestational diabetes, or obesity."

In March of this year, the Illinois Commission on Government Forecasting and Accountability (CGFA), who provides the Illinois Legislature with research and information regarding state and national economies, revenue projections, and operations of Illinois Government, issued its Fiscal Year 2024 Liabilities of the State Employees' Group Health Insurance Program. In the report, the CGFA estimated a 17%

¹⁹ Care Compass. State of Connecticut Benefit Information Pharmacy Information, https://carecompass.ct.gov/pharmacy/

²⁰ Connecticut Comptroller Sean Scanlon. (2024, June 13). Comptroller Sean Scanlon Announces Continued Partnership with Intellihealth [Press release]. https://osc.ct.gov/articles/comptroller-sean-scanlon-announces-continued-partnership-with-intellihealth/

Petrowich, Sarah. "State health insurance currently runs \$15 million deficit, cites eight loss medication as factor" Delaware Public Media. November 26, 2023. https://www.delawarepublic.org/science-health-tech/2023-11-26/state-health-insurance-currently-runs-15-million-deficit-cites-weight-loss-medication-as-factor

increase in state group health insurance liabilities and cited coverage of weight-loss drugs as one of the increase drivers.²²

Iowa

As of Jan. 1, 2024, weight-loss medications are no longer covered under the lowa state employee benefit plan.²³ Staff were unable to locate information regarding lowa's state employee weight-loss drug coverage or costs before the coverage ended.

Michigan

On June 14, 2024, it was announced that Blue Cross Blue Shield of Michigan was eliminating coverage of weight-loss drugs beginning Jan. 1, 2025, or on a group's 2024 health coverage renewal date. While Blue Cross Blue Shield of Michigan does provide health insurance coverage for Michigan state employees, the pharmacy benefit is carved out of health insurance coverage and is provided by Optum Rx. Because of this carve out, Michigan state employees will continue to have weight-loss drug coverage.

Wegovy is covered as a tier 3, non-preferred brand drug for Michigan State Employees with a \$60 copay for a 30-day supply of the drug. Zepbound is not covered on the most current drug formulary.²⁴

Minnesota

In 2023, the Minnesota Management and Budget State Employee Group Insurance Program (SEGIP) contracted with their PBM, CVS Caremark, to use a new Smart Logic utilization management protocol for weight-loss medications. Smart Logic identifies SEGIP members who are using GLP-1s for diabetes based on a prior diagnosis of diabetes and makes sure those members are not required to submit a prior authorization (PA) for coverage of the drug.

If Smart Logic does not find any history of diabetes, then a SEGIP member is required to submit a PA for the drug to be covered. The PA requires the prescriber to certify that the member meets the following qualifications:

- The member will use the weight-loss drug in conjunction with a reduced calorie diet and increased physical activity; and
- The member has participated in a weight management program prior to using the weight-loss drug; and
- The member meets BMI criteria.

McKinney, David. "Weight-loss drug coverage for Illinois State Workers Could Cost Hundreds of Millions of Dollars." Chicago Sun Times, April 30, 2024, https://chicago.suntimes.com/politics/2024/04/30/weight-loss-drug-coverage-illinois-state-workers-taxpayers-price-tag.5 June 2024

lowa Department of Administrative Services. 2024 Open Enrollment Period. https://das.iowa.gov/state-employees/human-resources/employee-benefits-programs/2024-open-enrollment-period

State of Michigan 2024 Select Standard Formulary. (2024, January 1) OptumRx. https://www.optumrx.com/content/dam/openenrollment/pdfs/som/2024-State-of-Michigan-Select-Formulary.pdf

ETF was unable to find the cost of coverage for the state of Minnesota and its employees.

North Carolina

On Oct. 26, 2023, the North Carolina State Health Plan for Teachers and State Employees (SHPNC) Board of Trustees voted to end coverage of any new weight-loss drug prescriptions for members as of Jan. 1, 2024. If a member was taking a weight-loss drug prior to Jan. 1, 2024, their coverage was grandfathered in, and the drug would continue to be covered. The SHPNC saw the cost of weight-loss drugs increase from \$3 million a month in 2020 to over \$14 million per month in 2023.

On Jan. 25, 2024, the SHPNC Board of Trustees voted to end coverage for those whose weight-lost drug coverage was grandfathered in for 2024. The Board of Trustees was presented with information that showed coverage for those grandfathered in would cost \$139 million annually. This increase over 2023 was due to weight-loss drug manufacturers eliminating all rebates, totaling \$54 million, because of the Board of Trustees' deviation from the FDA labeling. This deviation changed the utilization patterns of the drug.²⁵

North Carolina State Treasurer, Dale Folwell, along with the state's PBM, CVS Caremark, have been trying to negotiate with Novo Nordisk and Eli Lilly to find a price that would be agreeable to all parties and allow the SHPNC to again cover weight-loss drugs. Negotiations are ongoing.²⁶

West Virginia

West Virginia Public Employees Insurance Agency (PEIA) maintained a pilot program that covered most of the cost of weight-loss drugs. The total enrollment in the PEIA includes more than 75,000 public employees and dependents, while those participating in the pilot program include a little more than 1,000 of those members. The pilot program is ending due to the AOMs costing the PEIA around \$1.3 million a month for those members, and those enrolled will not have coverage of their weight-loss drugs after July 2025.

Brian Cunningham, PEIA Director stated, "that if it were expanded (the pilot program) as intended to include 10,000 people, the program could end up costing \$150 million a year, more than 40% of its (PEIA's) current spending on prescription drugs, leading to severe premium hikes."²⁷

²⁵ North Carolina State Health Plan for Teachers and State Employees GLP-1 Medications for Weight Loss January 25, 2024. https://www.shpnc.org/media/3391/download?attachment

Lovelace, Berkeley. McLaughlin, Erin. Kane, Jason. "How One State is Trying to Make Weight Loss Drugs Cheaper." NBC News, April 24, 2024. https://www.nbcnews.com/health/health-news/one-state-trying-make-weight-loss-drugs-cheaper-rcna148997

Whang, Oliver. "In States That Won't Pay for Obesity Drugs, "they May as Well Have Never Been Created." New York Times, June 26, 2024. https://www.nytimes.com/2024/06/25/health/obesity-ozempic-wegovy-west-virginia.html

Weight-Loss Drug Cost

Segal, the Board's actuary, reported in Feb. 21, 2024 (Ref. GIB | 02.21.24 | 7C, Table 1), that adding weight-loss drugs was calculated to cost between \$21 million and \$27 million a year for 2025 through 2030. Based on Segal's experience with other clients in 2025, their analysis assumed that 25% of those with a BMI over 35 would take a weight-loss drug, and that rate would increase by 5% a year, through 2030. Segal's cost analysis assumed 50% of that group would use Wegovy and 50% would use Zepbound, with full rebates from the manufacturers factored in.

Since February of 2024, Eli Lilly has begun to offer rebates on Zepbound, which in turn could lower Segal's cost analysis. However, based on the increase in production of Zepbound and Wegovy, the number of members interested in weight-loss drug coverage who have submitted a Board correspondence, and a knowledge of the Board's membership, staff believes Segal's estimate of the number of members who would start a weight-loss drug may be low. Segal's estimate, based on Navitus's prices for the drug, is still believed to be accurate.

Saxenda was not included in Segal's cost analysis because the newer weight-loss drugs require less frequent injections and cause greater weight loss and were therefore expected to reduce or eliminate Saxenda's market share.

Segal's Feb. 21, 2024, weight-loss drug cost analysis for 2025-2030 also considered medical savings the Board may realize for members that are on AOMs. Those medical savings varied from between \$3,503,319 in 2025 to \$40,423,105 in 2030.

The following are examples of benefit categories for which the Board spent a similar amount to the estimated cost of adding weight-loss drug coverage in the past year:

- Outpatient dialysis \$21,106,566
- Outpatient ultrasounds \$21,124,835
- Outpatient radiology \$21,178,475
- Commercial coverage of antidiabetic drugs, including Ozempic, Trulicity, Mounjaro, and others \$21,528,893
- Commercial coverage of oral chemotherapy drugs, including Revlimid, Verzenio, and others, \$26,175,457
- Outpatient physical therapy, occupational therapy, and speech therapy \$27,319,115.

Currently, the pharmacy benefit is a self-insured benefit. The Board contracts with Navitus to be the third-party administrator for the pharmacy program and takes on the responsibility of paying members' pharmacy claims. Most savings associated with weight-loss drugs, however, would be realized within the fully insured medical benefits

(e.g., diabetic hospitalizations, cancer treatments, etc.). This means that savings realized from adding weight-loss drug coverage will lag from the initial drug costs. This is because fully insured rates are now negotiated a year in advance, and since health plans bear the risk on the medical benefit, it is unlikely that they will provide concessions on price in the same year that the weight-loss drug costs will be incurred to the pharmacy program.

Future AOM Options

Though the Board is not acting on AOM coverage at the Aug. 14, 2024, meeting, ETF is providing the Board initial AOM coverage options for discussion, but as noted the landscape is ever-changing and potential options to consider may change as additional information becomes available.

The Board must adhere to <u>Wis. Stat. §40.03(6)(c)</u> when discussing any future AOM options. That statute states in part that the Board, "Shall not enter into any agreement to modify or expand benefits under any group insurance plan, unless the modification or expansion is required by law or would maintain or reduce premium costs for the state or its employees in the current or any future year…"

Each option below is discussed based on the Board's Healthcare Triple Aim strategy of examining the effects of any change on members' quality of life, program quality, and affordability (Ref. GIB | 11.13.19 | 5D).

Premium Increases

In 2023 the Board paid \$239,127,109 for commercial members' pharmacy coverage. This total includes the prescriptions, the per member per month administrative fee to Navitus, and accounts for rebates and network discounts. If the Board decides to include coverage for weight-loss drugs for commercial members, which is estimated to cost an additional \$21 million to \$27 million, they could reduce the cost of commercial drug coverage by 8.7% to 11.3% to comply with the statute.

The average number of commercial pharmacy members per month in 2023 was 205,400. If the Board were to pass the cost of adding weight-loss drugs on to each member, it would lead to an increase of \$102.24 to \$131.45 a year.

Copay and Deductible Increases

To offset the estimated increase for AOM coverage, the Board could consider increasing copays and deductibles non-Medicare members pay under the GHIP. ETF asked Segal to examine what benefit structure changes the Board would need to implement to add AOM coverage and have the change be cost neutral. Based on Segal's February estimate of a \$21 million increase in costs with AOM coverage for 2025, Segal provided the changes to copays and deductibles shown below. The changes below are only to the State GHIP's non-high-deductible health plan (HDHP) option and correlating Local GHIP program. Additional modeling would be needed to determine changes to the HDHP and other local program options.

Table 3: Plan Design Changes to Offset AOM Costs

Plan Design	2024 Copays and Deductibles	Proposed Change to Offset AOM Cost
Deductible (Individual/Family)	\$250/\$500	\$300/\$600
Out-of-Pocket Maximum (Individual/Family)	\$1,250/\$2,500	\$1,400/\$2,800
Primary Care Office Visit	\$15 copay	\$25 copay
Specialist Office Visit	\$25 copay	\$35 copay
Urgent Care	\$25 copay	\$35 copay
Emergency Room	\$75 copay	\$100 copay
Pharmacy Specialty/Tier 4	\$50 copay	\$75 copay
Pharmacy Maximum (Preferred/Non-Preferred/Specialty)	\$50/\$150/\$200	\$75/\$175/\$250

Under the proposed changes in Table 3 all coinsurance, pharmacy deductibles and pharmacy maximum out-of-pocket limits would remain unchanged. Segal noted that "the medical vendors would need to recognize plan design savings in their renewals in order to achieve the projected savings" with this option.

This proposed change would increase copays and deductibles to all non-Medicare GHIP members. However, the proposed changes would allow members to have the same current health and pharmacy benefits with the addition of AOMs while keeping the GHIPs deductibles and copays below state and national averages.²⁸

Other Benefit Reductions

Benefit reductions could be another possible avenue for the Board to examine. However, various state and federal laws mandate what benefits must be offered under medical and pharmacy insurance. These mandates limit what benefits the Board could reduce or end to help offset the cost of weight-loss drugs. Due to these legal limitations a series of small reductions may add up to cover the cover the cost of adding weight-loss drugs. For example, not eliminating physical therapy appointments but limiting the number would bring small savings to the Board. (Ref. GIB | 05.15.19 | 8C, Pages 7-8) Some reductions in benefits or services could cause disruption to members.

Average Annual Deductible per Enrolled Employee in Employer-Based health Insurance for Single and Family Coverage. Kaiser Family Foundation (KFF). <a href="https://www.kff.org/other/state-indicator/average-annual-deductible-per-enrolled-employee-in-employer-based-health-insurance-for-single-and-family-coverage/?currentTimeframe=0&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D

Pilot Program

A pilot program could allow a small subset of members who fit a pre-determined list of criteria to have prescriptions filled for AOMs. A pilot program could also include coaching and nutritional counseling to assist members. Weight-loss-oriented benefits from a pilot program within the wellness and/or medical programs are possible. This would allow for some members to receive AOMs and support while taking the drug, as well as give the Board a chance to examine the fiscal effects on a limited basis.

Current program agreements with the Board's health plans state a vendor may not assess a fee for a pilot program to ETF or to the member (Ref. GIB | 05.18.22 | 5D). This and other potential limitations need to be further vetted to assess the legal viability of establishing a pilot program.

It should be noted that a pilot program is usually offered for a limited time. The Board is then given the chance to expand or end the program. A possible pilot program for AOMs would give members coverage of the drug, but if the Board chose not to extend the program, members would then lose coverage of the drug. Those members would then have to stop taking the drug or pay for the full cost of the drug out of pocket. This is happening right now with West Virginia state employees (Whang, 2024).

Lifetime Limit

A lifetime limit for GLP-1 coverage would allow the Board to provide coverage to members, but with a cap. A lifetime limit could be a monetary amount or a limit on AOM prescriptions filled.

As of Jan. 1, 2024, employees at the Mayo Clinic have GLP-1 coverage with a lifetime limit of \$20,000, if the drug is prescribed for weight-loss.²⁹ As of May 1, 2024, staff at the University of Michigan have a maximum lifetime benefit of 24 one-month fills of GLP-1s to treat weight loss.³⁰

Imposing similar limits would allow members to have AOM coverage for up to two years. Many studies have shown that people do not take AOMs long term. A study released on July 10, 2024, showed that 85% of people taking a GLP-1 were no longer taking the drug after two years.³¹ Numerous studies indicated that individuals who discontinue

Emerson, Jakob. "Mayo Clinic Moves to Limit Weight Loss Drug Coverage for Employees" Beckers Hospital Review, November 13, 2023. https://www.beckershospitalreview.com/finance/mayo-clinic-moves-to-limit-weight-loss-drug-coverage-for-employees.html

University of Michigan Lifetime Drug Limits (Infertility, GLP-1 Drugs for Weight Loss. https://hr.umich.edu/benefits-wellness/health-well-being/prescription-drug-plan/coverage-drug-information/lifetime-drug-limits-infertility-glp-1-drugs-weight-loss

[&]quot;Prime continues to lead industry on GLP-1 research: 1 in 7 stays on GLP-1 drugs for weight loss after two years" July 10, 2024. https://www.primetherapeutics.com/news/prime-continues-to-lead-industry-on-glp-1-research-1-in-7-stays-on-glp-1-drugs-for-weight-loss-after-two-years/

AOMs often experience weight regain, although the extent and timing of this regain can vary.³²

Coverage limits would require any member who needs to take an AOM beyond the limits agreed on by the Board to pay for the full cost of the drug. This would create a large financial burden for those members.

Currently, creating any limit on coverage of GLP-1s would remove any rebates the Board receives from Eli Lilly and Novo Nordisk.

Tracking coverage limits would fall to the Board's PBM. This new administrative function may lead to an increase in PBM fees.

New AOM Drug Formulary Level

Under the current drug formulary, if the Board chooses to add AOMs, the drugs would be covered on level 2 of the formulary. On level 2, a member pays 20%, with a \$50 maximum payment. Given the high cost of AOMs, a member would pay the \$50 maximum for the drugs.

Table 4: 2025 Commercial Drug Formulary

Tier	Copayment/Coinsurance	Tier Description
Level 1	\$5 copayment	Preferred generic drugs and certain lower-cost preferred brand name drugs.
Level 2	20% coinsurance (\$50 max)	Preferred brand name drugs and certain higher- cost preferred generic drugs.
Level 3	40% coinsurance (\$150 max)	Non-preferred brand name drugs and certain high-cost generic drugs for which alternative/equivalent preferred generic and brand name drugs are covered.
Level 4	\$50 copayment	Includes only specialty drugs filled at a preferred specialty pharmacy.

A new, separate level on the drug formulary for only AOMs could be added with a higher copayment/coinsurance level. Requiring members to pay a higher copayment/coinsurance for AOMs would require those taking the drugs to help pay the higher cost of the drug. This copayment/coinsurance increase would limit or possibly eliminate an across-the-board premium increase for all members.

Adding a special tier for AOMs to the formulary could lead to member and pharmacy confusion. This change would also lead to increased out-of-pocket costs for those members.

³² Cox, David. "What Happens When You Stop Taking Weight-Loss Drugs" BBC. May 21, 2024. https://www.bbc.com/future/article/20240521-what-happens-when-you-stop-taking-ozempic

As stated previously, per Navitus's agreements with Eli Lilly and Novo Nordisk, creating a special level on a drug formulary for AOMs would remove any rebates the Board receives.

Increase BMI Requirements

The FDA currently recommends coverage of GLP-1s if a member has a BMI of 30 or greater, or a BMI of 27 with at least one weight-related comorbidity. The National Health Service in England has set a higher threshold for treatment, at a BMI of 35 or greater, or a BMI of 30 with at least one weight-related comorbidity.³³

Making this increase to the Board's BMI requirement for AOM coverage would align it with the Board's BMI requirement for bariatric surgery. Currently, bariatric surgery under the GHIP requires that a member must have a BMI of 35 or higher (Ref. GIB | 05.15.19 | 8C, Pages 10-14).

Increasing the BMI requirement would decrease the number of members eligible for AOM coverage. According to Navitus, this decreased number of members receiving the drug lowers the cost of the drug to the Board, even with the loss of rebates from the drug manufacturers because of the change.

In most cases the increased BMI requirement would require a member to be in worse physical condition to gain coverage of AOMs. This could lead to more members having more comorbidities, and result in an increase to the cost to the GHIP to treat those comorbidities.

BMI has increasingly been called outdated, and many now believe BMI should not be the only tool used by medical professionals to measure a person's health.³⁴ Others point out that the BMI was invented over 200 years ago, is based on European white men, and does not consider a person's sex, race, or ethnicity.³⁵

Next Steps

ETF will provide operational updates regarding AOM utilization, costs, changes in the drug class, legislation, and litigation at the Nov. 13, 2024, Board meeting, as well as subsequent Board meetings.

The Board will also receive an update at the November Board meeting on the bariatric surgery benefit that was added to the GHIP on Jan. 1, 2020. This update will include

³³ "Semaglutide for Managing Overweight and Obesity" National Institute for Health and Care Excellence. https://www.nice.org.uk/guidance/TA875/chapter/1-Recommendations

[&]quot;AMA Adopts New Policy Clarifying Role of BMI As a Measure in Medicine" American Medical Association. June 14, 2023. https://www.ama-assn.org/press-center/press-releases/ama-adopts-new-policy-clarifying-role-bmi-measure-medicine

Katella, Kathy. "Why you Shouldn't Rely on the BMI Alone" Yale Medicine. August 4, 2023. https://www.yalemedicine.org/news/why-you-shouldnt-rely-on-bmi-alone

information on the medical savings the Board realized for members who have received bariatric surgery.

Staff will be at the Board meeting to answer any questions.