From: [redacted]
To: ETF SMB Board Feedback
Cc: [redacted]
Subject: Request to Reconsider AOM Coverage for the 2025 Benefit Year
Date: Monday, April 8, 2024 7:12:42 AM
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Group Insurance Board Members,

Thank you for the time you have taken over the past two years to consider adding anti-obesity medication as a covered pharmacy benefit for members of the GHIP. While we were heartened by the level of board engagement at the February board meeting, we were confused by the Segal analysis and some of the responses that board members received to their questions. We write today in response to that analysis and some of the comments made by Segal and ETF staff. Given the responses below, Novo Nordisk respectfully requests that the board reconsider adding AOM coverage for the 2025 benefit year.

Rebate Loss

Board members asked at least four questions at the February meeting relating to rebates. ETF staff responded that manufacturer rebates are inflexible, which limits the board's ability to implement coverage options that would help to contain costs. Novo Nordisk and Eli Lilly have different rebate guidelines and we believe ETF's comments were only citing the 2023 guidelines for Wegovy. It's possible that Eli Lilly's rebate guidelines were unknown to ETF and Navitus at the time that the Segal analysis was produced. Around the time of the February meeting, Novo Nordisk began implementing new rebate guidelines, and discussions with PBMs are ongoing. New optionality regarding rebates may be available to ETF. Please reach out to Navitus for updated offerings. ETF should also ensure that Navitus is differentiating between the guidelines for Wegovy and Zepbound.

SELECT Trial

ETF requested an updated cost analysis from Segal due to two developments, the FDA approval of Zepbound and the results of the SELECT trial. Since the February meeting, the FDA approved a label expansion for Wegovy, which is now indicated for major adverse cardiovascular events.

Regarding long term outcomes measurement, we know that long-term outcomes support the effectiveness of anti-obesity medications for comorbid outcomes such as cardiovascular disease.

Novo Nordisk recently announced the headline results from the SELECT cardiovascular outcomes trial. The double-blinded trial compared subcutaneous once-weekly semaglutide 2.4 mg with placebo as an adjunct to standard of care for prevention of major adverse cardiovascular events (MACEs) over a period of up to five years. The trial enrolled 17,604 adults aged 45 years or older with overweight or obesity and established cardiovascular disease (CVD) with no prior history of diabetes. The trial achieved its primary objective by demonstrating a statistically significant and superior reduction in MACE of 20% for people treated with semaglutide 2.4 mg compared to placebo. The primary endpoint of the study was defined as the composite outcome of the first occurrence of MACE defined as cardiovascular death, non-fatal myocardial infarction or nonfatal stroke. All three components of the primary endpoint contributed to the superior MACE reduction demonstrated by semaglutide 2.4 mg. 1,270 first MACEs were accrued. These 5-year data were irrespective of weight loss achieved.

Novo Nordisk announced on March 8, 2024 that the US Food and Drug Administration (FDA) approved a label expansion for Wegovy® based on a supplemental New Drug Application (sNDA) for the indication of reducing risks of major adverse cardiovascular events (MACE) including cardiovascular death, non-fatal heart attack (myocardial infarction) or non-fatal stroke in adults with either overweight or obesity and established cardiovascular disease (CVD).

The approval is based on the SELECT cardiovascular outcomes trial, which demonstrated that Wegovy® statistically significantly reduced the risk of MACE by 20% compared to placebo when added to standard of care.

Uptake Assumptions

We have not seen claims data that supports a 25% uptake assumption for 2025 or even 2030. We would appreciate if Segal could share with the board the specific claims data that was used for this assumption. We have seen no other cost analysis that assumes 25 percent of those eligible will utilize AOMs. In fact, a February 2024 Milliman analysis for Medicare coverage projected single digit uptake over 10 years. 3-6-24_impact-of-covering_anti-obesity-medications-in-medicare-part-d.ashx (milliman.com)

Net Price Increases

We were surprised to see projected net price increases in the Segal analysis, especially given the magnitude of those increases. Those net price increases don't appear to be supported by the literature or the data. In fact, the Milliman study above projects annual 6 percent net price decreases due to additional competition and utilization, which is more in line with what we were expecting to see in the Segal analysis.

Consideration of Generics

We continue to believe that the uptake assumptions being modeled are wrong. First, as we shared in our February 12, 2024 communication to the board, generics should be included. Claims data clearly shows that generic phentermine constituted most of the AOM usage for GHIP members. With the December 30, 2023 patent expiration of liraglutide and generic versions of Saxenda expected this year, generics should continue to make up a substantial portion of overall uptake.

Medical Organization Statements

At the February board meeting, a board member asked if the AMA or any others had weighed in on AOM coverage. The American Medical Association has in fact endorsed AOM coverage, as have several other medical organizations.

Consensus Statement by Leading Obesity Organizations

Six leading U.S. organizations dedicated to the prevention and treatment of obesity collaborated to develop a consensus statement on obesity:

> Country's Leading Obesity Care Organizations Develop Consensus Statement on Obesity (prnewswire.com)

American Medical Association

The AMA recently issued a Press Release entitled, "AMA urges insurance coverage parity for emerging obesity treatment options" which states, "Providing evidence-based treatment options that include weight loss medications aligns with a comprehensive, multimodal approach to effectively manage obesity is important to reduce health complications..."

> AMA urges insurance coverage parity for emerging obesity treatment options | American Medical Association (ama-assn.org)

American Diabetes Association

The ADA released its 2024 Standards of Care in Diabetes. They have provided guidance on how obesity is related to diabetes, and how a healthy weight is part of that equation. They also recommend the use of new obesity medications, glucagon-like peptide 1 (GLP-1) agonists or dual glucose-dependent insulinotropic polypeptide (GIP) receptor agonists, to reach sustained weight management goals.

> 8. Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes: *Standards of Care in Diabetes–2024*

Also – The ADA has launched a new website to highlight their new obesity treatment access advocacy work as well as their Standards of Care related to obesity.

> Prevent Diabetes, Treat Obesity | ADA

Nurses Obesity Network

The Nurses Obesity Network issued a press release and Obesity Position Statement last May. The statement covers a broad range of topics and co-morbidities and calls for action in covering the full continuum of care for obesity.

> News - Nurses Obesity Network
>
> Microsoft Word - Nurses Obesity Network Coalition - Position Statement - FINAL 5 24 23

American College of Physicians

Below is the official announcement from ACP recognizing obesity in the U.S. population as both a public health issue and a health equity issue, which was featured in their online Annals of Internal Medicine Journal:

Advancing Equitable Chronic Obesity Care | ACP Online

Institute for Patient Access

IfPA is a physician-led policy research organization dedicated to maintaining the primacy of the physician-patient relationship in the provision of quality health care. Following is a link to a recent blog post from IfPA that discusses state action on obesity:

https://healthpolicytoday.org/2024/01/26/state-leaders-tackle-obesity/

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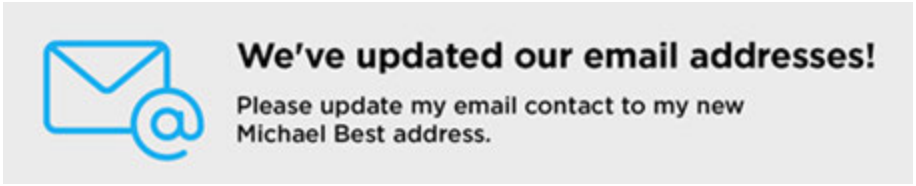

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May 2, 2024

Adam Barr
[redacted]

Good afternoon, Mr. Barr,

Thank you for your email regarding anti-obesity medications, and my apologies for the delay in response.

The Group Insurance Board's agenda for May has been set, and the focus of that discussion will be rates for the 2025 program year. The Board follows an annual calendar of topics in order to ensure rates can be developed timely, and so benefit change discussions have concluded for 2025. We understand that AOMs are an area of rapid development, however, and will continue to discuss the ability to add coverage with the Board; the topic will be addressed again at the Board's August meeting, and we will take into account the issues that you have raised in your email from April 8. AOMs will also be a topic of interest for discussion with pharmacy benefit managers during the request for proposals recently released by the Board.

If you have additional questions or concerns that I can help to address, please let me know.

Sincerely,

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