HECCD

Health Equity Coalition for Chronic Disease

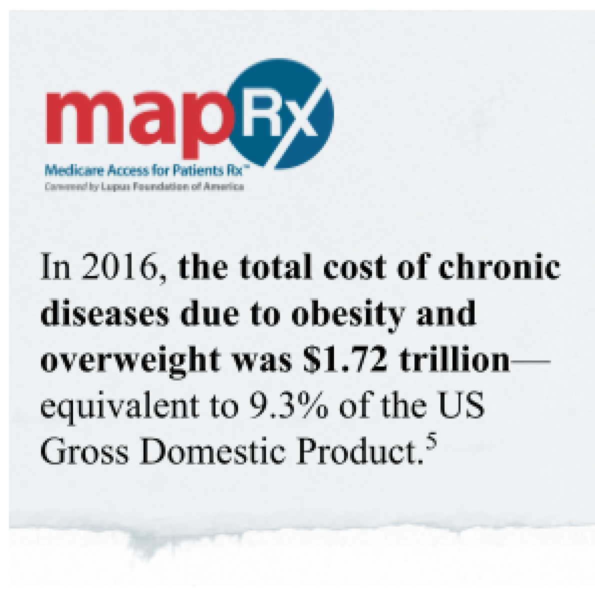
Access to Anti-Obesity Medications: Ensuring the Full Continuum of Care for People Living with Obesity

APRIL 2023

Background

More than two in five American adults live with obesity — and almost 50% of Black and Latino adults.[1] Obesity is a serious, progressive, chronic disease. It is also a major risk factor and the greatest contributor to a broad range of chronic conditions such as cardiovascular disease, type 2 diabetes, and hypertension; 47.1% of the total cost of chronic diseases nationwide can be linked to the disease of obesity.[2] **Obesity is an epidemic,[3] but it doesn't have to be. It is a preventable and treatable disease**. In 2013, the American Medical Association recognized obesity as a disease with multiple pathophysiological aspects requiring a full range of interventions for effective treatment. While there are numerous public and private efforts to prevent obesity, treatment of obesity continues to lag, often due to stigma and prejudice against people living with the disease. A focused effort is needed to truly change the trajectory of the disease.

Although lifestyle and behavioral therapy remains a cornerstone of treatment for this disease, the use of anti-obesity medications (AOMs), along with bariatric surgery, produce greater and more sustained weight loss in treatment-approved populations as compared with lifestyle modifications alone.[4] This paper focuses on the considerable barriers to access to AOMs which range from the lack of proper training of medical professionals to the denial of insurance coverage for these life-saving medical interventions.



The Health Equity Coalition for Chronic Disease (HECCD) is an advocacy coalition established to eliminate barriers to quality healthcare, particularly focusing on chronic disease by lifting the voices in communities of color and marginalized communities. HECCD is co-chaired by the Black Women's Health Imperative, the National Hispanic Medical Association, and the National Minority Quality Forum. Beginning with a focus on policies that impact obesity, HECCD is committed to disease prevention and management and equitable health outcomes.

1. Adult Obesity Facts https://www.cdc.gov/obesity/data/adult.html
2. America's Obesity Crisis: The Health and Economic Costs of Excess Weight, pp 1,16. https://milkeninstitute.org/sites/default/files/reports-pdf/Mi-Americas-Obesity-Crisis-WEB.pd
3. The Obesity Epidemic - transcript https://www.cdc.gov/cdctv/diseaseandconditions/lifestyle/obesity-epidemic-transcript.html
4. A Review of Current Guidelines for the Treatment of Obesity. https://www.ajmc.com/view/review-of-current-guidelines-for-the-treatment-of-obesity
5. Clinical Evidence Driving Patient Access in Medicare Part D, pp 2. https://maprx.info/wp-content/uploads/2022/09/MAPRx-Clinical-Evidence-Driving-Patient-Access-Obesity.pdf

AOMs have been improving dramatically. First generation AOMs resulted in patients losing 5% to 12% more weight than those whose obesity treatment protocol was confined to lifestyle changes;[6] new generation AOMs have produced weight loss of 15% to more than 20% in clinical trials.[7] AOMs also successfully sustain obesity reduction.[8]

However, these impactful tools to aid chronic weight management are not accessible to most Americans[9], including Medicare beneficiaries; this leaves millions of people exposed to costly chronic illnesses and premature death due to lack of treatment.[10] The time to start changing the lack of insurance coverage of AOMs is now, starting with the vulnerable population covered by Medicare.

CONVERSATIONS ON HEALTH CARE

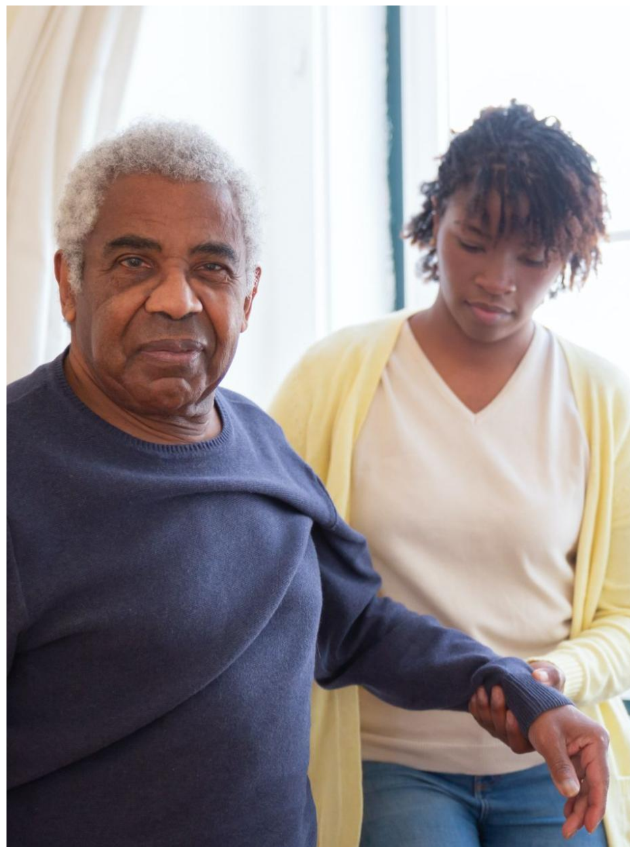
"[The use of AOMs] is going to be the beginning of a revolution in the way that we control weight."[11]

Dr. Robert Califf
FDA Commissioner

6. Clinical Evidence Driving Patient Access in Medicare Part D, pp 2. https://maprx.info/wp-content/uploads/2022/09/MAPRx-Clinical-Evidence-Driving-Patient-Access-Obesity.pdf
7. Medicare Part D Coverage of Anti-obesity Medications — Challenges and Uncertainty Ahead https://www.nejm.org/doi/full/10.1056/NEJMp2300516
8. Clinical Evidence Driving Patient Access in Medicare Part D, pp 2. https://maprx.info/wp-content/uploads/2022/09/MAPRx-Clinical-Evidence-Driving-Patient-Access-Obesity.pdf
9. Weight-loss drugs are a milestone for the obese but expose health inequity. https://www.washingtonpost.com/health/2022/12/19/ozempic-mounjaro-wegovy-weight-loss-drugs/
10. OCAN sign-on letter, 2021. https://acrobat.adobe.com/link/track?uri=urn:aaid:scds:US:d4ccb884-7db8-3bcf-afc1-29a44b8cf041, 3
11. FDA Commissioner Dr. Robert Califf Discusses the Top News Stories, 10:20. https://www.chcradio.com/episode/Robert-Califf/667

Medicare is the Outlier among Federal Payers

Food and Drug Administration (FDA) approved AOMs are a covered treatment option for individuals who receive health benefits from the Veterans Health Administration,[12] TRICARE since 2017,[13] and all Federal Health Employee Benefit (FEHB) plans since early 2022.[14] As recently as January 2023, the Office of Personnel Management reiterated that "FEHB carriers must have adequate coverage of FDA-approved anti-obesity medications on the formulary to meet patient needs."[15] In more than a third of US states, Medicaid fee-for-service or managed care now covers AOMs. Similarly, State Employee Health Benefit plans in over half the states have updated coverage policies to ensure access to AOMs.



Federal Payers Which Cover AOMs

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.

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.

TRICARE

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

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.

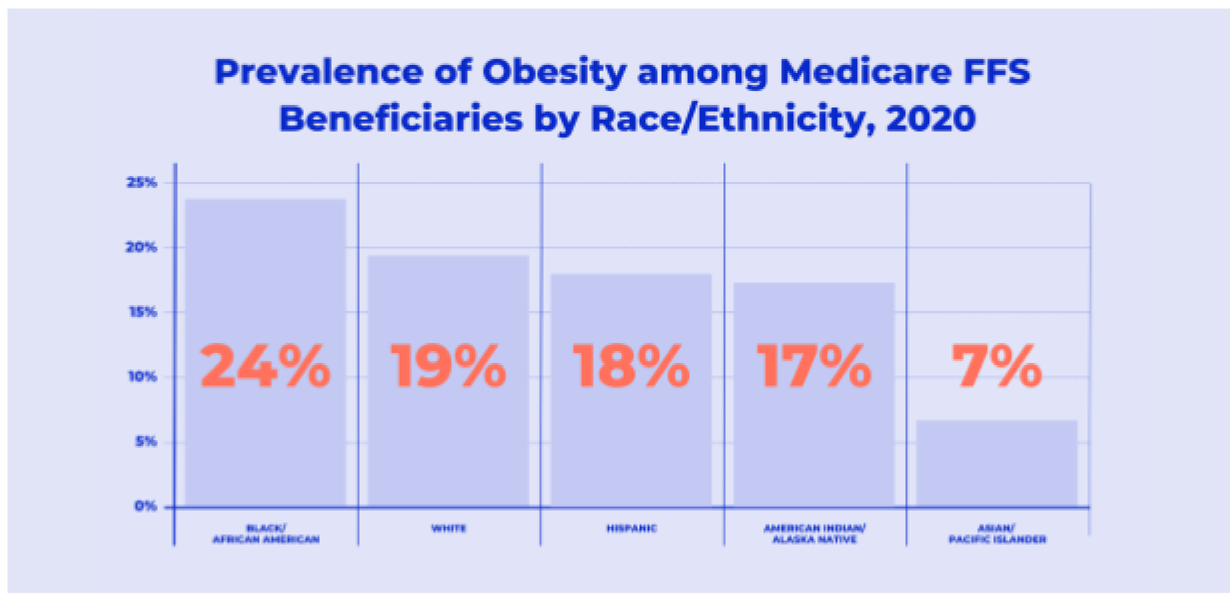
12. VA Clinician's Guide to Weight Management (2019), pp. 18. https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/WM_Provider_WeightManagementProviderGuide_IB101158.pdf
13. New Weight Loss Drugs Available to Servicemembers, TRICARE Beneficiaries https://www.moaa.org/content/publications-and-media/news-articles/2018-news-articles/new-weight-loss-drugs-available-to-servicemembers,-tricare-beneficiaries/
14. FEHB Program Call Letter, Letter Number 2022-03, pp 10. https://www.opm.gov/healthcare-insurance/healthcare/carriers/2022/2022-03.pdf
15. FEHB Program Carrier Letter, Prevention and Treatment of Obesity, Carrier letter 2023-01, pp 4. https://www.opm.gov/healthcare-insurance/healthcare/carriers/2023/2023-01.pdf

Medicare's Lack of Coverage of AOMs Must Change

Obesity prevalence among older Americans is increasing at an alarming rate. In a single generation—between 1988-1994 and 2015-2018—the share of U.S. adults ages 65 and older with obesity nearly doubled, increasing from 22% to 40%.[16] Within the Medicare population, obesity impacts communities of color most severely. The seriousness of that fact must drive action.

CMS has expressed the importance of treating the disease of obesity, the related comorbidities, and addressing stark health disparities; however, Medicare Part D does not cover FDA-approved AOMs. This CMS policy is divorced from the standard of care AND is based on an outdated interpretation of a general exclusion for "weight-loss" medications put in place over 15 years ago. In contrast, bariatric surgery is covered under Medicare Part B. Clearly, these policies are not in sync because CMS' coverage of bariatric surgery is conditioned on the failure of other interventions, including pharmacotherapy.

The American Medical Association updated its policy in 2022 with a comprehensive plan to address obesity and break down barriers to care which included working "to remove out-of-date restrictions at the state and federal level prohibiting healthcare providers from providing the current standard of care to patients affected by obesity."[17] Despite this mounting pressure, CMS has yet to update its coverage standard to keep pace with the science and best practice.



16. Clinical Evidence Driving Patient Access in Medicare Part D, pp 1. https://maprx.info/wp-content/uploads/2022/09/MAPRx-Clinical-Evidence-Driving-Patient-Access-Obesity.pdf
17. Addressing Adult and Pediatric Obesity D-440.954. https://policysearch.ama-assn.org/policyfinder/detail/obesity?uri=%2FAMADoc%2Fdirectives.xml-0-1498.xml
18. Treatments for Obesity Management: Final Policy Recommendations, pp. 1. https://icer.org/wp-content/uploads/2022/10/ICER_Obesity_Policy_Recommendations_102022.pdf

Paths to Provide AOM Coverage to Medicare Beneficiaries

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 legislation that would make this change.[19]

REGULATORY PATH

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.[20] CMS could use its interpretive authority to re-examine the exclusion of AOMs and permit coverage of these FDA-approved medicines to treat the chronic disease of obesity, while continuing to exclude therapies for weight loss. 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 for 'weight loss' does not include an FDA-approved anti-obesity agent as classified by the United States Pharmacopeia Drug Classification system."[21]

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 Secretary "may [exclude] from coverage or otherwise restrict…agents when used for anorexia, weight loss, or weight gain."[22] By using the term "may" instead of "shall", Congress unambiguously intended to authorize exclusion of such drugs, but did not mandate their exclusion.[23] Instead, the permissive language of "may" grants the 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 promoted weight gain and was used to combat wasting in patients with AIDS, thereby improving outcomes and reducing morbidity and mortality for those patients.[24] 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.[25] CMS should recognize the

19. S.3699 - Treat and Reduce Obesity Act of 2012. https://www.congress.gov/112/bills/s3699/BILLS-112s3699is.pdf
20. 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) https://acrobat.adobe.com/link/track?uri=urn%3Aaaid%3Ascds%3AUS%3Aa4babe82-dc7d-4883-8109-3013a16e26de&viewer%21megaVerb=group-discover
21. 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.PDF
22. 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).
23. 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).
24. 73 Fed. Reg. at 20490.
25. Guidance for Industry Developing Products for Weight Management, pp. 7 https://www.fda.gov/media/71252/download

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.

> "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."[26]

Standard of Care = Access to Anti-Obesity Medications

FDA-approved AOMs are now a standard-of-care tool used to treat the chronic disease of obesity and improve related comorbidities. Federal policy must change; Medicare coverage of AOMs would offer life-changing treatment for beneficiaries and lead the way for all insurers to provide access to these critical medications.

26. Clinical Evidence Driving Patient Access in Medicare Part D, pp 2.
https://maprx.info/wp-content/uploads/2022/09/MAPRx-Clinical-Evidence-Driving-Patient-Access-Obesity.pdf