

The American Medical Association (AMA) recognizes obesity as a progressive, chronic disease with multiple pathophysiological aspects.¹ Individuals suffering from chronic diseases often suffer from mental and emotional symptoms in addition to their physical ones. One study found that patients with chronic diseases like obesity were found to have two to three times the rate of major depression compared to age and gender matched patients who do not suffer from chronic diseases.²

For patients suffering from obesity, several comprehensive reviews have suggested that between 20 and 60% of people with obesity and extreme obesity suffer from psychiatric illness.³

These patients were more likely to suffer from bipolar disease, schizophrenia, depression, anxiety disorders, eating disorders, and personality disorders.⁴ Other studies have found that as the number and severity of comorbid conditions increases, quality of life decreases, making obesity — which is often associated with other chronic diseases — a significant burden on the quality of life and the mental health of a patient.⁵

For older adults, high rates of obesity leave them vulnerable to psychological disorders. Between 2017 and 2018, the National Center for Health Statistics found that almost half of Americans over 60 suffered from obesity.⁷ Already, mental health concerns are common for older adults, with 20% of people 55 years or older experiencing some type of mental health concern.⁸ These rates can be further compounded by the onset of obesity and other chronic conditions. Studies have shown that the onset or exacerbation of chronic health conditions which often coincide with aging, may increase the risk of depression.⁹

"Persons with extreme obesity ... are almost five times more likely to have experienced an episode of major depression in the past year as compared with those of average weight."⁶

How Treatment Can Help

Comprehensive treatment options to treat and manage the disease of obesity include both intensive lifestyle interventions and pharmacotherapy. In recent years, advances in pharmacotherapy have made treating obesity and its many comorbidities increasingly possible. Full access to the standard of obesity care will also help reduce risk of diabetes, heart disease, osteoarthritis, and a broad spectrum of mental health conditions.¹⁰ Anti-obesity medications (AOMs) can significantly reduce a patient's obesity. Older versions of AOMs increased average weight-loss from 5-7% to 15-20% and newer versions are showing well over 20% weight-loss.¹¹

HECCD Health Equily Coalition for Chronic Disease

Obesity and mental health conditions like depression have a bidirectional relationship - longitudinal studies have found that depression predicts the onset of obesity, and that obesity predicts the onset of depression.¹² Treating one will not entirely reduce the other; however, treating a patient's obesity can increase their ability to participate in activities which can further alleviate the symptoms of mental health distress such as exercising and socializing with friends and family.¹³

"Weight loss also is associated with significant improvements in psychosocial status. Most psychosocial characteristics (including symptoms of depression and anxiety, health- and weight-related quality of life, self-esteem, body image, and sexual functioning) improve with weight loss."

- David Sarwer and Heather Polonsky¹⁴

Therefore, best practices should include screening patients with obesity for mental health issues and vice versa at the onset of treatment and during weight loss in order to facilitate appropriate and comprehensive treatment.¹⁵

Barriers to Access

Obesity and mental health patients both experience significant barriers to access. The US Substance Abuse and Mental Health Services Administration (SAMHSA) found that of Americans 50 and older who sought treatment, 35% perceived an unmet need in care.¹⁶ Several barriers including internal attitudes, not knowing where to go for services, comorbid medical conditions, and other extrinsic barriers such as cost and access to transportation all prevent older adults from accessing mental health services.¹⁷ Patients struggling with excess weight may also avoid treatment for mental health disorders because certain antipsychotics, antidepressants, and mood stabilizers can cause weight gain as a side effect.¹⁸

We see similar gaps and barriers in obesity care. Currently, only 2% of U.S. adults eligible for obesity pharmacotherapy receive it.¹⁹ Comparably, many obesity patients report similar barriers preventing them from seeking treatment, including access to care, cost, and internalized bias.²⁰ Seniors may often hesitate to seek care for both conditions, thinking that anxiety, depression, and other psychiatric conditions as well as gaining weight are a part of aging.²² Stigma faced internally and externally makes individuals even less likely to seek out care.

"It is very challenging to live with obesity in our modern world ... a lot of patients start internalizing [obesity] bias."

Dr. Carolynn Francavilla²¹

HECCD Health Equity Cealition for Chronic Disease

One of the most significant barriers for older adults is Medicare's denial of coverage of AOMs. Medicare is the outlier in terms of coverage, while a number of other federal programs, including Medicaid, and most private insurers provide coverage.^{23, 24, 25} This leaves older adults especially vulnerable, causing some to lose access to their medication once they turn 65.

Paths to Provide AOM Coverage to Medicare Beneficiaries

We applaud CMS's efforts to increase behavioral therapy options for those suffering from obesity.²⁶ These will help hundreds of older adults make lifestyle changes necessary to improve their health; however, it is not enough. Medicare must cover AOMs in order to ensure equitable access to treatment for older adults.

Legislative Path

Lawmakers could respond to the medical advancements over the past 20 years and amend the Social Security Act to clarify that FDA-approved AOMs that treat the chronic disease of obesity are medically necessary treatments for "chronic weight management" and therefore eligible for coverage under Medicare Part D. Since 2012, a large number of bipartisan members of Congress have cosponsored the bipartisan *Treat and Reduce Obesity Act* (TROA) (H.R.4818/S.2407) that would make this change.²⁷

CMS Has the Regulatory Authority to Act

CMS has the authority to provide coverage for FDA-approved AOMs in order to appropriately address obesity and the myriad of other diseases linked to it. Section 1927(d)(2)(A) of the Social Security Act does not forbid coverage of AOMs; instead, it clearly states that the Secretary "may [exclude] from coverage or otherwise restrict...agents when used for anorexia, weight loss, or weight gain."²⁸ By using the term "may" instead of "shall", Congress unambiguously intended to authorize exclusion of such drugs, but did not mandate their exclusion.²⁹ Instead, the permissive language of "may" grants the

Federal Payers Which Cover AOMs

<u> His</u>

Federal Employees Health Benefits Program (FEHBP)

In 2023, OPM stated that FEHBP carriers must have adequate coverage of FDA-approved AOMs as part of its response to President Biden's Executive Order on advancing racial equity.

U.S. Department of Veterans Affairs Department of Veterans Affairs (VA)

The agency cites the myriad of health benefits associated with weight loss medications in individuals who are obese or overweight, and supports their long-term use.



In 2018, the Defense Health Agency (DHA) added generic weight loss medications to the Department of Defense's pharmacy formulary and in 2022,



Indian Health Service

TRICARE included the first branded AOMs.

In October 2023, the Indian Health Service announced that after a drug class review, the agency would expand the use of semaglutide to include treatment for obesity.

Medicaid Medicaid and Commercial Payers

While varied across states and plans, Medicaid and commercial payer coverage of AOMs is more robust than Part D.

Medicare Does Not Cover AOMs



Medicare Part D

Medicare Part D has remained unchanged since 2003, before obesity was recognized as a disease and AOMs were in their infancy.

HECCD Health Equity Coalition for Chronic Disease

Secretary the authority to provide coverage of AOMs to address the disease of obesity. An example of such Secretarial discretion is CMS' 1999 decision to cover SEROSTIM,[®] even though this drug is indicated for weight gain. CMS used its authority to interpret the statute and deem coverage appropriate because the treatment was used to combat wasting in patients with AIDS by promoting weight gain, thereby improving outcomes and reducing morbidity and mortality for those patients.³⁰ That same rationale should apply to FDA-approved AOMs which address a patient's weight while also contributing to improvement of a range of comorbidities, symptoms, and health risks associated with the disease of obesity.³¹

CMS's policy to exclude AOMs from Part D coverage was adopted in the preamble to a 2008 Part D final rule and can therefore be reversed through similar guidance.³² CMS could re-evaluate the statutory exclusion and provide revised guidance that reflects modern clinical understanding and does not preclude Part D coverage of AOMs–doing so would identify obesity as a complex chronic disease and recognize that AOMS are agents targeting obesity, rather than solely evaluating each in terms of their effect on weight. This action would build upon the 2022 Labor Health and Human Services Appropriations report language which reminded CMS that "access to obesity treatment, including anti-obesity medication, is an important part of the Administration's effort to combat chronic disease, reduce health care costs, and improve care" and "encourage[d] CMS to ensure access to treatments for obesity in Part D by clarifying [in the regulation's prohibition of coverage] that an agent [used] for 'weight loss' does not include an FDA-approved anti-obesity agent as classified by the United States Pharmacopeia Drug Classification system."³³ HECCD agrees that CMS should recognize the crucial role that AOMs play in the context of treating obesity and differentiate between general "weight loss" drugs and FDA-approved treatments for chronic weight management or obesity.

Maintaining a policy that prevents Medicare patients from accessing these FDA-approved drugs is: 1) inconsistent with the standard of obesity care; 2) fails to utilize effective medicines to address comorbidities; 3) increases avoidable costs to the federal government; and 4) is detrimental to the health of seniors.





- AMA https://policysearch.ama-assn.org/policyfinder/detail/obesity?uri=%2FAMADoc%2FHOD.xml-0-3858.xml
- The prevalence of co-morbid depression in adults with Type 2 diabetes: a systematic review and meta-analysis, https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1464-5491.2006.01943.x 2.
- 3. The Psychosocial Burden of Obesity, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6052856/#R1
- Obesity as pleiotropic risk state for metabolic and mental health throughout life, https://www.nature.com/articles/s41398-023-02447-w 4. 5.
- Associations between chronic disease, age and physical and mental health status, https://www.phac-aspc.gc.ca/publicat/hpcdp-pspmc/29-3/pdf/cdic29-3-3-eng.pdf The Psychosocial Burden of Obesity, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6052856/#R1
- 6.
- Prevalence of Obesity and Severe Obesity Among Adults: United States, 2017–2018, https://www.cdc.gov/nchs/products/databriefs/db360.htm The State of Mental Health and Aging in American, pp. 2, https://www.cdc.gov/aging/pdf/mental_health.pdf 8.
- 9
- The State of Mental Health and Aging in American, <u>https://www.cdc.gov/aging/pdf/mental_health.pdf</u> The Relative Value of Anti-Obesity Medications Compared to Similar Therapies, <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9886521/</u> 10.
- Medicare Part D Coverage of Anti-obesity Medications Challenges and Uncertainty Ahead, pp.2 https://www.nejm.org/doi/full/10.1056/NEJMp2300516 11.
- 12. Overweight, obesity, and depression: A systematic review and meta-analysis of longitudinal studies. Arch Gen Psychiatry 67(3):220–9. 2010.; Roger S. McIntyre, MD, professor of psychiatry and pharmacology at the University of Toronto retrieved from
- https://www.everydayhealth.com/obesity/does-being-overweight-make-depression-more-likely-even-if-it-doesnt-negatively-impact-metabolic-health/
- The Psychosocial Burden of Obesity, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6052856/#R1 13.
- The Psychosocial Burden of Obesity, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6052856/#R1 14. The Psychosocial Burden of Obesity, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6052856/#R1 15.
- SAMHSA, Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health, pp. 62, 16.
- https://www.samhsa.gov/data/sites/default/files/reports/rpt29393/2019NSDUHFFRPDFWHTML/2019NSDUHFFR1PDFW090120.pdf
- 17. A Systematic Review of Barriers Faced by Older Adults in Seeking and Accessing Mental Health Care, https://pubmed.ncbi.nlm.nih.gov/32936584/
- National Council on Aging, https://www.ncoa.org/article/how-excess-weight-impacts-our-mental-and-emotional-health 18.
- 19. Velazquez A, Apovian CM Updates on obesity pharmacotherapy. Ann N Y Acad Sci 2018 20. Barriers to Obesity Management: Patient and Physician Factors https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7789016/
- 21. Mental Health in Women with Obesity: An Expert Interview, https://www.patientcareonline.com/view/mental-health-in-women-with-obesity-an-expert-interview
- Seniors with Anxiety Frequently Don't get Help. Here's Why, https://kffhealthnews.org/news/article/seniors-anxiety-disorder-screening-mental-health-navigating-aging/ 22.
- VA Clinician's Guide to Weight Management (2019), pp. 18. 23.
- https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/WM_Provider_WeightManagementProviderGuide_IB101158.pdf New Weight Loss Drugs Available to Servicemembers, TRICARE Beneficiaries 24. https://www.moaa.org/content/publications-and-media/news-articles/2018-news-articles/new-weight-loss-drugs-available-to-servicemembers_tricare-beneficiaries/
- 25 1FEHB Program Call Letter, Letter Number 2022-03, pp 10. https://www.opm.gov/healthcare-insurance/healthcare/carriers/2022/2022-03.pdf
- 26
- CMS, Intensive Behavioral Therapy for Obesity, <u>https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=353</u> S.3699 Treat and Reduce Obesity Act of 2012. <u>https://www.congress.gov/112/bills/s3699/BILLS-112s3699is.pdf</u> 27.
- 28. Social Security Act, § 1860D-2(e)(2)(A) (cross referencing Social Security Act, § 1927(d)(2)(A), which also uses the discretionary language "may be excluded from coverage" at the option of the applicable State Medicaid plan).
- 29. The Supreme Court has recognized that the word "may", when used in a statute, "usually implies some degree of discretion" unless it is defeated by "indications of legislative intent to the contrary or by obvious inferences from the structure and purpose of the statute." Citizens & Southern Nat. Bank v. Bougas, 434 U.S. 35, 38, 54 L. Ed. 2d 218, 98 S. Ct. 88 (1977)
- 30. 73 Fed. Reg. at 20490.
- 31 Guidance for Industry Developing Products for Weight Management, pp. 7 https://www.fda.gov/media/71252/download
- National Council on Aging comment letter to 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program proposed rule (CMS-4192-P), 32. ://acrobat.adobe.com/link/track?uri=urn%3Aaaid%3Ascds%3AUS%3Aa4babe82-dc7d-4883-8109-3013a16e26de&vie
- 33. FY 2023 House Labor, Health and Human Services Report, pp 187. https://docs.house.gov/meetings/AP/AP00/20220630/114968/HMKP-117-AP00-20220630-SD003.PDE