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Convened by Lupus Foundation of America

Clinical Evidence Driving Patient Access in Medicare Part D

Case study for improving Obesity coverage

Medicare Part D is a critical benefit that has provided millions with access to prescription medications since 2006. However, despite the program's successes, there have been significant patient access challenges—specifically, Part D's exclusion of certain medically necessary drugs and services. As the medical community's understanding of disease states evolves, the Part D program must evolve. A key example is Part D's exclusion of Food and Drug Administration (FDA)-approved anti-obesity medications (AOMs) that address the treatable metabolic chronic disease of obesity.

The prevalence of obesity in the United States (US) population has increased steadily since the 1960s. Now more than 100 million Americans live with obesity,[1] and it has major health and economic implications for the country. As the nation continues to grapple with the COVID-19 pandemic, we have learned that obesity and obesity-related diseases are the second greatest risk factors, after older age, for hospitalization among COVID-19 patients.

Coverage policies constantly evolve as clinical evidence advances and, with that, the Medicare program advances its coverage of medications and services. The program has evolved over time, covering previously non-covered items based on new indications and clinical evidence. For example, Medicare has changed the way it covers mental health services and bariatric surgery. Yet it has not kept pace with advances in the medical community's understanding of obesity or its treatment, despite the prevalence of obesity, its significant negative impact on the health of Medicare beneficiaries, and the cost to society.

Approximately 35% (over 13 million) of adults in the US aged 65 and over between 2007 and 2010 were living with obesity.[2] Congress has an opportunity to amend the Social Security Act to clarify that FDA-approved AOMs that treat a chronic disease—obesity—are medically necessary treatments for "chronic weight management" and should be covered under Part D.

The Centers for Medicare & Medicaid Services (CMS) must recognize its authority to interpret the statutory exclusion of certain uses of drugs and categories of drugs to permit coverage of medically accepted indications of drugs, even when other uses of those drugs might be excluded under the statute. This authority should be applied to FDA-approved AOMs as it has done in other instances.

UNDERSTANDING OBESITY

There has been a significant paradigm shift in the clinical understanding of obesity. At the onset of the disease, scientists believed that obesity was simply an energy imbalance—more calories consumed than expended.

In 1994, leptin was discovered, changing the way the medical community thought about obesity.[3] The hormone, which is secreted by fat cells, acts in the brain to suppress appetite following a meal.[4]

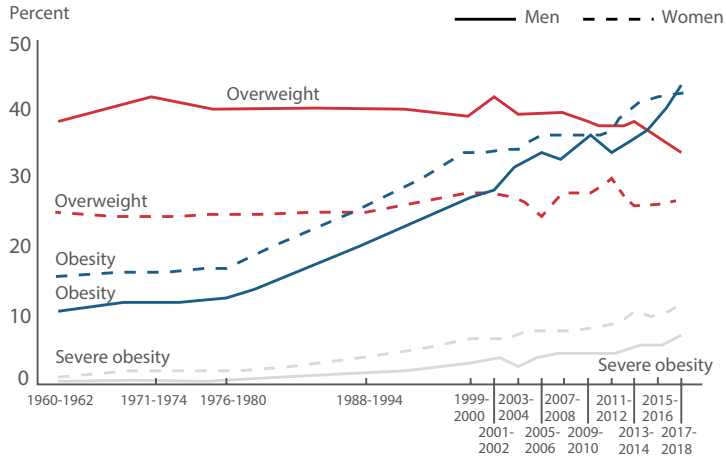
In 2013, the American Medical Association recognized obesity as a disease state with multiple pathophysiological aspects that require a range of interventions to advance obesity treatment and prevention.

The stunning rise of obesity in the US

According to the Centers for Disease Control and Prevention (CDC), obesity is epidemic in the US and a major risk factor for a broad range of chronic diseases including diabetes, hypertension, cardiovascular disease, Alzheimer's disease and related dementias, osteoarthritis, and several cancers.[5] As depicted in **Figure 1**, the obesity rate in the US has tripled in the last 50 years.[6] In the early 1960s, fewer than 14% of US individuals had a body mass index (BMI) over 30 vs 42% in the 2017 to 2018 period. It is important to note that 44.8% of adults aged 40 to 59 years live with obesity and as obesity prevalence continues to rise, Medicare must consider future costs and greater resource needs.

About **2 in 5** adults and **1 in 5** children and adolescents in the US live with obesity.[7]

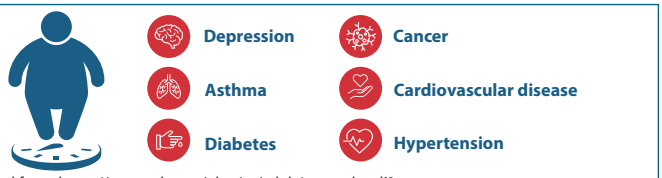
Figure 1. Age-adjusted trends in overweight, obesity, and severe obesity among men and women aged 20-74: US, 1960-2018



Notes: Data are age-adjusted by the direct method to the US Census 2000 estimates using age groups 20-39, 40-59, and 60-74. Pregnant women are excluded from the analysis.
BMI definitions: Overweight, 25.0-29.9 kg/m²; obesity, 30.0-39.9 kg/m²; severe obesity, ≥40.0 kg/m².
Key: BMI – body mass index; US – United States.

Obesity affects a wide range of other therapeutic areas

Obesity and obesity-related diseases are the second greatest risk factors, after older age, for hospitalization among COVID-19 patients. In fact, the CDC reported that 78% of patients who have been hospitalized, needed a ventilator, or died from COVID-19 lived with overweight or obesity and had at least 1 underlying health condition, many of which were obesity-related diseases.[8] One study showed that a 25% reduction in the rate of obesity could have led to 120,000 fewer hospitalizations, 45,000 fewer intensive care unit (ICU) admissions, and 65,000 fewer deaths from COVID-19 by April 2021.[9]



Adapted from: https://www.cdc.gov/obesity/adult/causes.html[10]

Obesity has also been implicated as a risk factor for certain types of cancer, cardiovascular disease, and diabetes, among other conditions that affect health and healthcare costs.[11] Additionally, adults living with obesity have a 55% higher risk of developing depression over their lifetime compared to people not living with obesity.[12]

The increase in these conditions' prevalence across the nation has major implications for the health and well-being of the population.

OBESITY IS A CRIPPLING PUBLIC HEALTH AND FINANCIAL THREAT IN THE US

The rising prevalence of obesity in the US imposes a substantial public health and economic burden due to both direct medical care costs and indirect productivity-related costs.

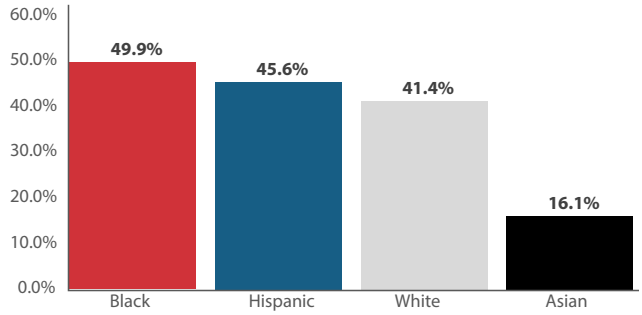
In 2016, the total cost of chronic diseases due to obesity and overweight was **$1.72 trillion**—equivalent to 9.3% of the US gross domestic product.

In 2016, chronic diseases driven by the risk factors of obesity and overweight accounted for $480.7 billion in direct healthcare costs in the US, with an additional $1.24 trillion in indirect costs due to lost economic productivity.[13] The total cost of chronic diseases due to obesity and overweight was $1.72 trillion—equivalent to 9.3% of the US gross domestic product. Obesity as a risk factor is by far the greatest contributor to the burden of chronic diseases in the US, accounting for 47.1% of the total cost of chronic diseases nationwide. Additionally, failure to treat those living with obesity with the full continuum of care leads to increased job absenteeism, presenteeism, disability, and payments from workers' compensation insurance. One study found that obesity raises the number of workdays lost to illness or injury by 3 days per worker per year (from 2.34 to 5.34), or by 128.2%.[14] These lost workdays translate to a per-worker annual productivity loss caused by obesity ranging from $270.79 to $541.58 and at the US national level, $13.42 billion to $26.84 billion.[14]

Racial and ethnic minorities live with obesity at higher rates

The burden and cost of obesity are particularly pronounced among communities of color. Non-Hispanic Black populations have the highest prevalence of obesity at 49.6%, followed by Hispanic populations at 44.8% and non-Hispanic White populations at 42.2% (**Figure 2**).[15] African American women live with obesity at the highest rate among any demographic group; approximately 4 out of 5 African American women live with overweight or obesity. Native Hawaiians/Pacific Islanders are 80% percent more likely to live with obesity than non-Hispanic White populations.[16] US-born Asians and Pacific Islanders are at higher risk of living with obesity, and the risk for immigrants increases with the duration of residency.[17] Living with obesity places racial and ethnic groups at higher risk for the development of obesity-related diseases such as diabetes, hypertension, high cholesterol levels, heart disease, stroke, and some cancers.[18]

Figure 2. Adults living with obesity by race/ethnicity



As CMS continues to emphasize the need to examine health equity, the agency must assess whether its programs and policies perpetuate systemic barriers that limit full and equal participation by people of color and underserved groups and aim to identify the best methods to assist agencies in assessing equity with respect to obesity.

CLINICAL EVIDENCE EVOLVES; SO SHOULD COVERAGE POLICIES

Science and innovation drive the need for access

Clinical guidelines recommend evidence-based obesity care including intensive behavioral therapy (IBT), AOMs, and bariatric surgery, stating "the addition of pharmacotherapy produces greater weight loss and weight loss maintenance compared with lifestyle therapy alone."[19] The American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) clinical practice guidelines identify 5 FDA-approved AOMs: CONTRAVE (naltrexone HCl and bupropion HCl), SAXENDA (liraglutide), BELVIQ (lorcaserin hydrochloride) (discontinued), XENICAL (orlistat), and QSYMIA (phentermine/topiramate ER).[20] The guidelines recommend that "clinicians and their patients with obesity should have access to all approved medications to allow for the safe and effective individualization of appropriate pharmacotherapy" and identify drug preferences and contraindications for patients with certain comorbidities and clinical characteristics. However, seniors currently only have limited coverage for IBT and surgery.

AOMs are a critical part of the obesity care continuum, particularly for people for whom lifestyle intervention alone does not work or who have multiple comorbidities. Most patients living with obesity are not able to achieve and maintain a healthy weight with healthy eating and increased physical activity alone.[19] FDA-approved AOMs are proven to help patients living with obesity. One study found that when combined with lifestyle intervention, all drugs currently approved by the FDA for chronic weight management produced greater obesity reduction (5%-12%) and sustained the obesity reduction for a greater length of time than did lifestyle intervention alone.[21] As a result, a growing number of commercial and Medicaid plans recognize the importance of AOMs in the obesity care continuum and offer coverage for AOMs; however, patients covered under these plans lose access to the medicines they need when they turn 65 and enroll in Medicare.

CMS currently excludes AOMs from coverage on the basis that they are "agents for weight loss."[22] However, modern AOMs are not "agents for weight loss." In fact, modern AOMs are very different from weight loss products that were commercialized in decades past. For example, in the 1990s, use of fen-phen drove the perception that weight loss drugs are unsafe and can have severe side effects. ("Fen-phen" refers to the use in combination of the drugs fenfluramine/phentermine and phentermine/dexfenfluramine.) In the 1990s, some physicians began prescribing fenfluramine or dexfenfluramine in combination with phentermine, often for extended periods of time, for use in weight loss programs, often by people who did not have the disease of obesity.[23]

While the prescription medications fenfluramine, phentermine, and dexfenfluramine received individual approval by the FDA, use of the drugs in combination never received FDA approval. In September 1997, the FDA asked the manufacturers to voluntarily withdraw dexfenfluramine and fenfluramine from the market.[24] The FDA's withdrawal request came after echocardiogram testing of patients taking fen-phen suggested that fenfluramine and dexfenfluramine were the likely cause of heart valve problems. In the 1990s, several other weight loss medications were withdrawn from the market due to severe cardiovascular side effects, including aminorex (pulmonary hypertension), phenylpropanolamine (stroke), and sibutramine (myocardial infarction and stroke).[25,26]

Modern AOMs approved by the FDA are significantly different from products withdrawn from the market in previous years because they are included within more comprehensive treatments than just weight loss. In 2007, the FDA issued draft guidance to manufacturers outlining expectations for AOMs.[27] The FDA has encouraged manufacturers developing AOMs to look not only at the effectiveness of these medications with respect to weight but also importantly at the impact of these medications on "secondary efficacy endpoints" such as blood pressure and pulse, lipoprotein lipids, fasting glucose and insulin, and HbA1c (in type 2 diabetics). The FDA has further stated that changes in common obesity comorbidities "should be factored into the efficacy assessment of investigational and weight-management products." The FDA also stated that its draft guidance on weight management drugs applies to products "for medical weight loss, which can be defined as a long-term reduction in fat mass *with a goal of reduced morbidity and mortality through quantifiable improvements in biomarkers such as blood pressure, lipids, and HbA1c.*"

Since this guidance was issued, several products have since been approved by the FDA to meet this standard, with an indication of "chronic weight management." Unlike the products of the past, studies have shown that many of the currently approved products generally have favorable effects on cardiometabolic parameters.[28] Many of these products are approved for long-term use, and they are recommended in specialty society guidelines and guidelines for the Department of Defense. When combined with lifestyle changes, beneficiaries taking AOMs lose 3% to 12% more weight than those who do not include prescription medications in their obesity treatment. Those taking medication also sustained obesity reduction.

Pharmacotherapy agents can be grouped by treatment period as short-term weight loss agents and chronic weight management agents.[29] ACE and ACE clinical practice guidelines emphasize that obesity is a chronic condition and identified 5 AOMs for use as an adjunct to behavioral interventions: naltrexone/bupropion, liraglutide 3 mg, orlistat, phentermine/topiramate, and lorcaserin HCl (discontinued).[19] (The FDA subsequently approved a sixth AOM, IMCIVREE [setmelanotide].) The guidelines recommend that "clinicians and their patients with obesity should have available access to all approved medications to allow for the safe and effective individualization of appropriate pharmacotherapy" and identify drug preferences and contraindications for patients with certain comorbidities and clinical characteristics.[19,30]

CASE STUDIES FOR TREATMENTS THAT ARE NOW ROUTINE AFTER EVIDENCE EVOLVES

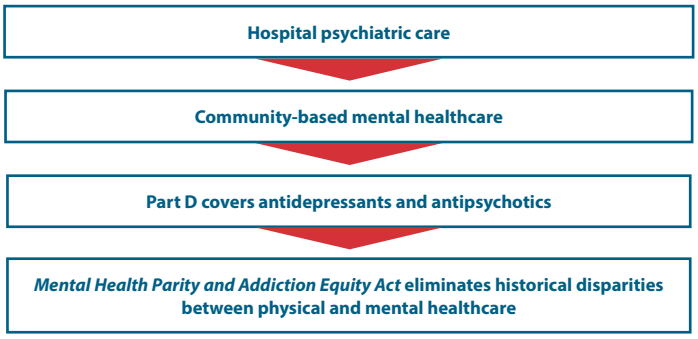
Health insurance coverage of treatments and procedures typically follows the clinical evidence. As the medical community's understanding of the clinical efficacy of a therapeutic evolves, treatments that may not have been covered in the past can become routine. Additionally, payers can become nuanced about how they cover treatments, such as providing access to products for FDA-approved uses while prohibiting coverage for treatments that are not.

As the following case studies demonstrate, coverage for services and products is not static; changes occur as clinical evidence emerges to support use.

Mental health

Treatment for mental illness has changed dramatically over the past century, but particularly in the past quarter-century. The evolution of insurance coverage for mental health treatment has also shifted. Insurers did not begin including mental health services until the 1950s, when insurance policies included hospital psychiatric care. Before the period of deinstitutionalization, which started in the late 1950s when most long-term care in psychiatric hospitals was replaced with community-based mental healthcare, there was little reason for private insurers to cover services that were paid for by the government (**Figure** 3).[31]

Figure 3. The advancing progress of mental healthcare



The modern view of mental illness has evolved tremendously, with a shift in the cultural conversation and availability of more effective treatments. For example, the American Psychological Association conducted a poll in 2018 of over 1,000 US adults; 87% agreed that having a mental health disorder is nothing to be ashamed of.[32]

Before the expansion of Medicare Part D, depression was often undertreated in adults over 65. In 2003, Congress established Medicare Part D, which allowed Medicare coverage of outpatient prescription drugs. This change provided much-needed prescription drug coverage for seniors and people living with disabilities, including many people living with mental illness. The current policy requires all Part D prescription drug plans and Medicare Advantage plans to include "all or substantially all" of the medications in 6 protected classes on their drug formularies.[33] Two of the 6 protected classes are antidepressants and antipsychotics. Congress included this policy to ensure that Medicare beneficiaries living with some of the most complex conditions, like mental illness, are not discriminated against. It also ensures that they have access to a range of treatment options that meet their individual needs.

In 2008, Congress passed the *Mental Health Parity and Addiction Equity Act* to eliminate historical disparities between insurance coverage of behavioral health treatment and medical treatment.[34] As a result of the legislation, large group health plans that offer mental health coverage must place this coverage equal to physical illness coverage. A few years later, the *Affordable Care Act* required small group and individual health plans sold in the insurance marketplaces to cover mental health services at a level comparable to that of medical services.[35] Moreover, parity rules were also applied in 2016 to Medicaid managed care plans, thus covering the bulk of low-income residents covered by the program.[36] Due to those laws, insurers cannot write policies that charge higher copays or deductibles for mental healthcare, nor may they impose lifetime or annual upper limits on the amount of mental health coverage.

Most recently, mental health has been affected in the wake of the coronavirus pandemic and subsequent changes in the daily lives of Americans. Stress and worries associated with contracting COVID-19, along with job loss, child-care arrangements, and loss of loved ones, are some of the many ways the pandemic might affect mental health.

As the Commonwealth Fund noted, numerous recent policy changes have facilitated Medicare beneficiaries' ability to access mental health services during the pandemic, including the implementation of coinsurance parity for outpatient mental healthcare, the closing of the "doughnut hole" for prescription drugs, and new financial mechanisms to support depression screening and mental health management.[37]

Bariatric surgery

As previously stated, the medical community's understanding of obesity has evolved over the past 20 years. Through 2005, Medicare reimbursed for bariatric procedures on a regional basis. A study performed that year of the complete, nationwide fee-for-service Medicare population undergoing bariatric surgery from 1997 through 2002 found that the early risk of post-surgical death in this population was higher than suggested by prior studies.[38] Additionally, the study found bariatric surgery performed at higher-volume facilities and by higher-volume surgeons led to improved outcomes in the older Medicare population. CMS responded by restricting coverage of bariatric surgery to hospitals designated as centers of excellence (COEs) by 2 major professional organizations.[39]

Because of its proven effectiveness, bariatric surgery is now widely covered by health insurance, including Medicare and Medicaid.

Since 2002, government researchers have noted that bariatric surgery has become safer due to a combination of factors that include, but are not limited to, increased use of the laparoscopic approach, achievement of the learning curve as bariatric surgeons have gained more experience, and more regimented fellowship training programs.[40] CMS subsequently lifted the COE requirement, broadening access to beneficiaries.

The rising prevalence of the obesity epidemic and its harmful effects on overall health have increased public support for obesity treatments. It is now widely accepted that diet and exercise do not always lead to long-term, significant obesity reduction.[41] Bariatric surgery can greatly improve a patient's chance of achieving long-term obesity reduction and reduce obesity-related comorbidities. Because of its proven effectiveness, bariatric surgery is now widely covered by health insurance, including Medicare and Medicaid.[42] As the obesity epidemic continues to worsen in the US, increasing coverage of these effective and life-saving surgeries is a valuable option for patients and providers.

SEROSTIM (somatropin [rDNA origin] for injection)

In the past, CMS has recognized its authority to interpret the statutory exclusion of certain uses of drugs and categories of drugs to permit coverage of medically accepted indications of drugs, even when other uses of those drugs might be excluded under the statute. For example, CMS interpreted the prohibition on agents for weight gain to permit Part D coverage of drugs used to treat AIDS wasting and cachexia. SEROSTIM is indicated for the treatment of HIV patients with wasting or cachexia "*to increase lean body mass and body weight* and improve physical endurance."[43] Despite this indication, CMS covers the drug under Part D, noting that "prescription drug products being used to treat AIDS wasting and cachexia *are not considered agents used for weight gain*"[22] but treat a medically accepted chronic disease. In this instance, CMS has clearly exercised its interpretative authority to cover an FDA-approved drug whose primary indication is "to increase lean body mass and body weight" and will not be considered an agent used for weight gain.

PART D IS AN OUTLIER; OTHER PAYERS COVER AOMs

Part D's coverage exclusion of AOMs makes it an outlier among payers across the healthcare system. While coverage varies, other payers recognize obesity as a chronic disease and the important role AOMs play in improving health, reducing disease, and increasing health equity. The following payers and payer groups do cover AOMs:

Federal Employees Health Benefits Program (FEHBP)

The FEHBP's annual call for benefit and rate proposals (call letter) to carriers sets forth the policy goals and initiatives for the program for the coming plan year. In its 2023 call letter, FEHBP reminded carriers of the Office of Personnel Management's (OPM) letter in 2014 clarifying "that it is not permissible to exclude weight loss drugs from FEHB coverage on the basis that obesity is a 'lifestyle' condition and not a medical one or that obesity treatment is 'cosmetic.'"[44,45]

OPM stated in the 2023 call that carriers "…are not allowed to exclude AOMs from coverage based on a benefit exclusion or a carve-out. FEHB carriers must have adequate coverage of FDA-approved AOMs on the formulary to meet patient needs and must include their exception process within their proposal." It is important to note that OPM's emphasis on coverage of AOMs was a key part of its response to President Biden's Executive Order on advancing racial equity and supporting underserved communities.

Department of Veterans Affairs (VA)

The VA's Clinician's Guide to Weight Management states that "Obesity is a chronic, complex disease requiring lifelong commitment to treatment and long-term maintenance."[46] It acknowledges that although lifestyle changes alone can result in weight loss for some, many patients who are overweight and obese need additional interventions for weight reduction.

The agency supports long-term use of weight loss medications in individuals who are obese or overweight, as it "can improve blood pressure, dyslipidemia, glycemia, markers of inflammation, and insulin resistance."

TRICARE

Since 2017, TRICARE has covered AOMs, changing a longstanding policy that excluded coverage for obesity. In 2018, the Defense Health Agency (DHA), which delivers the TRICARE health plan, added 4 generic weight loss medications to the Department of Defense's pharmacy formulary—phentermine, benzphetamine, diethylpropion, and phendimetrazine—and would cover several other medications, including SAXENDA, BELVIQ (since discontinued), and XENICAL, under certain circumstances.[47] In 2022, TRICARE included the first branded AOM on formulary

In supporting coverage for AOMs, the then-director for disease prevention, disease management, and population health policy and oversight in the office of the Assistant Secretary of Defense for Health Affairs supported coverage of the drugs, stating, "It's clear from the scientific literature, if you can reduce excess body fat in the individual, then you lower their risk of comorbid diseases related to excess body fat… this is the general literature, not specific to DHA or Health Affairs, but a 5% to 10% reduction in body weight can lower blood pressure [and] decrease insulin requirements for diabetics. It's in the best interest for preventing major chronic diseases."

Medicaid and commercial payers

Medicaid and commercial payer coverage for obesity treatments is varied across states and plans. However, as with other payers, Medicaid and commercial coverage of AOMs is more robust than Part D, providing beneficiaries with treatment options not available under Part D and making Part D's coverage exclusion even more of an outlier among payers.

It is clear that, with the exception of Part D, payers across the health system have evolved coverage policies of AOMs to reflect changes in our understanding of obesity as a disease and the role AOMs can play in improving health. Moreover, AOM coverage policies of the payers above help to improve health equity among their covered populations.

PART D MUST EVOLVE TO COVER AOMs

As demonstrated in this paper, coverage for valuable treatments can evolve when clinical evidence emerges to support medical necessity. And yet, while clinical evidence can shift the access paradigm for beneficiaries, it does not always adapt quickly enough. The Medicare Part D program can continue to ensure beneficiaries have access to the care they need that could ultimately benefit the health of the entire program.

Covers AOMs

- FEHBP
- VA
- TRICARE
- Medicaid
- Commercial plans

Does not cover AOMs

- Medicare Part D

AOMs do not treat "weight loss" or "weight gain" but provide chronic weight management.

Like any medical or scientific discipline, the evidence for obesity treatment continues to evolve. However, the Medicare Part D coverage policy for AOMs has stagnated; the coverage exclusion for weight loss drugs is obsolete in the face of new FDA-approved AOMs.

FDA-approved AOMs are used to treat obesity, a chronic and treatable disease state with multiple pathophysiological aspects. AOMs do not treat "weight loss" or "weight gain" but provide chronic weight management, with the goal of improving the medical condition of obesity, which itself has clinical markers that go beyond the issue of weight. As discussed above, our understanding of obesity and our ability to treat it has evolved significantly in the past 20 years.

Given the linkage of obesity with chronic, life-threatening diseases; the higher risk of adverse COVID-19 outcomes for those living with obesity; and the availability of multiple, safe, long-term anti-obesity treatments, it is long overdue that Medicare Part D recognize AOMs as important therapies that treat a severe, chronic disease—obesity. Further, AOMs help manage associated conditions, beyond weight loss alone, to reduce overall morbidity and mortality.

Legislative solution

Congress has an opportunity to amend the Social Security Act to clarify that FDA-approved AOMs are not "agents for weight loss" but rather clinically recommended treatments for "chronic weight management" that treat a chronic disease—obesity—and may therefore be covered under Part D.

Congress could also encourage CMS to use its interpretative authority to update its coverage policy on FDA-approved AOMs.

Regulatory solution

CMS does not require congressional action, but instead can use its interpretative authority to establish AOM coverage through revised Part D plan guidance and/or regulation. The agency must evolve its thinking and stop minimizing the obesity space by saying it is about weight loss.

Policy solutions for Part D to enable access to AOMs

Congress can act to make a technical change clarifying that AOMs are Part D-covered drugs

CMS can establish AOM coverage through revised Part D plan guidance and/or regulation

REFERENCES

1. Centers for Disease Control and Prevention. Adult obesity facts. 2020. Accessed Jul. 7, 2022. https://www.cdc.gov/obesity/data/adult.html#:~:text=Obesity%20affects%20some%20groups%20more%20than%20others&text=Non%2DHispanic%20blacks%20(49.6%25),%2DHispanic%20Asians%20(17.4%25)
2. Centers for Disease Control and Prevention. Prevalence of obesity among older adults in the United States, 2007–2010. Accessed Jul. 21, 2022. https://www.cdc.gov/nchs/products/databriefs/db106.htm#:~:text=About%2035%25%20of%20adults%20aged,and%20women%20(Figure%201)
3. Friedman J. The long road to leptin. *J Clin Invest*. 2016;126(12):4727-4734.
4. Tufts University. Leptin discovery. Sep. 17, 2019. Accessed Feb. 11, 2022. https://www.nutritionletter.tufts.edu/healthy-eating/leptin-discovery/
5. Centers for Disease Control and Prevention. The obesity epidemic – transcript. Accessed Jun. 28, 2020. https://www.cdc.gov/cdctv/diseaseandconditions/lifestyle/obesity-epidemic-transcript.html
6. Fryar CD, Carroll MD, Afful J. Prevalence of overweight, obesity, and severe obesity among adults aged 20 and over: United States, 1960–1962 through 2017–2018. NCHS Health E-Stats. Updated Jan. 29, 2021. Accessed Feb. 22, 2022. https://www.cdc.gov/nchs/data/hestat/obesity-adult-17-18/obesity-adult.htm
7. Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of obesity among adults and youth: United States, 2015-2016. National Center for Health Statistics data brief. 2017. Accessed Feb. 22, 2022. https://www.cdc.gov/nchs/data/databriefs/db288.pdf
8. Centers for Disease Control and Prevention. Body mass index and risk for COVID-19–related hospitalization, intensive care unit admission, invasive mechanical ventilation, and death — United States. Mar. 11, 2021. Accessed Jun. 29, 2022. https://www.cdc.gov/mmwr/volumes/70/wr/mm7010e4.htm?s_cid=mm7010e4_w
9. Xcenda. The impact of obesity on COVID-19 outcomes of hospitalizations and mortality. Jun. 2021. Accessed Jun. 29, 2022. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_covid_obesity_update_june2021.pdf
10. Centers for Disease Control and Prevention. Adult obesity causes & consequences. Mar. 22, 2021. Accessed Nov. 2, 2021. https://www.cdc.gov/obesity/adult/causes.html
11. Carroll KK. Obesity as a risk factor for certain types of cancer. *Lipids*. 1998;33(11):1055-1059. Accessed Jun. 29, 2022. https://doi.org/10.1007/s11745-998-0305-8
12. Luppino FS, de Wit LM, Bouvy PF, et al. Overweight, obesity, and depression: a systematic review and meta-analysis of longitudinal studies. *Arch Gen Psychiatry*. 2010;67(3):220-229.
13. Waters H, Graf M. America's obesity crisis: The health and economic costs of excess weight. Milken Institute. Sep. 22, 2020. Accessed Feb. 1, 2022. https://milkeninstitute.org/report/americas-obesity-crisis-health-and-economic-costs-excess-weight
14. Cawley J, Biener A, Meyerhoefer C, et al. Job absenteeism costs of obesity in the United States. *J Occup Environ Med*. Jul. 2021;63(7):565-573.
15. Centers for Disease Control and Prevention. Adult obesity facts. May 17, 2022. Accessed Jun. 29, 2022. https://www.cdc.gov/obesity/data/adult.html
16. Office of Minority Health. Obesity and Native Hawaiians/Pacific Islanders. Mar. 26, 2020. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=85
17. American Psychological Association. Ethnicity and health in America series: the issue of obesity among Asian-Americans and Pacific Islanders. 2015. Accessed Jun. 29, 2022. https://www.apa.org/pi/oema/resources/ethnicity-health/asian-american/obesity
18. National Heart, Lung, and Blood Institute. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. NIH publication 98-4083. Sep. 1998. Accessed Dec. 14, 2021. http://www.nhlbi.nih.gov/files/docs/guidelines/ob_gdlns.pdf
19. Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. *Endocr Pract*. Accessed Jun. 29, 2022. doi:10.4158/EP161365.GL
20. AACE, ACE. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. *Endocrine Pract*. 2016;22(Suppl 3):26.
21. Kushner RF, Ryan DH. Assessment and lifestyle management of patients with obesity: clinical recommendations from systematic reviews. *JAMA*. 2014;312(9):943-952.
22. CMS. Part D drugs/Part D excluded drugs. Apr. 19, 2006. Accessed Jun. 29, 2022. https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/partddrugspartdexcludeddrugs.pdf
23. Blanck HM, Khan LK, Serdula MK. Prescription weight loss pill use among Americans: patterns of pill use and lessons learned from the fen-phen market withdrawal. *Prev Med*. 2004;39(6):1243-1248.
24. Elliott WT, Chan J. Fenfluramine and dexfenfluramine withdrawn from market. Relias Media. Oct. 30, 1997. Accessed Jun. 29, 2022. https://www.reliasmedia.com/articles/36557-fenfluramine-and-dexfenfluramine-withdrawn-from-market
25. Onakpoya IJ, Heneghan CJ, Aronson JK. Post-marketing withdrawal of anti-obesity medicinal products because of adverse drug reactions: a systematic review. *BMC Med*. 2016;14(191):1-11.
26. Fishman AP. Aminorex to fen/phen: an epidemic foretold. *Circulation*. 1999;99(1):156-161.
27. FDA. Draft guidance for industry - developing products for weight management. Feb. 2007. Accessed Jun. 29, 2022. https://www.fda.gov/media/71252/download
28. Chao AM, Wadden TA, Berkowitz RI, Quigley K, Silvestry F. The risk of cardiovascular complications with current obesity drugs. *Expert Opin Drug Saf*. 2020 Sep;19(9):1095-1104.
29. Joo JK, Lee KS. Pharmacotherapy for obesity. *J Menopausal Med*. 2014;20(3):90-96.
30. Apovian CM, Aronne LJ, Bessesen DH, et al. Still, pharmacological management of obesity: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metabolism*. 2015;100(2):342-362.
31. Barry CL, Huskamp HA, Goldman HH. A political history of federal mental health and addiction insurance parity. *Milbank Q*. 2010;88(3):404-433.
32. American Psychological Association. Survey: Americans becoming more open about mental health. May 2019. Accessed Feb. 11, 2022. https://www.apa.org/news/press/releases/2019/05/mental-health-survey
33. CMS. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D drugs and formulary requirements. Jan. 19, 2016. Accessed Dec. 10, 2021. https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf
34. CMS. The Mental Health Parity and Addiction Equity Act (MHPAEA). Accessed Feb. 8, 2022. https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/mhpaea_factsheet
35. Office of the Assistant Secretary for Planning and Evaluation. Affordable Care Act expands mental health and substance use disorder benefits and federal parity protections for 62 million Americans. Feb. 19, 2013. Accessed Feb. 8, 2022. https://aspe.hhs.gov/reports/affordable-care-act-expands-mental-health-substance-use-disorder-benefits-federal-parity-protections-0
36. CMS. Medicaid fact sheet: Mental health and substance use disorder parity final rule for Medicaid and CHIP. Mar. 29, 2016. Accessed Feb. 8, 2022. https://www.medicaid.gov/sites/default/files/2019-12/fact-sheet-cms-2333-f.pdf
37. McGinty B. Medicare's mental health coverage: how COVID-19 highlights gaps and opportunities for improvement. The Commonwealth Fund. Jul. 9, 2020. Accessed Feb. 8, 2022. https://www.commonwealthfund.org/publications/issue-briefs/2020/jul/medicare-mental-health-coverage-covid-19-gaps-opportunities
38. Flum DR, Salem L, Broeckel Elrod JA, et al. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. *JAMA*. 2005;294(15):1903-1908.
39. CMS. Bariatric surgery for the treatment of morbid obesity. National coverage analysis. CAG-00250R. Feb. 21, 2006. Accessed Feb. 13, 2022. https://www.cms.gov/medicare-coverage-database/view/nca.aspx?NCAId=160
40. Agency for Healthcare Research and Quality. Data points #17: trends in bariatric surgery in Medicare beneficiaries. Nov. 30, 2012. Accessed Feb. 13, 2022. https://effectivehealthcare.ahrq.gov/products/bariatric-surgery-trends/research
41. Geier E. Bariatric surgery and the complicated reality of weight loss. Columbia University Irving Medical Center. Jan. 19, 2022. Accessed Feb. 7, 2022. https://www.cuimc.columbia.edu/news/complicated-reality-weight-gain-weight-loss-and-weight-stigma
42. CMS. Bariatric surgery. Accessed Feb. 7, 2022. https://www.medicare.gov/coverage/bariatric-surgery
43. EMD Serono. Serostim prescribing information. Jun. 2019. Accessed Jul. 7, 2022. https://www.emdserono.com/us-en/pi/serostim-pi.pdf
44. Office of Personnel Management. Federal Employees Health Benefits Program call letter. Feb. 17, 2022. Accessed Jul. 7, 2022. https://www.opm.gov/healthcare-insurance/healthcare/carriers/2022/2022-03.pdf
45. Office of Personnel Management. Supplemental guidance: management of obesity in adults. Mar. 20, 2014. Accessed Jul. 7, 2022. https://www.opm.gov/healthcare-insurance/healthcare/carriers/2014/2014-04.pdf
46. Department of Veterans Affairs. A VA clinician's guide to weight management. Jul. 2019. Accessed Jul. 7, 2022. https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/WM_Provider_WeightManagementProviderGuide_IB101158.pdf
47. Military Officers Association of America. New weight loss drugs available to servicemembers, TRICARE beneficiaries. Nov. 6, 2018. Accessed Jul. 7, 2022. https://www.moaa.org/content/publications-and-media/news-articles/2018-news-articles/new-weight-loss-drugs-available-to-servicemembers,-tricare-beneficiaries/
48. Chena F, Sua W, Ramasamyb A. Ten-year Medicare budget impact of increased coverage for anti-obesity intervention. *J Med Econ*. 2019;22(10):1096-1104.