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Correspondence Memorandum

Date: October 15, 2024

To: Group Insurance Board

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Subject: Weight-Loss Drugs: Current Events, Options, and Cost Analysis

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

Background

At the August 14, 2024, Group Insurance Board (Board) meeting, the Board heard a presentation with several coverage considerations regarding weight-loss drugs, also known as anti-obesity medications (AOMs) and glucagon-like peptide 1 agonist (GLP-1) drugs. The two best-selling GLP-1 drugs currently on the market for weight loss are Wegovy, manufactured by Novo Nordisk, and Zepbound, by Eli Lilly.

This memo provides the Board with requested information, including an updated AOM cost analysis from the Board's actuary, Segal, redirecting funds from the Well Wisconsin Program to help address the cost of AOMs, considerations for the establishment of a pilot program, and various other questions. This memo also includes an update on information regarding AOM utilization, costs, changes in the drug class, legislation, and litigation.

Weight-Loss Drug Cost Analysis

Per the Board's request, ETF asked Segal to conduct an updated cost/savings analysis for covering AOMs under the Board's pharmacy benefit. Segal conducted a cost/savings analysis earlier this year (Ref. GIB | 02.21.24 | 7C | Page 4).

Segal's two new cost/savings analyses reflect new agreements with Eli Lilly and Novo Nordisk held by Navitus Health Solutions (Navitus), the Board's pharmacy benefit manager (PBM) that were signed during the past spring and summer. These new agreements include new prices and rebates for Zepbound and Wegovy. These new agreements also include tiered pricing/rebates if a payer does not adhere to the Food and Drug Administration's (FDA's) recommendation for coverage. The FDA recommends Wegovy and Zepbound coverage for weight loss only for people with a

Reviewed and approved by Renee Walk, Director, Office of Strategic Health Policy
Electronically Signed 11/01/2024

Board	Mtg Date	Item #
GIB	11.13.24	13

body mass index (BMI) of 30 or greater, or a BMI of 27 with at least one weight related comorbidity. According to the agreements there are still some changes, such as creating a new AOM drug formulary level and lifetime limits on AOM coverage, a payer can make to their coverage that will eliminate all rebates offered by the drug manufacturers.

In Table 1 below, Segal projected what the cost/savings of AOMs would be to the Board if FDA BMI indications were adhered to and the Board realized all the rebates available. Though the Board did not include AOM coverage for 2025, the information is included in these tables for comparison to Segal's cost analysis from earlier this year.

Table 1: Segal Weight-Loss Drug Cost Analysis 2025-2030 with Full Rebates

Year	Utilizers	AOMs Prescriptions	AOM Cost	Medical Savings	Net Loss
2025	13,053	56,129	$37,185,614	$6,175,060	-$31,010,553
2026	16,234	84,530	$59,012,775	$21,716,516	-$37,296,259
2027	17,078	97,049	$71,382,889	$34,977,832	-$36,405,057
2028	17,461	106,382	$82,425,828	$48,469,853	-$33,955,975
2029	17,520	113,381	$92,524,228	$62,186,799	-$30,337,428
2030	17,355	118,429	$101,772,140	$75,948,834	-$25,822,306

To conduct this analysis, Segal had to make several assumptions, including the following key assumptions:

- Using data from the Centers for Disease Control and Prevention (CDC) specific to the State of Wisconsin to project obesity prevalence for the Board's plan.
- Only those who are obese would take an AOM.
- Based on Segal's experience with other clients covering AOMs for obesity, in 2025, 20% of those eligible would take an AOM, and that rate would increase by 5% a year through 2030 based on Segal's experience with other clients covering AOMs for obesity, in 2025.
- The number of utilizers is a function of the number of eligible members, the take rates, and persistence rates.
- Based on research of other payers' pharmacy and medical claims, 60% of members would stop taking the AOM during the first year of beginning the drug[1].
- Using costs for AOMs provided by Navitus.
- 50% of the eligible population utilized Wegovy and the remaining 50% took Zepbound.

[1] Prime Therapeutics LLC, Magellan Rx Management. (2023, July 11). *Real-World Analysis of Glucagon-Like Peptide-1 Agonist (GLP-1a) Obesity Treatment One Year Cost-Effectiveness and Therapy Adherence* [Press release]. https://www.primetherapeutics.com/wp-content/uploads/2023/07/GLP-1a-obesity-treatment-1st-year-cost-effectiveness-study-abstract-FINAL-7-11.pdf

- Using the assumed economic value of AOMs on obese adults based on a 2021 study sponsored by Novo Nordisk[2], the maker of Wegovy.
- Medical savings include inpatient visits, physician-office visits, emergency room visits, and pharmacy costs.

Other sources Segal used to create Table 1 are listed in the "Follow-Up on Anti-Obesity Medications (AOMs) Discussion from February 2024 Board Meeting and Current Events" memo (Ref. GIB | 05.23.24 | 10A).

Segal's second cost/savings analysis assumes all utilizers have a BMI of 35 or higher. This same assumption was used in the cost analysis on page 4 of the "2025 Final Benefit Changes" memo (Ref. GIB | 02.21.24 | 7C).

A new tier included in Navitus's contracts with AOM manufacturers includes a price for AOMs if a payer changes the BMI requirement from the FDA indications. While the price for the drugs on this new contractual tier is lower than if there were no rebates available on the drug, the price is still higher than the full rebate cost. Though the price of AOMs is higher with the new BMI requirements, the estimated number of users is lower than in Table 1.

Table 2. Segal Weight-Loss Drug Cost Analysis 2025-2030 with Partial Rebates

Year	Utilizers	AOMs Prescriptions	AOM Cost	Medical Savings	Net Loss
2025	7,406	31,844	$26,908,178	$3,503,319	-$23,404,859
2026	9,315	48,406	$43,069,498	$12,373,407	-$30,696,091
2027	9,602	54,802	$51,335,325	$19,912,500	-$31,422,825
2028	9,412	58,174	$57,363,445	$27,175,462	-$30,187,983
2029	8,950	59,520	$61,774,139	$34,048,327	-$27,725,812
2030	8,390	59,612	$65,112,307	$40,423,105	-$24,689,201

To conduct the Table 2 analysis, Segal used all the same sources and made the same assumptions as they did for Table 1 except in one instance. Segal assumed 25% of those eligible, not 20% that was used to create Table 1, would take a weight-loss drug in 2025 and that rate would increase by 5% a year through 2030. This increased rate of utilization is due to findings showing that the greater a person's BMI, the more likely that person is to take an AOM and continue to take the drug.

It should be noted that Segal prepared the cost analyses found in Tables 1 and 2 prior to Prime Therapeutics releasing a study on October 24, 2024, regarding GLP-1 costs in the first two years of treatment. The study found people without diabetes who take GLP-1 drugs for obesity experienced an average of $4,206 higher cost of care in their second year of coverage and no reduction in medical events in the first two years of taking the drugs compared to people not taking GLP-1 drugs for obesity. With no medical offset for

[2] Ding, Y., Fan, Z., Blanchette, C. M., Smolarz, B., Weng, W., & Ramasamy, A. (2021). Economic value of nonsurgical weight loss in adults with obesity. Journal of Managed Care + Specialty Pharmacy, 37-50.

GLP-1 treatment for weight-loss in the first two years the study found the total cost of care to be $11,200 per person in those first two years.[3]

Update on Future AOM Options

There were a variety of possible AOM coverage options provided as part of the "Weight-Loss Drugs Analysis and Coverage Considerations" discussion at the August meeting (Ref. GIB | 08.14.24 | 4). Throughout the Board's conversation on this topic, the Board suggested some additional, new options and posed questions about the options ETF had outlined. ETF committed to following up with the Board on these points.

Increase BMI Indications

At the August 14, 2024, Board meeting, the option of increasing BMI requirements for AOM coverage to help manage program costs was discussed. The costs of AOM coverage with increased BMI requirements are included in Table 2 above.

The FDA currently indicates 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. Some payers have set a higher BMI threshold to qualify for AOM coverage. The largest of these payers to set a higher BMI threshold is the National Health Service in England (NHS). The NHS's indications for AOM coverage are either a BMI of 35 or higher with one weight-related comorbidity, or a BMI of 30 or higher and meeting the criteria for referral to specialist weight management services.[4]

NHS research found that "people from some minority ethnic family backgrounds have an equivalent risk from obesity at a lower BMI than people from a White ethnic family background." This research led the NHS to use lower BMI requirements for "people of Asian, Chinese, Middle Eastern, Black African or African-Caribbean origin."[5]

Currently, the Board requires a BMI of 35 or higher for a member to qualify for bariatric surgery under the Group Health Insurance Program (GHIP). If the Board were to implement a BMI requirement of 35 to gain coverage for AOMs, this would align the requirements for both AOMs and bariatric surgery.

Segal's previous cost/savings analysis using the requirement of a BMI of 35 or higher had a cumulative loss for covering AOMs, inclusive of medical savings, of $144,262,501. Table 2 shows a cumulative loss of $166,126,771. This difference of $21,864,270 is due to Segal's previous cost analysis realizing more rebate dollars.

[3] Gleason, P. Urick, B, Marshall, L, Qui, y. Leslie. R, Friedlander, N. Chodroff, M. Lassen, D. "Real-World Analysis of Glucagon Like Peptide-1 (GLP-1) Agonist Obesity Treatment Year-Two Clinical and Cost Outcomes. Prime Therapeutics, 24 October 2024. https://www.primetherapeutics.com/documents/d/primetherapeutics/glp-1-year-2-cost-effectiveness-study-abstract-10-24-24

[4] Obesity Treatment, England National Health Service, https://www.nhs.uk/conditions/obesity/treatment/

[5] Semaglutide for managing overweight and obesity recommendations technology appraisal guidance, National Institute for Health and Care Excellence,04 September 2023, https://www.nice.org.uk/guidance/TA875/chapter/1-Recommendations

Rebates are limited if the BMI requirements are changed from the FDA's indications in Navitus' new agreements with Novo Nordisk and Eli Lilly.

Nutritional Counseling

During the Board's discussion of possible AOM coverage options, the subject of the lack of nutritional counseling coverage was discussed. It was noted that currently the GHIP only covers nutritional counseling for weight management when a member is preparing for bariatric surgery.

On February 21, 2024, the Board approved removing the bariatric surgery requirement for coverage of weight-related nutritional counseling beginning January 1, 2025 (Ref. GIB | 02.21.24 | 7C). In the February 2024 memo, Segal noted that, "removing the bariatric surgery requirement for coverage of weight-related nutritional counseling will result in minimal additional cost since most health plans are already covering this. Additionally, the Well Wisconsin program includes weight management coaching programs for subscribers and spouses. ETF recommends refining the language for nutritional counseling to allow for nutritional counseling services related to weight management."

Due to the Board's action, the 2025 State of Wisconsin Group Health Insurance Program Certificate of Coverage, under the covered services section on page 45 states:

> *29. Nutritional Counseling*
> *Nutritional Counseling is covered when provided by a participating registered dietician or an In-Network Provider (for Access Plan or other PPO Plan Participants, an Out-of-Network Provider may provide covered services).*
>
> *Nutritional Counseling consists of the following services:*
> a. *Consult evaluation and management or preventive medicine service codes for medical nutrition therapy assessment and/or intervention performed by a physician.*
> b. *Re-assessment and intervention (individual and group).*
> c. *Diabetes outpatient self-management training services (individual and group sessions).*
> d. *Dietitian visit.*

With the 2025 expansion in nutritional counseling coverage, the Board could attach a requirement to any coverage of AOMs for nutritional counseling through the health plans, and/or nutritional coaching through the wellness and disease management vendor.

If the Board chooses to require nutritional counseling and/or coaching either before or during coverage for AOMs, it will require Navitus and the health plans and/or wellness and disease management vendor to work together in coordinating coverage for members. Currently, Navitus, the Board's contracted health plans, and the wellness and

disease management vendor exchange files regularly regarding members' drug utilization and high deductible health plan (HDHP) accumulator amounts. Therefore, adding this requirement would not require a new process.

Requiring nutritional counseling for AOM coverage could lead to added costs for members who will have to pay their medical deductible and any copays that are required for nutritional counseling.

Well Wisconsin Program Considerations

During the Board's discussion on August 14, 2024, an idea was presented to redirect funds from the Well Wisconsin Program to help pay for the cost of AOM coverage. The total cost of the Well Wisconsin Program (administered by WebMD) over each of the last three years, including program administration fees and incentives paid to members, is included in Table 3.

Table 3: Well Wisconsin Program Costs

Year	Fees Paid to WebMD	Incentives Paid to Members	Total Costs
2021	$8,641,014.09	$7,169,400.00	$15,810.414.09
2022	$8,407,008.42	$7,194,150.00	$15,601,158.42
2023	$8,377,679.05	$7,601,399.48	$15,979,078.53

The initial term of the contract with WebMD expires December 31, 2026, with the option for two, two-year extensions. Redirecting funds solely from the Well Wisconsin Program would not be enough to cover the expected costs of AOMs, as estimated by Segal, as noted in Tables 1 and 2. The Board would also need to take funding from other health and/or pharmacy benefits or increase member cost-share to offset the total estimated cost of coverage for AOMs.

Excluding Well Wisconsin from the GHIP would remove availability of uniform wellness services, including weight-loss services such as lifestyle management coaching, intensive weight-loss programming, and additional physical activity and nutrition-based classes, challenges, and education. These services are aligned with the Total Health Management approach to healthcare, where preventive and chronic care is provided proactively to support members during and between medical encounters. The Board adopted this approach following a recommendation by Segal in 2015 (Ref. GIB | 03.25.15 | 4.C). Well Wisconsin services can directly benefit members who would use prescription AOMs if the Board decides to add this coverage. Furthermore, the FDA approved AOMs "for use, *in addition* [emphasis added] to a reduced calorie diet and increased physical activity." Support for reducing calories and increasing physical activity is available via the Well Wisconsin Program.

The Board could reverse its 2015 decision and request health plans to administer well-being and condition management support. This would likely result in increases to health plan administrative costs and a lack of uniformity, as was the case when Well Wisconsin began with the health plans from 2013 – 2016. ETF could work with the health plans

over time to aim for as much uniformity as possible.

ETF previously used DAISI, the data warehouse administered by Merative, to evaluate the impact of the Well Wisconsin program. The last analysis included data showing participants' rate of relative risk increases at a lower rate, utilization of healthcare services are better (e.g., lower emergency room utilization, higher rates of preventive care, etc.), and the difference between actual and expected per member per year in healthcare spending is more favorable when compared to non-participants (Ref. GIB | 11.16.22 | 12). A return-on-investment analysis will be completed by Merative in 2026, per the Board contract with WebMD.

Based on WebMD analysis, ETF has experienced success with its weight management programming to date. There was an aggregate risk reduction of 6.9% for intensive weight management program participants in 2023. The program appeared to have a greater impact for members with Class I and II obesity with a transition to a lower class. Members with Class III obesity did not transition as much. WebMD reported a 7.3% reduction in health risks for repeat 2022–2023 subscribers who engaged in lifestyle management coaching (Ref. GIB | 02.21.24 | 8).

Members who carry excess weight may also have other comorbidities. Well Wisconsin services can help members with managing these as well. Examples include the Diabetes Prevention Program, mental health coaching for depression, anxiety, stress management, etc. (added as a benefit in 2024), and condition management services for diabetes, asthma, chronic obstructive pulmonary disease, congestive heart failure, and coronary artery disease. Members using these services who may not be considered overweight or obese, but have one or more of the diagnoses listed above, would also be affected by the loss of this program. Attachment A to this memo includes a select list of services available via Well Wisconsin and engagement with over 55,000 members in 2023.

ETF included information on participant satisfaction and health outcomes in the 2023 State of Wisconsin Group Health Benefits Annual Report (Ref. GIB | 05.23.24 | 10D). As noted in the report, over 90% of participants are satisfied with the health screening, health assessment and portal experience, health coaching, and condition management. There was a 5.2% improvement in health risks in 2023 as compared to 2022 for repeat participants, and a 4.8% improvement in health risks for those who completed a condition management program. ETF regularly receives testimonials from members about the difference the program is making in their lives. This was also highlighted in the 2023 State of Wisconsin Group Health Benefits Annual Report, which included a link to a video of member testimonials to that effect.

Pilot Program

The purpose of pilot programs is to evaluate the impact of a potential benefit change to determine whether it should be implemented as a uniform benefit within the GHIP.

As discussed at the August 2024 meeting, a pilot program could allow a small subset of members who fit a pre-determined list of criteria, such as receiving coaching and nutritional counseling, to have prescriptions for AOMs paid consistent to terms defined by the pilot program (Ref. GIB | 08.14.24 | 4). A pilot program of this nature would be different than the current pilot programs ETF has with health plans, whereby they are not allowed to assess a fee or pass along costs to ETF.

ETF's Office of Legal Services (OLS) assessed whether covering the cost of a prescription medication for patients that are registered within a defined pilot program through the self-funded prescription drug program would be considered an ''agreement to modify or expand benefits under any group insurance plan" such that Wis. Stat. § 40.03(6)(c) applies.

OLS determined that a pilot program generally is not an "agreement to modify or expand benefits under any group insurance plan," as the pilot program benefits do not modify or expand benefits that a member is entitled to when they enroll in GHIP coverage. Instead, members accepted into a pilot program would qualify to receive only what is defined within the pilot program, as structured, in consideration for their participation and compliance with the pilot program requirements. Therefore, it is possible to consider a pilot program in which participants receive AOMs while also receiving existing GHIP benefits including coaching and nutritional counseling for the purpose of the Board gathering data on the fiscal effect of AOM coverage.

However, establishing the criteria for a limited number of members to participate in the pilot program would create challenges and legal risk in additional appeals. Additionally, the Board would be required to exercise its fiduciary responsibility in evaluating the costs and benefits of any proposed pilot program.

As of October 1, 2024, ETF had 211,303 commercial members enrolled in the GHIP. As shown in Table 2 of this memo, Segal estimates that in 2025, 7,406 commercial members with a BMI of 35 or higher would take an AOM. Any pilot program design would be limited to a small subset of those members. For example, if ETF's pilot program enrollment limit was set at 1,000, ETF would need to establish criteria that eliminated an estimated 6,406 people from participating in the pilot program. Based upon the noted interest in AOM coverage, and with benchmarks established allowing 1,000 members to qualify, it is likely that a subset of those members that are not accepted into the pilot program would appeal the determination that they did not qualify or were not accepted for the pilot program.

Costs associated with a pilot program covering AOMs would be subject to similar cost analysis as presented above. Under Navitus' current contracts, costs for Wegovy and Zepbound, with full rebates and assuming for purposes of an example a 1,000-person pilot program, would be about $8.6 million. This assumes 500 members filling prescriptions for each drug for a full year. With reduced rebates due to straying from the FDA indication on BMI requirements, the cost of AOMs would rise to about $10.7 million

for 1,000 members. If the Board were to lose all rebates due to any restrictions or changes, AOMs for 1,000 members would cost approximately $14.4 million. The Board could see additional fees charged to the GHIP for other supporting programs, to the extent the pilot program requirements increased usage of these services.

Pilot programs can take many years, from initial conception to data collection and evaluation process.[6] The Board's general guidance has been to implement a pilot program for three to five years, after which the Board would need to decide to continue with the pilot program, implement the program as a uniform benefit for all members, or end the program. The Board could receive information from DAISI to make data-informed decisions. The PBM shares pharmacy claims with the data warehouse administrator, Merative. ETF could use this claims data to identify participants in the pilot program to evaluate changes in participants' health spend and health outcomes. Enrollees in this pilot program would be made aware of the monitoring. Enrollee's privacy would remain de-identified for ETF and the Board, similar to other pilot programs.

If the Board decided to end the pilot program, participants would lose coverage for AOMs, possibly in the middle of treatment. This would cause members to stop taking AOMs or pay for the full cost of the drugs out of pocket. To assist in a situation like this, the Board could approve an off-ramp benefit from the pilot program, which may include extending coverage of AOMs through the end of the pilot program for a set time or dollar amount, requiring the PBM to assist in getting pilot program members enrolled in any possible rebate or manufacturer coupon programs, and the Board covering health lifestyle services for members after the pilot program ends.

Currently, none of the Board's health insurance vendors, PBM, or wellness and disease management vendors could offer a pilot program that includes prescriptions for AOMs while also offering coaching and nutritional counseling for members on their own. Some could offer certain aspects of the proposed pilot, but no one vendor could offer the complete pilot program.

There is some history of vendors partnering together in the GHIP to offer pilots. WebMD and Navitus work together to administer the *It's Your Health: Diabetes* program. Members who engage in WebMD's diabetes coaching program receive a reduction in their diabetes-related prescription copays. ETF would need to design and oversee the pilot because existing vendors have limited experience in designing, implementing, and evaluating a comprehensive weight management program that includes AOMs.

None of the Board's health insurance vendors that offer an It's Your Choice traditional or HDHP have coverage across all of Wisconsin. Offering a pilot program through one

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[6] Hussey, P., R. Bankowitz, M. Dinneen, D. Kelleher, K. Matsuoka, J. McCannon, W. Shrank, and R. Saunders. 2013. From Pilots to Practice: Speeding the Movement of Successful Pilots to Effective Practice. *NAM Perspectives.* Discussion Paper, National Academy of Medicine, Washington, DC. https://doi.org/10.31478/201304e

of these health insurers could limit participation in the pilot program based on where a member lives. Alternatively, the Access plan and HDHPs currently offered through Dean Health Plan both offer coverage throughout Wisconsin. However, the premiums for the Access plans in 2025 are generally higher than the traditional plans.

With the popularity of AOM coverage, there is a chance that offering a pilot program through one insurer could drive members to enroll with that insurer because of the pilot program. The GHIP offers Uniform Benefits to avoid the problem of steering membership based on different programs being offered by different health insurers. A pilot program for AOM coverage offered only though a particular insurer would likely result in a change to that philosophy.

Alternatively, the Board could choose to release a request for proposals (RFP) seeking a vendor to administer a pilot program for qualifying members. This would allow the Board to find a vendor that has experience administering all aspects of a proposed pilot program.

North Carolina State Health Plan for Teachers and State Employees recently released a Request for Information (RFI), asking for information to “find a way to provide obesity medications for its members in a financially sustainable way.”[7] ETF could use this information to draft an RFP for a vendor to administer a pilot program. At this time, it is estimated that it would take 2-3 years before a new vendor could be procured through the RFP process, in part due to staff workload given current scheduled RFPs.

Members are used to getting GHIP services through their insurer, their PBM, and their wellness and disease management vendors. Member education will need to be a large part of any pilot program the Board may wish to go forward with, but especially if the Board contracts with a vendor that only offers a weight management pilot program.

New AOM Drug Formulary Level

Currently, if the Board chooses to add AOM coverage to the commercial drug formulary, AOMs would be covered as Level 2 drugs. On the commercial drug formulary, Level 2 is for preferred brand name drugs and certain higher cost preferred generic drugs. The copayment/coinsurance for Level 2 drugs is 20% with a $50 maximum payment. Given the current price of AOMs, members would pay the $50 maximum payment each time they filled a prescription.

Adding a new Level to the drug formulary, for only AOMs could require members to pay a higher copayment for the drugs. This would allow only members who are prescribed AOMs to shoulder the cost instead of all members being required to pay higher premiums and copays.

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[7] North Carolina State health Plan for Teachers and State Employees GLP-1 Request for Information, https://www.shpnc.org/blog/2024/03/07/statement-regarding-glp-1-coverage

Due to AOM drug manufacturers' agreements with Navitus, a new formulary Level would not allow the Board to realize any rebate payments for the drugs. Table 4 demonstrates the increase in copays needed to cover the projected net loss. The Board would not have increased costs when creating a new formulary Level for AOMs. These projections are based on Segal's utilization, AOM prescription and medical savings assumptions from Table 1, and the Board paying Navitus's agreement rate for Wegovy and Zepbound, with no rebates.

Table 4: Member Copays Required to Cover Cost of AOMs

Year	AOMs Prescriptions	Net Loss	Copay Required Per Prescription
2025	56,129	-$61,179,890	$1,090
2026	84,530	-$79,719,484	$944
2027	97,049	-$74,281,118	$766
2028	106,382	-$79,188,547	$745
2029	113,381	-$73,870,551	$652
2030	118,429	-$66,166,116	$559

While the copay required per prescription to pay for adding AOMs to the drug formulary on a newly created tier does decrease over the five years, the amount required with the current price of AOMs would create significant costs for members. At this time, members would be eligible to participate in drug manufacturer coupon and copay assistance programs that would help to offset their copay costs for AOMs.

Copay and Deductible Increases

In August, the Board was presented with plan design changes to offset AOM costs based on Segal's January 2024 cost analysis (Ref. GIB | 08.14.24 | 4). This option would increase copays and deductibles for all State GHIP non-HDHP options and correlating Local GHIP members.

With Segal's new cost analysis, shown in Tables 1 and 2, the increase needed in copayment and deductibles to offset the cost of AOMs will need to be greater than before. However, as discussed previously, the cost of AOMs could decrease or rebates could change based on new drugs, new variations, or new indications of AOMs currently on the market.

New copay/coinsurance structures for 2026 will be considered as part of annual benefits changes, which will be presented to the Board in early 2025.

Other States' Public Employee Weight-Loss Drug Coverage

Previously, ETF has discussed with the Board how other states are handling AOM coverage for their state employees (Ref. GIB | 06.30.22 | 4) and (Ref. GIB | 08.14.24 | 4). On August 9, 2024, the Washington State Health Care Authority sent a questionnaire regarding AOM coverage for state employees to members of the State and Local Government Benefits Association (SALGBA) list serve. In September, the

Washington State Health Care Authority shared the results with ETF. Below is a summary of the state employee health plans information:

Alabama State Employees Insurance Board
Alabama does not offer coverage for AOMs and does not plan to cover the drugs in 2025. Alabama stated that their "main sticking point with the medications currently available for weight loss is cost."

State of Arizona Employees
Arizona does not cover weight-loss drugs for employees but has explored adding coverage. The issues that Arizona has faced is the "potentially high cost to the Plan and [we] want members to engage in our lifestyle wellness programs."

State of Kansas
Kansas covers GLP-1 drugs for weight loss for their state employee's health plan (SEHP) and requires a prior authorization (PA). In 2023, AOMs represented 6.4% of their overall net spend on pharmacy.

South Carolina Public Employee Benefit Authority (PEBA)
The South Carolina PEBA does not cover weight-loss drugs for public employees. Their analysis found that coverage of weight-loss medications would bring about a return on investment (ROI) of $0.34 saved per dollar spent. With this information, their Board concluded coverage of AOMs was not financially sustainable.

Tennessee Group Insurance Program
Tennessee provides GLP-1 weight-loss coverage to its members with a PA. From 2020 to 2021 and from 2021 to 2022, Tennessee saw the number of weight-loss drug utilizers increase by more than 100% each year. From 2022 to 2023, the number of utilizers increased 65%, and as of July of 2024, utilization was up 23% over 2023.

In 2023, Tennessee spent 6.7% of their total pharmacy spend, after rebates, on weight-loss drugs. From January through July of 2024, they saw 14% of their pharmacy spend, after rebates, paying for weight-loss drugs.

Utah Public Employees
Utah does not cover GLP-1 drugs for weight loss. They have considered adding coverage of the drugs but the cost, which is estimated to be a $20 per member per month increase, "would be astronomical."

Through the National Academy for State Health Policy (NASHP), ETF has learned some additional information about other states' coverage of AOMs for their state employees:

ETF asked the group of over 48 state employee health plan staffers from all over the country if their plan did cover GLP-1 drugs, were they seeing a 20% utilization rate. ETF

asked this question as this is one of the assumptions that Segal makes when assembling the cost/savings analyses. The states in the meeting indicated that they did see at least a 20% utilization rate in the first year they offered coverage of AOMs and that the rate did increase each year. Many states said that they are seeing utilization increases month to month, since adding AOM coverage for their employees.

State employee health plan staff for states that do not cover AOMs indicated that they do not provide coverage because of the expense of covering the drugs. These states have done cost analyses for their membership and have found the price to be too high.

Some state employee health plans mentioned that they have reached out to AOM manufacturers directly or through their PBM to try to negotiate lower prices for AOMs. None of the state employee health plans have been successful in getting lower pricing.

Other state employee health plans staff voiced frustration that there are no independent studies on the long-term effects and possible savings on AOM drugs. It was mentioned that state employee health plans need studies that examine all groups of people. This diversity is needed because state employee health plan members tend to be older, more female, and are ethnically and economically diverse.

This frustration was echoed by Milliman in its Novo Nordisk commissioned report on the impact of AOM coverage in the Medicaid and commercial markets. In the report Milliman wrote, “Ultimately, only one article was used to inform the modeling for the single assumptions used in our estimates.”[8]

Current Events Related to AOMs

<u>US Senate Hearing</u>

On September 24, 2024, Novo Nordisk President, and Chief Executive Officer Lars Fruergaard Jørgensen testified before the United States Senate Committee on Health, Education, Labor, and Pensions (HELP) in a full committee hearing entitled, “Why is Novo Nordisk Charging Americans with Diabetes and Obesity Outrageously High Prices for Ozempic and Wegovy?”

During his testimony, Mr. Jørgensen stated that Novo Nordisk pays, “75 cents for every dollar of medicine we sell back into this complex system in rebates, discounts, and fees — meaning the “net” price Novo Nordisk ultimately receives for medicines it sells is far below the published “list” price. And while the rebates we pay to PBMs and insurers as a share of each dollar earned have increased dramatically over the last decade, this has

[8] Klaisner J., B. Bostros, R. LeRoy. A Ally. K Niakan. “Impact on anti-obesity medication coverage in the Medicaid and commercial markets” Milliman. 7 June 2024 https://www.milliman.com/en/insight/impact-of-anti-obesity-medication-coverage-in-the-medicaid-and-commercial-markets

not resulted in a proportionate reduction in out-of-pocket costs for patients at the pharmacy counter." [9]

During his prepared remarks, HELP Committee Chairman Senator Bernie Sanders displayed a chart that showed the following information.[10]

Table 5: Cost of Wegovy Around the World

Country	Cost of Wegovy
Canada	$265
Denmark	$186
Germany	$137
United Kingdom	$92
United States	$1,349

In response to Senator Sanders' questions about why Wegovy costs more in the United States than in other countries, Mr. Jørgensen reiterated what he said in his opening remarks stating that it's because of PBMs, and stressing that 80 percent of U.S. patients with insurance pay less than $25 per prescription.[11] Mr. Jørgensen did not address the price that payers, such as the Board, pay for drugs such as Ozempic and Wegovy.

During Senator Sanders questioning of Mr. Jørgensen, he said that he had written commitments from the United States' three biggest PBMs (Optum, Caremark, and Express Scripts) that they would expand coverage of Wegovy if Novo Nordisk lowered the list price of the drug.[12] Mr. Jørgensen made no commitments to cut the price of Wegovy during the HELP committee hearing.

Congressional Budget Office Analysis of Possible Medicare AOM Coverage

On October 8, 2024, the Congressional Budget Office (CBO) released a paper estimating the federal budget effects of authorizing Medicare to cover AOMs.[13] The CBO is a nonpartisan entity that produces independent analyses on budgetary and

[9] Jørgensen, Lars Fruergaard. Testimony of Lars Fruergaard Jørgensen, Novo Nordisk President, and Chief Executive Officer before the Senate Committee on Health, Education, Labor and Pensions. 24 September 2024, https://www.help.senate.gov/imo/media/doc/fa475d00-dca5-9b2c-4565-e5bdc272566d/2024-09-24%20Lars%20Fruergaard%20J%C3%B8rgensen%20Written%20Testimony.pdf

[10] Sanders, Senator Bernie. Prepared remarks of Senator Bernie Sanders, before the Senate Committee on Health, Education, Labor and Pensions. 24 September 2024, https://www.help.senate.gov/chair/newsroom/press/prepared-remarks-sanders-leads-help-committee-hearing-with-novo-nordisk-ceo-on-outrageous-ozempic-and-wegovy-prices

[11] Gilbert, Dan. "Senators press Novo Nordisk CEO on why Ozempic and Wegovy cost less abroad. Washington Post. 24 September 2024. https://www.washingtonpost.com/business/2024/09/24/ozempic-weight-loss-price-sanders/

[12] Aboulenein, Ahmed and Wingrove, Patrick, "US Senator Sanders says middlemen won't punish Novo if it cuts weight-loss drug prices" Reuters 24 September 2024, https://www.reuters.com/business/healthcare-pharmaceuticals/novo-nordisk-ceo-faces-us-congress-scrutiny-over-weight-loss-drug-pricing-2024-09-24/

[13] Congressional Budget Office, October 2024. "How Would Authorizing Medicare to Cover Anti-Obesity Medications Affect the Federal Budget?" https://www.cbo.gov/system/files/2024-10/60441-medicare-coverage-obesity.pdf

economic issues to support the Congressional Budget process, and produces budget analyses and reports about the cost of proposed legislation on the federal level.[14]

While stating that knowing "how many people would use AOMs and for how long are significant sources of uncertainty in the CBO's estimates," the report estimates 2% or 0.3 million of the over 12.5 million Medicare members in 2026 would use an AOM. The report goes on to assume that with approval for AOMs to treat additional conditions, 1.6 million or 14% of the estimated Medicare enrollment would be using AOMs in 2034.

The report found that in 2026, of the estimated 29 million people in Medicare who would qualify for AOM coverage, about half, or 16 million, would have access to AOMs for other health issues such as diabetes, cardiovascular coverage, and other indications approved by the FDA. In 2034, of the 33 million estimated Medicare members who would be eligible for AOM coverage, 21 million would qualify for coverage on the basis of non-weight related indications.

The CBO's report estimates that the annual cost to cover AOMs for a Medicare member in 2026 will be $5,600. That cost is estimated to decrease to $4,300 by 2034. The CBO also estimates that the average offsetting medical savings for each user would be $50 in 2026 and reach $650 in 2034.

Table 6 shows the CBO's estimated net cost of AOMs per year for Medicare through 2034, along with the estimated medical saving per year.

Table 6: Budgetary Effects in the Billions of Medicare Covering AOMs

	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
Direct Cost of Coverage AOMs	$1.6	$1.8	$2.9	$3.8	$4.3	$5.1	$5.8	$6.5	$7.1	**$38.8**
Savings from Improved Health	*	*	-$0.1	-$0.2	-$0.3	-$0.4	-$0.6	-$0.8	-$1.0	**-$3.4**
Net Cost	$1.5	$1.8	$2.8	$3.7	$4.0	$4.7	$5.2	$5.7	$6.1	**$35.5**

* Between $0 and $50 million.

FDA Declares Tirzepatide Shortage Over and Then a Reversal

On October 2, 2024, the FDA put out a statement advising that the shortage of tirzepatide, the active ingredient in Eli Lilly's weight-loss drug Zepbound and diabetes drug Mounjaro, had been resolved.[15]

[14] Congressional Budget Office, Nonpartisan Analysis for the U.S. Congress, https://www.cbo.gov/about/overview

[15] FDA clarifies policies for compounders as national GLP-1 supply begins to stabilize, United States Food and Drug Administration, https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize

When a drug is on the FDA drug shortage list some federal laws such as laws on compounding of the drugs are lifted.[16] Compounding is when a drug is combined, mixed, or the ingredients are altered to create a different medication.[17] During the shortage of tirzepatide, people have been able to get compounded versions of Zepbound and Mounjaro from compounders at a fraction of the price others have been paying to get the uncompounded version of the drug manufactured by Eli Lilly. Removing tirzepatide from the drug shortage list makes most compounding of tirzepatide illegal, a fact that was pointed out in the FDA's announcement of the removal of tirzepatide from the drug shortage list.

The removal of tirzepatide has caused compounders, compounding pharmacy trade groups, and some consumers, to state that the drug shortage is not over as people are still having a difficult time finding Zepbound and Mounjaro at pharmacies. On October 8, 2024, Outsourcing Facilities Association, a compounding pharmacies trade group, filed a lawsuit against the FDA arguing that a shortage of tirzepatide still exists and the FDA acted unlawfully in removing the drug from the list.[18]

In a court filing, in response to the Outsourcing Facilities Association lawsuit, the FDA on October 11, 2024, said it would reconsider its decision to remove tirzepatide from the shortage list and for now would not "pursue regulatory action against certain compounding pharmacies making copies of the drugs." [19]

Compounders point to the price of the drug and the difficulty of locating the drug as possible reasons people may get their tirzepatide from illegal or non-FDA approved compounding facilities now that legitimate facilities cannot legally make the drugs. The products that are produced by illegal or non-FDA approved compounding facilities could be sub-par and/or cause medical issues to those that use those drugs.

Possible New GLP-1 Drug Indications

Since the last Board briefing on new indications for Wegovy and Zepbound, the FDA has not approved any changes to the drugs' labeling. However, both drugs are currently being studied as possible treatments for a variety of different conditions.

Wegovy continues to be investigated as a treatment for metabolic dysfunction-associated steatohepatitis (MASH), heart failure with preserved ejection fraction (HFpEF), cardiovascular outcomes, Alzheimer's, and osteoarthritis. Zepbound is being studied as a possible treatment for MASH, HFpEF, obstructive sleep apnea,

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[16] Compounding when Drugs are on FDA's Drug Shortages List, United States Food and Drug Administration, https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list

[17] Human Drug Compounding, United States Food and Drug Administration, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding

[18] Outsourcing Facilities Association v. United States Food and Drug Administration, Civil Action No. 4:24-cv-953, Stat News, https://www.statnews.com/wp-content/uploads/2024/10/outsourcing-facilities-assn-v-fda.pdf

[19] Palmer, Katie. "In stark reversal, FDA to reconsider removal of Eli Lilly weight loss drug from shortage list" State News 11 October 2024. https://www.statnews.com/2024/10/11/fda-tirzepatide-compounders-eli-lilly-zepbound-mounjaro/

cardiovascular outcomes, chronic kidney disease, psoriasis, and inflammatory bowel disease.

New AOMs

As of September 5, 2024, there were 133 weight-loss drugs in the various stages of development.[20] Some of this development includes approved drugs, like Wegovy and Zepbound, that are currently weekly-injectable weight-loss drugs being studied as possible monthly injectable drugs or as oral drugs. Some of the drugs are being studied to treat other diseases such as Parkinson's or spinal muscular atrophy and have been found to cause significant weight loss in trials.

Table 7: Weight-Loss Drug Study Phases

Phase	Number of Studies
Preclinical	49
Phase 1	34
Phase 2	37
Phase 3	8
Approved	5

As discussed with the Board at the May 23, 2024, meeting, phases in drug development and approval can take many years, and with each phase of development comes the possibility that a drug may fail or have to repeat a phase (Ref. GIB | 05.23.24 | 3).

New Weight-Loss Drug Program

On August 27, 2024, Eli Lilly announced that people could get 2.5 milligrams (mg) and 5 mg vials of Zepbound directly from the drug manufacturer. The single-dose vials are only available to self-pay patients with prescriptions, at a cost of $399 and $549, respectively, for a month supply and are delivered directly to peoples' homes.[21]

Zepbound prescriptions filled through a pharmacy are for single use auto-injector pens. According to GoodRx, a carton of four Zepbound auto-injector pens of either 2.5 mg or 5 mg bought in Rhinelander, Wisconsin, for example, would cost between $1,040 and $1,118.

International AOM News

On October 3, 2024, England's NHS announced that it will begin offering Zepbound (in England the drug is called Mounjaro) to people. The NHS's three-year plan for coverage would initially offer Zepbound to people who are medically obese and have three of the following weight related health conditions: sleep apnea, hypertension, cardiovascular disorders, and unhealthy levels of lipids. The phased roll out of the plan calls for Zepbound after the first year being offered to people with two of the conditions in the

[20] Chen, Elaine, DeAngelis, Allison, Parker, J. Emory "STAT+ Obesity Drug Tracker" https://www.statnews.com/2023/09/12/new-weight-loss-drug-tracker-novo-nordisk-eli-lilly/

[21] Cerullo, Megan, "Eli Lilly slashes prices of weight-loss drug Zepbound for single-use vials" CBS News 28 August 2024, https://www.cbsnews.com/news/zepbound-price-cut-single-use-vials-eli-lilly/

plan's second year, and then people with only one of the conditions being eligible in the third year of the three-year plan.[22]

Kaiser Family Foundation (KFF) Employer Health Benefits Survey

On October 9, 2024, the KFF released its 26th annual Employer Health Benefits Survey. The survey includes results from 1,970 private sector businesses and 172 state/local public sector employers with three or more employees.[23]

This year's survey found that 18% of businesses surveyed with 200 or more employees cover GLP-1 drugs for weight loss. Of those businesses that offer AOM coverage, 24% require employees to meet with a professional, such as a dietitian, psychologist, case worker, or therapist, before approving GLP-1 drug coverage, and 26% have conditions or requirements, such as prior authorization, that require a higher BMI threshold before the AOMs will be covered. The survey revealed that 62% of businesses surveyed are "not likely" to begin covering GLP-1s for weight loss within the next 12 months, 23% said that they are "somewhat likely" to do so, and 3% stated that they are "very likely" to do so.[24]

Novo Nordisk Meeting

On September 13, 2024, ETF met with representatives from Novo Nordisk, including Novo Nordisk's contracted Wisconsin lobbyist. Novo Nordisk shared similar information from when ETF met with them on November 6, 2023. When asked about lowering the price for the drug, Novo Nordisk pointed out that the price of Wegovy could be lower in the future, when more AOM drugs are available on the market. Novo Nordisk also said that they had signed a contract with Navitus for lower pricing, and the new contract contained tiers that allowed for some changes to the FDA regulations in return for lower rebates.

Member and Provider Input on AOM Coverage

ETF is aware of the continued interest of members in adding weight-loss drug coverage to the pharmacy benefit, as demonstrated in Board correspondence. The majority of this correspondence has come from medical professionals from University of Wisconsin (UW) Hospitals and Clinics over the past three years. The Board has discussed AOMs at several prior meetings.[25]

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[22] "England's NHS to offer Lilly's weight-loss drug to some patients" Reuters 3 October 2024 https://www.reuters.com/business/healthcare-pharmaceuticals/englands-nhs-offer-lillys-weight-loss-drugs-some-patients-2024-10-03/

[23] 2024 Employer Health Benefit Survey, Survey Design and Methods, Kaiser Family Foundation, 09, October 2024, https://www.kff.org/report-section/ehbs-2024-survey-design-and-methods/

[24] 2024 Employer Health Benefit Survey, Section 13: Employer Practices, Prover Networks, Coverage for GLP-1s, Abortion and Family Building Benefits, Kaiser Family Foundation, 09 October 2024, https://www.kff.org/report-section/ehbs-2024-section-13-employer-practices-provider-networks-coverage-for-glp-1s-abortion-and-family-building-benefits/

[25] See memos from the following meetings: May 18, 2022 (Ref. GIB | 05.18.22 | 5C), June 30, 2022 (Ref. GIB | 06.30.22 | 4), Nov. 16, 2022 (Ref. GIB | 11.16.22 | 13), May 17, 2023 (Ref. GIB | 05.17.23 | 3C), Feb. 21, 2024 (Ref. GIB | 02.21.24 | 7C), May 23, 2024 (Ref. GIB | 05.23.24 | 10A), and August 14, 2024 (Ref. GIB | 08.14.24 | 4)

ETF met with members of the Wisconsin Obesity Society on September 27, 2024, to discuss the history of AOM coverage through the GHIP, the path forward regarding AOMs, and how they may be able to assist ETF with gathering information for future Board presentations.

Next Steps

At the January 15, 2025, special meeting, the Board is scheduled to assess and deliberate on awarding the Third-Party Administration of Pharmacy Benefits Program contract. In the RFP for this contract, ETF posed questions to potential vendors regarding AOM coverage.[26] ETF will share those vendor answers and RFP results with the Board during the January meeting.

After the Board votes on issuance of a letter of intent to award the contract, ETF will begin negotiating with the vendor on the contract that will be effective January 1, 2026. Any proposed benefit changes, such as AOM coverage, will be discussed with the Board before the new contract is signed.

ETF will provide an operational update at the February 26, 2025, Board meeting regarding AOM utilization, costs, changes in the drug class, legislation, and litigation.

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

Attachment A: 2023 Member Engagement in Wellness and Disease Management Services Administered by WebMD

[26] RFP administrative Services for the State of Wisconsin Pharmacy Benefit Manger Program, questions 7.6.3 and 7.12.3, https://etf.wi.gov/node/35431