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CMS Obesity Coverage as CV Benefit Emerges

TROA Is Pricey but CBO Looks to Consider Downstream Cost Savings

Relevant Companies

Our Take & Next Up

Treat and Reduce Obesity Act (TROA) is not likely to pass this year due to bill cost (hundreds of billions over ten, as we highlighted in February), but lawmaker support for Medicare coverage is growing due to cardiovascular (CV) and overall health benefit. We could see a CBO score in the next few months as advocates have been asking for a score for several years and CBO was asked to score the bill in late 2022. However, we may see a better-than-expected savings that lowers costs somewhat if CBO factors in the long-term health benefits from the management of obesity comorbidities including diabetes, and cardiovascular disease.

Key Points

There is no CBO score of the bill, but the CBO today asks for analysis & predicts that coverage at current prices (accounting for rebates and discounts) would significantly increase overall federal spending. CBO notes that the amount of potential savings on cardiac care and other health care would be less than the current net federal cost of the meds as federal spending on people with obesity who have lost weight has not fallen substantially (aka they're not cheaper to care for).

CBO notes it would consider cost savings on downstream care (e.g., cardiac care), a positive sign. The agency is asking for more research that could help its analysis including info on take-up rates, patients' adherence to drugs currently available, and expectations about the prices and effectiveness of drugs that are being developed. As a reminder, a 2015 CBO analysis, found no evidence for significant savings from covering obesity medications. Lawmakers are pushing for this comprehensive cost analysis ("dynamic scoring") that would lower TROA costs and facilitate passage.

In August 2023, the House Budget Committee (Chair Jodey Arrington, R-TX) launched a new Health Care Task Force that is looking at ways to improve CBO's modeling of health care policies. The committee is being led by Rep. Burgess, M.D. (R-TX) who is seeking ways to reduce health care spending, modernize and personalize the health care system, and support policies to fuel innovation. This is a taskforce with 7 GOP members. The committee is requesting feedback on ways to improve outcomes and reduce federal health care by October 15. The committee is expected to discuss CMMI (innovation in

Medicare), CBO's modeling capabilities, and preventative health, among other topics. We expect obesity care to be discussed as the taskforce weighs on how CBO can look at broader long-term savings beyond the 10-year window.

Earlier this summer, the Treat and Reduce Obesity Act (S.596, H.R. 4818) was reintroduced in both chambers but is said to cost "tens of billions" per year.

- The bill expands Medicare coverage to FDA approved prescription drugs for chronic weight management starting 2 years after enactment.
- It also expands coverage of obesity behavioral treatments to include behavioral counseling from community-based programs, dietitians, and psychologists.

The bill is bipartisan and bicameral and was first introduced in 2012. The reintroduction was led by Senators Carper (D-DE) and Cassidy (R-LA, also a physician), Ranking Member of the Senate HELP committee and by House Representatives Ron Kind (D-WI), Tom Reed (R-NY), Raul Ruiz (D-CA) and Brad Wenstrup (R-OH). We note that the bill was first introduced in 2012 and has been reintroduced since then but failed to gain movement due to the potential costs of coverage and the adverse side effects of the available weight loss drugs.

The lobby pressure is on, of late, but CMS cannot do much without Congress, particularly as additional health benefits are proven. CMS can do little without a legislative change due to the statutory ban, but the agency may approve coverage for a small subset of obese patients with cardiovascular disease if the drugs obtain additional FDA-approved indications in prevention of major cardiovascular events (as seen in the SELECT clinical trial).

Diabetes and weight loss drug manufacturers (LLY, NVO), primarily NVO, are engaging in an aggressive campaign to change the perception of obesity and obesity drugs, targeting CBC and other minority groups. There is increased momentum around TROA. Physicians who have publicly advocated for the health and societal benefits of addressing obesity and Medicare coverage often have financial ties to NVO. These conflicts of interests include prior work as paid consultants to the company and/or research funding received. NVO has also focused on funding health equity initiatives and contributed to nonprofits tied to the Congressional Black Caucus, and the Congressional Asian Pacific American Caucus. The CBC in particular represents a key lobbying bloc with Black Americans 1.3 x more likely to be obese and more likely to suffer from the heart disease and stroke risk factors.

Stakeholders have noted that the Center for Medicare and Medicaid Innovation (CMMI) could leverage its waiver authority to regionally test coverage policies, including obesity drug coverage. However, CMMI would have to prove that waiving the exclusion would reduce costs without compromising quality and a new model that provides coverage to a limited number of enrollees is likely to be unpopular and creates equity issues. Advocates for coverage are also making the argument that current obesity medications are distinct from treatments solely for weight loss and therefore eligible for coverage.

The long-term health and economics benefits of addressing obesity are increasingly being highlighted ($175+ B in savings) as critical for Medicare coverage. A study from the USC Schaeffer Center found that Medicare coverage of weight-loss therapies would save the program $175 B to $245 B over 10 years depending on whether private insurance also covers the treatments. Most of the savings would materialize from reducing (a) hospital inpatient care and (b) skilled nursing care demands under Part A and recommended that policymakers consider the long-term benefit of Medicare coverage. However, key questions remain as not all obese patients will stay on the drugs for more than a year or two due to side effects or see the same benefits.

We do not believe the study will push Medicare for coverage because CMS has to balance the "potential savings" with the real cost of the drugs. Earlier this year, a New England Journal of Medicine paper estimated that if 10% of Medicare beneficiaries with obesity use Wegovy, the annual cost to Medicare could be $13.6 B (based on a 21% obesity rate from traditional Medicare diagnoses) to $26.8 B (based on a 41.5% obesity rate from survey data for adults ages 60 and older).

Health insurers are also paying attention to increasing reports of side effects (pancreatitis, stomach paralysis, suicide

ideation). Individuals using GLP-1 therapies (Ozempic, Wegovy, Victoza) have seen an increased risk of pancreatitis, stomach paralysis with the FDA recently adding risk of intestinal blockage to possible side effects. EU regulators have launched an investigation on the risk of suicide ideation and mental side effects of the drugs after 150 reported cases of self-injury and suicidal thoughts. The review is expected to conclude in November 2023. Obesity medications in the past have been hindered by serious side effects. While GLP-1 therapies have proven to be effective in weight loss, it will take time for the full risk profile of the drugs to be well known. This may add to CMS's hesitancy to cover the meds in the wider, obese Medicare patients who may already be medically frail.

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
