May 10, 2024

Maryland Prescription Drug Affordability Board
16900 Science Drive Suite 112-114
Bowie, MD 20715

VIA EMAIL TO: comments.pdab@maryland.gov

Re: Drugs Referred to the Stakeholder Council Comment

Dear Maryland Prescription Drug Affordability Board:

Novo Nordisk appreciates the opportunity to submit written comments to the Maryland Prescription Drug Affordability Board (Board) regarding the inclusion of Ozempic® on a list of drugs that may be subject to a cost review. Novo Nordisk is a global healthcare company committed to improving the lives of those living with serious chronic conditions, including diabetes, hemophilia, growth disorders, and obesity. The Novo Nordisk Foundation, our majority shareholder, is among the top five largest charitable foundations in the world. Accordingly, our company's mission and actions reflect the Foundation's vision to contribute significantly to research and development that improves the lives of people and the sustainability of society.

The Board should decline to conduct a cost review of Ozempic®, as the unintended consequences of an upper payment limit (UPL) could adversely impact access to treatment and worsen health outcomes for patients living with diabetes and related chronic diseases.

Throughout our company's hundred-year history, we have had a steadfast focus on improving the lives of patients living with chronic diseases. Chronic diseases are the single biggest threat to life expectancy in the United States, erasing more than twice as many years as all car accidents, suicide, homicides, and overdoses combined. Furthermore, chronic diseases are responsible for 7 in 10 deaths each year,[1] and they are the primary reason that Americans have lower life expectancy than those in peer nations.[2] Despite these statistics, real progress in treating and preventing serious chronic diseases continues to be undermined by misguided policies that are unlikely to benefit patients. Novo Nordisk respectfully requests that the Board decline to conduct a cost review of Ozempic® for reasons summarized in greater detail below:

[1] US Centers for Disease Control and prevention. Chronic Diseases https://www.cdc.gov/chronicdisease/center/index.htm
[2] "An Epidemic of Chronic Illness is Killing Us Too Soon." Washington Post. October 3, 2023. https://www.washingtonpost.com/health/interactive/2023/american-life-expectancy-dropping/

Ozempic® *is a highly effective treatment option for Marylanders living with diabetes and co-morbid conditions.*

Diabetes imposes a particularly high lifetime burden of illness, this is in part due to its chronic nature, but also because of the serious complications that can arise if it is not managed effectively. These complications can include heart disease, stroke, kidney failure, vision loss, and nerve damage. Managing the disease requires continuous daily monitoring, medication, lifestyle changes and regular medical care, all of which contribute to an increase burden on individuals and healthcare systems. However, because of decades of research and development, people with diabetes now have highly effective new treatment options to treat and prevent complications arising from metabolic-related chronic diseases.

Ozempic® is a once weekly GLP-1 receptor agonist (RA) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (T2D) and to reduce the risk of major adverse cardiovascular (CV) events (MACE) (CV death, non-fatal myocardial infarction (MI) or non-fatal stroke) in adults with T2D and established CV disease.[3] Our clinical trials have demonstrated Ozempic's® significant impact on diabetes and several of its comorbidities. This includes the some of the following findings: Ozempic® reducing A1C up to 2.1% in the SUSTAIN-FORTE clinical trial[4]; and a 26% relative risk reduction in MACE with a 39% reduction in rate of non-fatal stroke in SUSTAIN-6[5].

The efficacy and safety of Ozempic® was evaluated in the SUSTAIN clinical trial program. For glycemic efficacy, Ozempic® was compared to several other antidiabetic medications including sitagliptin 100 mg, exenatide ER 2 mg, insulin glargine U-100, dulaglutide 0.75 mg and 1.5 mg, canagliflozin 300 mg, and liraglutide 1.2 mg. Mean reductions in A1C from baseline ranged from 1.2%-1.5% and 1.5-1.8% for Ozempic® 0.5 mg and 1 mg, respectively, after 30 to 56 weeks of treatment, compared to 0–1.4% with placebo and active comparators. Throughout the glycemic control trials, both the 0.5 mg and 1 mg doses of Ozempic® demonstrated superior improvements in A1C vs. comparators.

Additionally, research and clinical trials have demonstrated the superiority of GLP-1 RA to other antihyperglycemic drugs in improving glycemic efficacy, reducing weight and blood pressure, and delivering a cardioprotective effect – all without the risk of hypoglycemia.[6] These drugs have transformed treatment guidelines for the management of patients with diabetes and are widely recognized as a standard of care.[7] While it is critical that patients who can benefit the most from these medications receive them, access issues persist. Recently conducted research in collaboration with Mass General Brigham[8] showed that within that healthcare system, 82.5%

[3] Ozempic® Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc. https://www.novo-pi.com/ozempic.pdf
[4] Frías JP, Auerbach P, Bajaj HS et al. Efficacy and safety of once-weekly semaglutide 2.0 mg versus 1.0 mg in patients with type 2 diabetes (SUSTAIN FORTE): a double-blind, randomized, phase 3B trial. Lancet Diabetes Endo.
[5] 2021;9(9):563-574. doi:10.1016/S2213-8587(21)00174-1Marso SP, Bain SC, Consoli A, et al; SUSTAIN-6 Investigators. Semaglutide and cardiovascular outcomes in patients with type 2 diabetes. N Engl J Med. 2016;375(19):1834-1844.
[6] Latif W, Lambrinos KJ, Rodriguez R. Compare and Contrast the Glucagon-Like Peptide-1 Receptor Agonists (GLP1RAs) [Updated 2023 Mar 27]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK572151/
[7] American Diabetes Association. Standards of care in diabetes—2024. Diabetes Care. 2024;47(suppl 1):S1- S321.
[8] J. Blood, Aleander et. Al., "Randomized Evaluation of a Remote Management Program to Improve Guideline-directed Medical Therapy: The Diabetes Remote Intervention to Improve Use of Evidence-based Medications (DRIVE) Trial." 7 April 2024. https://doi.org/10.1161/CIRCULATIONAHA.124.069494. Circulation. 2024;0

of patients with T2D also have a CV and/or kidney condition. Among those patients with multiple conditions, 66.9% are not receiving guideline-recommended care (either SGLT2i or GLP-1 RA therapy). Patients who are not receiving the standard of care for the treatment of diabetes are more likely to face complications that require further medical care, which subsequently places additional burdens on the patient and the healthcare system.

In 2022, the total direct medical costs associated with those living with diabetes was $307 billion[3]. Of that $307 billion, only 8%, or $24.7 billion, was associated with the costs of non-insulin antidiabetic medications such as Ozempic®. On the other hand, medical expenses such as inpatient hospital care, ER visits, and outpatient office visits accounted $169.5 billion, or 55.2% of the direct medical costs. According to the most recent Maryland Diabetes Action Plan, direct medical spending accounted for $4.29 billion in 2017.[9] GLP-1 medications hold the promise of saving the healthcare system billions of dollars over a ten-year period by reducing demand for hospital and skilled nursing care.[10]

Novo Nordisk is committed to ensuring patients living with diabetes can afford our medications, and this is a responsibility we take seriously.

At Novo Nordisk, we strive to develop sustainable affordability options that balance patient affordability, market dynamics, and evolving policy changes. Novo Nordisk contracts with payers throughout the state, offering rebates to ensure formulary placement and appropriate patient access to our medications**.** In 2023, Novo Nordisk's cumulative rebates and discounts across our entire US portfolio amounted to 74% of gross sales (75% in 2022 and 75% in 2021).[11] In addition to paying rebates in the commercial market, manufacturers are also required to pay significant statutory discounts and rebates to the government. Under the current reimbursement paradigm, rebates play a central role in how insurers manage the prescription drug benefit. A recent analysis of data from SSR Health's net price database across 10 major manufacturers showed that the gap in value between list prices and net prices (after rebates and other reductions) among brand name drugs reached $300 billion in 2022. The unweighted average discount off the list price was 53.5%, meaning that manufacturers sold their products, on average, for less than half of the list price.[12]

However, when examining the overall costs to health care systems in Maryland, the Board evaluated gross spend, i.e. the list price, which is a poor indicator of the cost of a medication for most patients and health insurers. According to a recent analysis, brand-name drugs' list prices grew at mid-single-digit rates in 2023. Net prices, however, dropped for a sixth consecutive year and by 7% after adjusting for inflation.[13] Despite the growing divergence between list and net prices, average out-of-pocket (OOP) spending for most diabetes prescriptions in the U.S. remains low. According to an analysis by IQVIA, OOP spending was less than $30 across 83%

[9] Maryland Diabetes Action Plan 2020. Diabetes Action Plan June 1 2020.pdf (maryland.gov)
[10] Alison Sexton Ward, PhD, Bryan Tysinger, PhD, PhuongGiang Nguyen, MSPH, Dana Goldman, PhD and Darius Lakdawalla, PhD. Benefits of Medicare Coverage for Weight Loss Drugs. April 18, 2023.https://healthpolicy.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/.
[11] Novo Nordisk. 2023 Annual Report. Novo Nordisk Annual Report 2023 (PDF)
[12] Fein, AJ. Gross-to-Net Bubble Update: 2022 Pricing Realities at 10 Top Drugmakers. *Drug Channels Institute*. 2023 Jun 13 [cited 2024 Jan 18]. Available from: https://www.drugchannels.net/2023/06/gross-to-net-bubble-update-2022-pricing.html
[13] Fein, AJ. U.S. Brand-Name Drug Prices Fell for an Unprecedented Sixth Consecutive Year (And Will Fall Further in 2024). https://www.drugchannels.net/2024/01/tales-of-unsurprised-us-brand-name-drug.html. January 3, 2024.

of diabetes prescriptions (based on April 2020 claims data across payers).[14] Internal data shows that 99.6% of patients in Maryland in Medicaid on average have an OOP cost of less than $5, and 82.5% of Marylanders who have commercial insurance pay less than $25 on average for Ozempic®.[15]

However, for patients who continue to struggle to afford their medication, either due to inadequate plan benefit design or a lack of coverage altogether, Novo Nordisk provides additional financial support through our affordability programs. We allow uninsured patients in financial need to access our products at no cost, and we also provide copay assistance for Ozempic® that reduces a commercially insured patient's out-of-pocket cost to as little as $25. Information about our patient assistance programs can be found at www.novocare.com. Novo Nordisk remains committed to ensuring access to our medications by reducing the out-of-pocket cost burden, simplifying a complex pricing system, and fostering better pricing predictability for the patients we serve.

A UPL could disrupt patient access to diabetes treatments in Maryland.

As demonstrated by our efforts, we share the Board's interest in making prescription drugs affordable to patients, but shortsighted policies that impose price controls will only undermine these efforts, as patient access is likely to be compromised. The largest pharmacy benefit managers (PBMs) in the US exert significant control over the treatment options available to patients.[16] Through formulary designs, PBMs direct patients to medications that can generate the highest rebates from manufacturers. A recent Government Accountability Office (GAO) report found that "…plan sponsors frequently gave preferred formulary placement to highly rebated, relatively higher-gross-cost brand-name drugs compared to lower-gross-cost competitor drugs, which generally had lower rebates".[17] Because of these perverse incentives, products subject to a UPL may be *less* attractive to insurers and PBMs relative to competitor products that can continue to offer higher rebates.

Numerous case studies underscore these unintended consequences within the prescription drug supply chain. In one recent example, a drug manufacturer launched a biosimilar of the long-acting insulin glargine at a 65% lower price relative to the reference product's wholesale acquisition cost (WAC). After little formulary uptake, the biosimilar manufacturer opted to launch a higher-priced version of the same product, with the ability to now pay rebates at a similar level to the reference product. According to an IQVIA analysis, PBMs largely favored the higher-priced version because it allowed them to generate rebate revenue.[18]

[14] IQVIA. *Diabetes Costs and Affordability in the United States*. 2020 Jun 29 [cited 2024 Feb 7]. Available from: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/diabetes-costs-and-affordability-in-the-united-states

[15] IQVIA LAAD February 2023 – January 2024.

[16] Fein AJ. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." Drug Channels. April 5, 2022. https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html

[17] Government Accountability Office (GAO). CMS Should Monitor Effects of Rebates on Drug Coverage and Spending. Statement of John E. Dicken, Director, Health Care Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives. https://www.gao.gov/assets/gao-23-107056.pdf. September 19, 2023.

[18] IQVIA. Lessons from Semglee: Early Perspectives on Pharmacy Biosimilars. 2022 [cited 2024 Apr 25]. Available from: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2022/lessons-from-semglee-early-perspectives-on-pharmacy-biosimilars.pdf

Despite these risks, the Board is embarking on cost reviews with little consideration for the potentially significant unintended consequences of a resulting UPL. The Board has not taken steps to ensure that patients will be able to access products that may be subjected to a UPL. There are presently no beneficiary protections or formulary requirements for patients seeking treatment for a product that may be subjected to a UPL. This heightens the risk of downstream access barriers for patients, including an interruption in continuity of care, prior authorization hurdles in accessing a prescribed therapy, and improper utilization management tactics that force patients to switch or delay treatment.

The Board assumes that a UPL will work for Marylanders—but recent evidence suggests otherwise. UPLs fail to recognize the complex dynamics within the supply chain and are more likely to cause foreseeable harm to patients' ability to access prescribed medications.

Maintaining access to Ozempic® is crucial for patients living with T2D. With its proven effectiveness in lowering blood sugar levels and reducing the risk of cardiovascular events, Ozempic® represents a valuable treatment option for managing diabetes and improving overall health outcomes. Ensuring access to Ozempic® enables patients to benefit from its therapeutic advantages, which ultimately leads to better disease management, enhanced quality of life, and to potentially reduced health-care costs associated with diabetes-related complications.

Novo Nordisk is committed to working with patients and payers to ensure that those who benefit from our medications have access to them. Because Ozempic® is both highly effective and broadly affordable, we respectfully request that the Board not move forward with a cost review, as the unintended consequences of a UPL could upend care for thousands of Marylanders living with diabetes.

Thank you for the opportunity to provide comments and for your consideration of the issues raised in this letter. Should you have any questions or concerns, please contact Ryan Urgo, Head of Policy, at RVUR@novonordisk.com for additional information.