# **CAPITOL STREET**

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#### **Medicare Obesity Coverage Loophole**

House Approves Long Term CBO Scoring, Reducing Costs of TROA

Relevant Companies











# >>> Our Take & Next Up

FDA's Wegovy (NVO) approval in reducing the risk of cardiovascular death, heart attack and stroke will improve Medicare uptake, as CBO releases thoughts on obesity coverage bill (TROA) & longer-term (30 year) CBO scoring helps the cause. The FDA CV indication would be for those with CV disease and are either obese or overweight here. We expect CMS to provide Wegovy coverage for this cardiovascular indication. As a result, we expect there to be a significant increase in access to Wegovy under Medicare as CV disease is a common indication in older, obese patients, and therefore a backdoor way to provide obesity medication to Medicare folks. We also expect commercial coverage to significantly improve as more payers look for ways to provide coverage, likely under a focused obesity management program (which controls costs).

# >>> Key Points

Medicare uptake of Wegovy is expected to significantly increase with the new cardiovascular indication. As a reminder, if a Part D plan includes a particular drug on its formulary, the plan must cover that drug for every indication approved by the FDA. Semaglutide is already covered to treat diabetes and following mid-year formulary updates, we are likely to see Part D plans to begin covering semaglutide more broadly under the cardiovascular indication.

The cardiovascular indication allows manufacturers to reach a significant proportion of overweight and obese individuals in Medicare as cardiovascular disease is one of the common comorbidities of obese patients and one of the most common comorbidities seen generally in patients that are 65+.

The actual uptake in the Medicare population will likely depend on increased GLP-1 adoption by cardiologists. We expect increased patient demand for cardiologists to prescribe Wegovy, however, cardiologists might not be comfortable with widespread use of GLP-1s in patients with heart disease due to side effect concerns (low blood sugar; pancreas, gallbladder, kidney, or eye problems, among others) and the ongoing shortage of the drug.

Additional FDA indications also *lower* the cost of obesity drug coverage under Medicare improving the upcoming score of TROA (Treat and Reduce Obesity Act).

- The Congressional Budget Office (CBO) <u>expects</u> that CMS will cover the cardiovascular indication for adults with obesity and will add the costs of covering GLP-1s in those patients to the baseline.
- This lowers the total cost of TROA as the amount of spending attributed to the baseline is not attributed to the legislation.
- Cost remains a major issue as CBO predicts that obesity coverage will result in "considerable demand for and use by Medicare enrollees".
- At the current GLP-1 drug prices, TROA is expected to cost more than the savings generated from lowering other health care spending.

Beyond baseline changes, proposed legislative changes to CBO scoring may also further lower costs of TROA. Yesterday, the House passed legislation that would extend the Congressional Budget Office's fiscal evaluation window from 10-year to a 30-year span for legislation advancing evidence-based preventive services on request from the Budget Committees. A 30-year outlook for TROA is much more favorable for calculating saving as the chronic disease benefits from weight loss are expected to be more notable over a longer period. However, the bill does not allow the savings to be used for official "paygo" purposes. Senate passage remains unclear despite the bipartisan support in the House. Senate lawmakers may be resistant to changing CBO scoring rules due to concerns that lengthening the required window may make projections less reliable.

CBO is also considering all future pricing factors (drug negotiation, generics) for TROA. The current price for a four-week supply of a GLP-1 ranges from about \$1,100 to \$1,300. CBO notes that the future price trajectory is highly uncertain. The agency expects semaglutide to be selected for CMS Drug Negotiation Program within the next few years which could potentially have a class wide impact on GLP-1 pricing. This is the most near-term pricing threat for GLP-1s as CBO does not expect generic competition to start until the second decade following Part D obesity medication coverage.

Wegovy is the first (but not the last) weight loss medication to be approved to prevent cardiovascular events in adults who are either obese or overweight. The approval was based on data that showed Wegovy cut the risk of strokes, heart attacks and other cardiovascular problems by 20% among overweight adults with a history of heart disease. Other GLP-1 obesity drug developers are expected to pursue a cardiovascular indication in addition to obesity treatment. Tirzepatide (LLY) is in Phase 3 trials for treatment obstructive sleep apnea and for reduction of adverse cardiovascular outcomes.

Commercial coverage is also expected to improve with the cardiovascular approval. This label expansion supports the coverage argument that Wegovy offers tangible health benefits beyond weight loss and could save costs in the long run by reducing heart complications and subsequent hospitalizations. Employers and plans have balked at the steep price of approved GLP-1 therapies. With the widening pool of patients for Wegovy, we are likely to see obesity focused programs from insurers to manage utilization and costs. For example, in early March, CI launched a financial guarantee <u>program</u>, EncircleRx, that caps employer spending on GLP-1 weight loss therapies at 15% annually.

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