ACKNOWLEDGMENTS

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EXECUTIVE SUMMARY

The prevalence of obesity in the U.S. continues to rise, including in older adults, and is higher among communities of color and historically disadvantaged communities. This poses a significant challenge for public health, health care providers, and public and private payers, all of whom are struggling with the double burden of COVID-19 and rising rates of obesity and chronic disease. Given the serious health and financial ramifications of obesity, policymakers should consider the value of increased investment in obesity prevention and treatment efforts.

Currently, Medicare provides limited coverage for bariatric surgery, Intensive Behavioral Therapy (IBT) for weight loss, and the Medicare Diabetes Prevention Program (MDPP) for those who qualify. IBT and MDPP are covered as no-cost preventive services for those who meet eligibility criteria, but coverage for IBT is limited to primary care settings, and uptake of both services has been low. In addition, Medicare does not cover the full continuum of care for obesity, including anti-obesity medications and all evidence-based behavioral interventions.

Given that prior efforts have failed to stem rising rates and costs of obesity, this policy brief aims to stimulate discussion as to what would be required for policymakers to expand access to obesity treatments in public insurance programs, and in Medicare specifically. We first present current data on the prevalence and costs of obesity overall and for those above age 65. Overall, obesity is estimated to be responsible for $248 billion (in 2020) in annual medical expenditures, which equates to 6.2% of total expenditures. We then present the results of a systematic review summarizing the evidence base of obesity treatments that are not currently covered in the Medicare program. The review identified five Food and Drug Administration-approved (FDA) pharmaceuticals and two behavioral health interventions that could be considered for coverage. All but one showed statistically significant weight loss at 12 months or greater; however, none of the reviews specifically focused on older adults or those most likely to be enrolled in public insurance programs.

Even though obesity is a growing epidemic, a leading risk factor for serious cases of COVID-19, and a dire health equity issue, this policy brief demonstrates potential gaps in Medicare coverage of evidence-based obesity treatments. To close these gaps, policymakers should remove the statutory prohibition on Medicare Part D coverage for FDA-approved anti-obesity medications. Further studies in the older adult population could help Centers for Medicare and Medicaid Services (CMS) in their consideration for coverage of treatments. In addition, expanded access to existing evidence-based obesity treatments such as IBT will be critical to ensure older adults have access to the full continuum of obesity care.
Introduction

Despite several decades of widespread recognition of the country’s obesity epidemic, rates of obesity (estimated as body mass index (BMI) ≥ 30kg/m²) continue to increase. The most recent data from National Health and Nutrition Examination Survey (NHANES) reveals that the prevalence of obesity among adults increased from 30.4% in 1999-2000 to 42.4% in 2017-2018. Among those at the highest end of the obesity spectrum, those with Class III or “severe” obesity (BMI ≥ 40), prevalence increased at an even faster rate, from 4.7% to 9.2%. These increases translate into 107 million adults with obesity, including 23 million with Class III obesity, in the United States as of 2018. This data is from prior to the start of the COVID-19 pandemic, which has made it more difficult for individuals to maintain a healthy weight and compounded the health risks associated with obesity. To put these numbers in perspective, there were as many adults with obesity in the U.S. in 2018 as there were total residents in the five most populous states combined (California, Texas, Florida, New York, and Pennsylvania), and more adults with Class III obesity than there were adults in the state of Texas. Even among older adults (aged 60+), the prevalence of obesity is 42.8%, similar to the level among younger and middle-aged adults, and the prevalence of Class III obesity among those aged 60+ is 5.8%. More than 20% of the population will be 65 years of age or older by 2030, up from 15% today, highlighting the importance of addressing obesity in this specific population.

Aside from the sheer magnitude of the numbers, there are three reasons the rise in obesity rates is alarming.

First, these numbers mask significant sociodemographic disparities in rates of obesity. People in lower income groups are more likely to live with obesity than those in higher income groups and generally experience severe disease at higher rates. Moreover, even after controlling for income and other measures of socioeconomic position, the prevalence of obesity is higher among Black and Hispanic adults compared to their white counterparts. These disparities promote social stigma and psychological distress.

Second, as has been well-documented, obesity adversely affects nearly every system in the human body. Those with obesity are more likely to experience high blood pressure, high cholesterol, Type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, psoriasis, sleep apnea, several forms of cancer, mental illness, pain, difficulty with physical functioning, and other maladies. Recent data further reveals that excess weight is a significant predictor of increased morbidity and mortality from COVID-19, with 30.2% of
COVID-19 hospitalizations attributable to obesity. Moreover, the likelihood of adverse health conditions resulting from excess weight increases disproportionately with increasing weight such that those with Class II (BMI ≥ 35.0 – 39.9) and Class III obesity are at much greater risk, including from COVID-19. Because individuals tend to gain weight as they age and duration of excess weight is also a risk factor for adverse health effects, older adults are far more likely to be diagnosed and treated for obesity-related conditions. Older adults with obesity are also twice as likely to have chronic pain, and more likely to have functional and mobility limitations compared to healthy-weight older adults. For example, 70-year-olds with obesity can expect to face 2.8 additional years of limitations in activities of daily living, two years of which will involve moderate to severe levels of disability.

Third, obesity generates enormous economic consequences. Adults with Class I obesity (BMI ≥ 30-34.9) incur roughly $1,220 (in 2020) greater per capita annual medical expenditures than those with a healthy weight (BMI 18.5 to 24.9), and adults with Class II/III obesity incur $2,640 greater per capita annual costs. When focusing on adults age 65 and older, the corresponding figures increase to $1,920 ($2,220) for men (women) with Class I obesity and $3,960 ($4,710) for men (women) with Class II/III obesity. These increases are largely due to higher incidence of costly obesity-related medical events, such as heart attacks and strokes. Average costs for these events exceed $20,000 and can be several times that when surgical interventions are required.

Overall, obesity is estimated to be responsible for $248 billion (in 2020) in annual medical expenditures, which equates to 6.2% of total expenditures. These expenditures result almost entirely from treating the conditions exacerbated by obesity, as opposed to treating obesity itself, as few obesity treatments are currently covered by Medicare and other insurers. Additionally, uptake for covered services is extremely low relative to the size of the eligible population.
MEDICARE & OBESITY TREATMENTS

Despite the high prevalence and costs of obesity, there are several unique challenges that reduce the incentives for any single payer to address the obesity epidemic, with the exception of Medicare. First, individuals tend to change jobs every four years, and those with individual health insurance coverage frequently switch their health plans. Second, the adverse health effects of obesity often do not materialize for years or even decades after the onset of excess weight. These circumstances mean that any investment in obesity prevention is likely to be recouped by another entity, thus limiting the incentives to invest, and further fueling the obesity epidemic at older ages. The incentives for investment in obesity prevention in Medicare differ from those of private sector payors, given that most individuals with Medicare coverage enter at age 65 and are enrolled for life, which is roughly 20 additional years for the typical new enrollee.

Some have suggested that the adverse health effects of obesity predispose older adults to an early demise, thus minimizing economic incentives to invest in obesity treatment for Medicare beneficiaries. Although older adults with obesity have a predicted 4.5-year shorter life expectancy than adults with a healthy BMI, this decrease is not enough to offset the increase in costs when alive. Estimates suggest that the lifetime costs of obesity for a 65-year-old adult are $22,670 (in 2020). Multiplying this figure times the current prevalence of obesity among Medicare beneficiaries yields a staggering total of ~$524 billion in lifetime Medicare expenditures attributable to current beneficiaries with obesity. Clearly, the CMS, the agency that oversees Medicare, has both a health and financial incentive to address obesity among beneficiaries.

One solution is to increase access to obesity treatments. Currently, Medicare coverage for obesity treatments is limited to bariatric surgery (for beneficiaries with BMI ≥ 35 and comorbidities), IBT (for beneficiaries with a BMI ≥ 30), and since 2018, MDPP for beneficiaries with a BMI ≥ 25 and a diagnosis of prediabetes. IBT and MDPP are covered as no-cost preventive services for those who meet eligibility criteria. However, partly due to policy barriers, uptake for bariatric surgery and these behavioral programs is extremely low, especially among minority and disadvantaged populations, leaving millions of beneficiaries with obesity untreated. For example, Medicare’s coverage of IBT is limited to primary care providers in primary care settings. It does not cover the full range of obesity care specialists, registered dietitians, psychologists, or evidence-based community-based programs. For these reasons, few medical practices provide IBT for Medicare beneficiaries with obesity, and fewer than 1% of qualified beneficiaries receive the treatment.
Medications for obesity are recommended by clinical guidelines as the next step in the continuum for patients who are unsuccessful with IBT alone. However, Medicare currently does not cover any anti-obesity medications due to a statutory prohibition of cosmetic “weight loss drugs” that predates the enactment of Medicare Part D in 2003. These restrictions have also been in effect long before consensus built in the medical community that obesity is a disease, and before many anti-obesity medications were approved by the FDA and made available to the public.

To assess the effectiveness of obesity treatments that CMS could consider covering under Medicare, we conducted a systematic review of randomized controlled trials (RCTs) that evaluated nonsurgical commercially available weight loss interventions of at least one year in duration that are not currently covered by Medicare. We found 21 studies that present evidence for five FDA-approved pharmaceuticals (orlistat [Xenical], phentermine/topiramate [Qsymia], naltrexone/bupropion [Contrave], liraglutide [Saxenda], and semaglutide [Wegovy], and two behavioral interventions (WW (formerly Weight Watchers) Meetings and WW online). All but WW online showed statistically significant weight loss at 12 months or greater. We summarize the available evidence for each treatment, including evidence for older adults, in the sections that follow.

**Evidence of Effectiveness**

### Medications

**Orlistat (Xenical)**

Six RCTs evaluated orlistat in conjunction with a reduced-calorie diet in adults ages 18-77 in the U.S. and Europe. Weight loss in the orlistat group ranged from 7.5% to 10.2% of body weight at 12 months. Four of the six RCTs also evaluated an additional 12 months of orlistat treatment. Continuing orlistat for the second year of the study was associated with greater weight maintenance or continued weight loss in all four trials.
Table 1. RCTs evaluating Orlistat 120mg

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Treatment</th>
<th>Control</th>
<th>Age</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davidson, 1999</td>
<td>Orlistat 120mg with low calorie diet</td>
<td>Placebo with low-calorie diet</td>
<td>≥ 18 years</td>
<td>Treatment lost 8.8%, 3.0 percentage points more than placebo*</td>
</tr>
<tr>
<td>Finer, 2000</td>
<td>Orlistat 120mg with low-calorie diet</td>
<td>Placebo with low-calorie diet</td>
<td>≥ 18 years</td>
<td>Treatment lost 8.5%, 3.1 percentage points more than placebo</td>
</tr>
<tr>
<td>Hauptman, 2000</td>
<td>Orlistat 120mg with low-calorie diet</td>
<td>Placebo with low-calorie diet</td>
<td>≥ 18 years</td>
<td>Treatment lost 7.9%, 3.7 percentage points more than placebo*</td>
</tr>
<tr>
<td>Krempf, 2003</td>
<td>Orlistat 120mg with low-calorie diet</td>
<td>Placebo with low-calorie diet</td>
<td>18-65</td>
<td>Treatment lost 7.47%, 2.77 percentage points more than placebo</td>
</tr>
<tr>
<td>Rossner, 2000</td>
<td>Orlistat 120mg with low-calorie diet</td>
<td>Placebo with low-calorie diet</td>
<td>≥ 18 years</td>
<td>Treatment lost 9.7%, 3.3 percentage points more than placebo*</td>
</tr>
<tr>
<td>Sjostrom, 1998</td>
<td>Orlistat 120mg with low-calorie diet</td>
<td>Placebo with low-calorie diet</td>
<td>≥ 18 years</td>
<td>Treatment lost 10.2%, 3.9 percentage points more than placebo*</td>
</tr>
</tbody>
</table>

*Author calculation

Phentermine/topiramate (Qsymia)

Only one identified RCT evaluated phentermine/topiramate. After 56 weeks, participants with BMI 27-45 and two or more comorbidities who received phentermine/topiramate lost between 7.8% and 9.8% of baseline weight depending on the dosage.24

Table 2. RCTs evaluating phentermine/topiramate

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<thead>
<tr>
<th>Author, Year</th>
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</thead>
<tbody>
<tr>
<td>Gadde, 2011</td>
<td>Phentermine 7.5mg + topiramate 46mg OR Phentermine 15mg + topiramate 92mg</td>
<td>Placebo</td>
<td>18-70</td>
<td>Phentermine 7.5mg + topiramate 46mg lost 7.8%, Phentermine 15mg + topiramate 92mg lost 9.8%, placebo lost 1.2%. Treatment groups lost 6.6 and 8.6 percentage points more than placebo, respectively.*</td>
</tr>
</tbody>
</table>

*Author calculation
Naltrexone/bupropion (Contrave)

Three RCTs evaluated naltrexone/bupropion (NB) in adults ages 18-65 in the U.S. Weight loss in the NB groups ranged from 6.1% to 9.3% at 12 months.

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Apovian, 2013</td>
<td>NB</td>
<td>Placebo</td>
<td>18-65</td>
<td>Treatment lost 6.4%, 1.2 percentage points more than placebo*</td>
</tr>
<tr>
<td>Wadden, 2011</td>
<td>NB with low-calorie diet and exercise</td>
<td>Placebo with low-calorie diet and exercise</td>
<td>18-65</td>
<td>Treatment lost 9.3%, 4.2 percentage points more than placebo*</td>
</tr>
<tr>
<td>Greenway, 2010</td>
<td>NB with diet and intensive behavior modification</td>
<td>Placebo with diet and intensive behavior modification</td>
<td>18-65</td>
<td>Treatment lost 6.1%, 4.8 percentage points more than placebo*</td>
</tr>
</tbody>
</table>

*Author calculation

Liraglutide (Saxenda)

Three RCTs evaluated liraglutide 3.0mg in conjunction with lifestyle modification in adults ages 18-70 in the U.S. At 12 months, weight loss in the medication groups ranged from 6.2% to 11.8% of body weight.

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<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Pi-Sunyer, 2015</td>
<td>Liraglutide with lifestyle modification counseling</td>
<td>Placebo with lifestyle modification counseling</td>
<td>≥ 18</td>
<td>Treatment lost 8%, 5.4 percentage points more than placebo</td>
</tr>
<tr>
<td>Wadden, 2013</td>
<td>Liraglutide with diet and exercise counseling</td>
<td>Placebo with diet and exercise counseling</td>
<td>≥ 18</td>
<td>Treatment lost 6.2%, 6.1 percentage points more than placebo</td>
</tr>
<tr>
<td>Wadden, 2019</td>
<td>Liraglutide with IBT OR Liraglutide with IBT and meal replacements</td>
<td>IBT only</td>
<td>21-70</td>
<td>Liraglutide with IBT lost 11.5%, multicomponent lost 11.8%, and IBT alone lost 6.6%. Liraglutide groups lost 4.9 and 5.2 percentage points more than placebo, respectively.*</td>
</tr>
</tbody>
</table>

*Author calculation
Semaglutide (Wegovy)

Five RCTs evaluated semaglutide (2.4mg) in combination with lifestyle modification in adults ages 18-70 in the U.S. Weight loss in the intervention groups ranged from 9.6% to 16% of body weight. Inclusion criteria varied across studies, and four of the five RCTs excluded those with diabetes. This may account for some of the observed differences in effectiveness.

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<tr>
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<th>Age</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wilding, 2021</td>
<td>Semaglutide with lifestyle intervention</td>
<td>Placebo with lifestyle intervention</td>
<td>≥ 18</td>
<td>Treatment lost 14.9%, 12.4 percentage points more than placebo</td>
</tr>
<tr>
<td>Davies, 2021</td>
<td>Semaglutide with lifestyle intervention</td>
<td>Placebo with lifestyle intervention</td>
<td>≥ 18</td>
<td>Treatment lost 9.64%, 6.21 percentage points more than placebo</td>
</tr>
<tr>
<td>Rubino, 2021</td>
<td>Semaglutide with lifestyle intervention</td>
<td>Placebo</td>
<td>≥ 18</td>
<td>Treatment lost 7.9%, while placebo gained 6.9%. In total, treatment lost 14.8 percentage points more than placebo.</td>
</tr>
<tr>
<td>Wadden, 2021</td>
<td>Semaglutide with IBT and meal replacements</td>
<td>Placebo with IBT and meal replacements</td>
<td>≥ 18</td>
<td>Treatment lost 16%, 10.3 percentage points more than placebo</td>
</tr>
<tr>
<td>O’Neil, 2018</td>
<td>Differing daily doses of semaglutide</td>
<td>Placebo</td>
<td>≥ 18</td>
<td>Treatment with most efficacious dose of semaglutide (0.4mg daily) lost 13.8%, 11.55 percentage points more than placebo</td>
</tr>
</tbody>
</table>

**Behavioral Interventions**

Many community-based, commercially available behavioral weight loss interventions are available in the United States. Yet our search identified randomized controlled trial evidence of effectiveness at 12 months for only WW (formerly Weight Watchers) in-person meetings and WW online programs. Our review identified three RCTs of WW. For WW in-person meetings, average weight loss in the intervention groups was 4.6% and 7.1%. For WW online, weight loss was 2.2%. However, whereas WW in-person meetings led to statistically significant weight loss at 12 months, WW online did not.
Table 6. RCTs evaluating Weight Watchers

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Treatment</th>
<th>Control</th>
<th>Age</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heshka, 2003</td>
<td>Weight Watchers in-person meetings</td>
<td>Self-help usual care</td>
<td>18-65</td>
<td>Treatment lost 4.6%, 3.2% more than usual care*</td>
</tr>
<tr>
<td>Ahern, 2017</td>
<td>Weight Watchers in-person meetings</td>
<td>Print materials of weight loss strategies</td>
<td>≥ 18 years</td>
<td>Treatment lost 7.1%, 3.7% more than print materials</td>
</tr>
<tr>
<td>Thomas, 2017</td>
<td>Weight Watchers online or Weight Watchers online with activity tracker</td>
<td>Online newsletter</td>
<td>18-70</td>
<td>Weight Watchers online with activity tracker lost 0.3 percentage points more than online newsletter, and Weight Watchers online lost 0.8 percentage points more than newsletter, but differences were not statistically significant.*</td>
</tr>
</tbody>
</table>

*Author calculation

Discussion

Obesity treatment guidelines from the American Heart Association/American College of Cardiology/The Obesity Society, the Endocrine Society, and the American Association of Clinical Endocrinology provide comprehensive recommendations for obesity screening, diagnosis, and treatment, including lifestyle interventions and the use of weight loss medications, when appropriate.\(^{25,26,27}\) Weight loss of ≥5% of body weight has been found to improve blood sugar, blood pressure, triglycerides, HDL cholesterol, use of lipid-lowering medications, obstructive sleep apnea, knee osteoarthritis, and incidence of chronic conditions.\(^{28}\) Our literature review reveals that the included anti-obesity medications led to 6-16% weight loss in 52-68 weeks, and in-person behavioral interventions led to 5-7% weight loss (statistically significant at 12 months), suggesting that these treatments have the potential to improve health. Sixteen of the 21 studies included in our review enrolled participants over age 65. No studies looked exclusively at the 65+ population.

With respect to the cost of interventions, while Medicare is statutorily prohibited from considering costs as part of coverage decisions, policymakers and the Congressional Budget Office (CBO) have expressed interest in the impact of obesity treatment interventions on the federal budget. In 2015, CBO published a blog titled "Estimating the Effects of Federal Policies Targeting Obesity: Chal-
Challenges and Research Needs.” The authors noted that “despite a rapidly growing body of literature that explores the effects of obesity on health and health care spending, research on the effects that policy interventions aimed at weight loss would have on the federal budget is largely lacking,” and as a result, “The Congressional Budget Office has determined that the available evidence does not support the conclusion that certain policies to stem obesity ... would generate significant savings for the federal government.”

This policy brief documents the continued high costs of obesity and reveals that clinically effective interventions (at ranges between 12 and 24 months) for treating obesity that are not currently covered by Medicare are available.

However, limited evidence exists to document the likely effects of increased coverage on the federal budget. Answering that question requires information not only on the costs of obesity and intervention effectiveness, but also on the cost of the interventions, the duration that individuals are expected to remain on treatment, the degree of weight loss, and the extent to which weight loss generates health improvements and cost savings.

Finally, it is important to note the existing policy barriers limiting access to presently covered evidence-based obesity treatments for Medicare beneficiaries. Currently, IBT must be provided by a primary care provider in a primary care setting, even though these professionals are not best trained to provide nutrition counseling, nor are they most cost effective. The Bipartisan Policy Center’s Food and Nutrition Security Task Force recently reviewed available research and recommended that the eligibility of providers to bill Medicare for delivery of IBT be expanded to include registered dietitians. The task force also recommended that uptake of MDPP be enhanced by increasing the number of providers, conducting outreach in communities at increased risk for Type 2 diabetes, and providing a virtual option for the program to increase participation and retention.

Given the continued rise and high rates of obesity in the older adult population, it is critical that policymakers understand the potential gaps in Medicare coverage of evidence-based obesity treatments. Obesity is now recognized as a chronic disease, and there are now FDA-approved medications for obesity; thus, policymakers should remove the statutory prohibition on Medicare Part D coverage for FDA-approved anti-obesity medications. Further studies in the older adult population could help CMS in their consideration of coverage for treatments. In addition, policymakers should expand access to existing evidence-based obesity treatments such as IBT and MDPP, including specifically by expanding the types of providers eligible to bill Medicare for delivery of IBT and the settings in which reimbursable IBT may be provided.
Endnotes


W.T. Garvey, J.I. Mechanick, et. al., “American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines For Medical Care of Patients with Obesity,” July 1, 2016. Available at: https://www.endocrinepractice.org/article/S1530-891X(20)44630-0/fulltext.


