CAPITOL STREET

August 20, 2024

Obesity (GLP-1) Update

Semaglutide Likely for 2027, *TROA* Unlikely in 2024, End of Year Outlook

Relevant Companies

Our Take & Next Up

We do not believe *TROA* will pass in 2024, and fully expect NVO's semaglutide to be on the list for 2027. Rising spend on semaglutide only increases pressure for selection of semaglutide for negotiation in 2027. On the legislative front, we have said and continue to believe that the *Treat and Reduce Obesity Act* (*TROA*) will not pass this year. However, the bill may gain momentum under a GOP landscape from the increased focus on promoting innovative medicine coverage (plus physicians want Medicare to cover it). *TROA* may not be "needed" to significantly expand access as coverage of GLP-1s continues to grow with seniors taking the drugs for new FDA-approved indications (heart failure, sleep apnea). GLP-1s may be selected for negotiation as early as 2027 with semaglutide (NVO). Our take on Part D restructuring, rebating, next gen GLP-1s as well as commercial market opportunity can be found below.

Key Points

Medicare drug spend on GLP-1s is ballooning as predicted, increasing agency focus. List prices for a month's supply of the drugs can cost from $936 to $1,349. In 2022, Medicare spent $5.7 B for GLP-1 drugs. A Health Affairs analysis of the cost of coverage in 2025 found that if 5% or 10% of newly eligible enrollees with obesity or overweight were prescribed a GLP-1, annual Medicare costs would increase by $3.1 B or $6.1 B respectively. The spending increase is corroborated by the 2024 Medicare Trustee report which reported a 4.4% increase in 2023 expenditure due to the unanticipated rapid increase in the use of antidiabetic drugs (GLP-1s).

Semaglutide is likely to be selected for negotiation in 2027.

- **As a reminder, the 2027 list is due by February 1, 2024.** Based FDA approval, semaglutide is the first GLP-1 eligible for negotiation (7 years). Capitol Street projections (here) put Ozempic (NVO) within the top four eligible drugs based on historical data.
- **Commercially, GLP-1 rebates are estimated to be between 40-50% of the list price.** Part D rebating is not disclosed but plans are also likely seeing significant rebating on GLP-1s. If semaglutide is selected for negotiation, the value proposition becomes complicated. On the one hand NVO prices may drive access, but LLY may continue to offer steep rebates (but not face the same price cuts) to earn to

preferred formulary status. As a result, semaglutide is at a potential disadvantage beyond negotiated prices.

We note GLP-1 complicating & competitive factors: Part D reform, Rebating dynamics, Next gen ~ NVO/LLY. As a reminder, most drugs in the class are considered peptides (small molecules). Tirzepatide (LLY) is not eligible in '27 due to a later FDA approval date. However, there is likely to be a class impact as negotiated prices are taken into account when determining prices of similar products selected in the future. GLP-1s are likely to see a slight positive impact from the change as they benefit from the elimination of the donut hole (partially offset by an expansion of the low-income subsidy program). Also, recall that next-generation GLP-1s allow LLY/NVO to shift usage to more efficacious products with a longer runway to inclusion. Overall, the majority of obesity sales are expected to come from the commercial market.

Medicare coverage of obesity medicines is not expected to pass in 2024, but innovation friendly bills are likely to see increased attention in 2025 in a more divided or GOP environment. An amended *Treat and Reduce Obesity Act* (*TROA*) passed out of the House Ways & Means committee (Chair Smith, R-MO) in Spring. However, full passage is unlikely this year.

- **The amended *TROA* restricts coverage to obese individuals in 2027 already on weight loss drugs prior to aging into Medicare and cost approx. $2 B /ten** (versus the significant costs of covering all beneficiaries). Medicare Part D coverage will only be allowed for treatment of obesity and will be limited to seniors who have been continuously taking weight loss medications during the year prior to Part D plan start.
- **We anticipate a new more limited coverage route (for obesity) in 2025 that may pass muster.** We note that *TROA* received its first Committee vote this past spring. The bill is also referred to House E&C and will not move until 2025 in our view as legislators work on a more palatable “modified pathway.”

Despite no legislative action, obesity drugs are becoming more easily accessible for Medicare patients with chronic care indications (heart failure with preserved ejection fraction, sleep apnea). Wegovy (NVO) is already FDA approved to reduce the risk of cardiovascular death, heart attack and stroke in overweight or obese adults. NVO plans to resubmit to the FDA data on heart failure with preserved ejection fraction (HFpEF) in obese patients in the beginning of 2025. LLY has already submitted Zepbound data for obstructive sleep apnea in June and reported positive Phase 3 results for HFpEF in obese patients. Other potential future approvals include treatment of chronic kidney disease, reducing risk of diabetes, and MASH.

As a reminder, in a lame duck healthcare legislative package, we still expect telehealth, PBM reform, likely BIOSECURE and some form of PAMA delay to pass. We continue to believe that a 2-year extension of telehealth benefits will pass ($4 B costs) this year with the upcoming Dec. deadline to extend coverage. On PBM reform, the House E&C Committee in June passed the Medicaid spread pricing ban and we expect it may be used as a pay-for in an end of the year package, along with additional Medicare (transparency) reforms. See our past analysis here on possible anti-PBM reforms and outlook. BIOSECURE passed out of the House Oversight and Accountability Cmte (Chair Comer, R-KY) in May, and last month Speaker Mike Johnson (R-LA) pledged to hold a vote before the year is out. Our BIOSECURE analysis here. We also expect clinical labs to see some type of relief in the form of another PAMA delay, as it generates additional savings without having to reform the system (per *SALSA* Act); our take on clinical labs is here.

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com

202.250.3741 I www.capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

CAPITOL STREET