OBESITY CARE
ADVOCACY NETWORK

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The Obesity Care Advocacy Network's Policy Priorities for Ensuring Patient Access to Comprehensive Obesity Care:

Blueprint for Action for the Biden-Harris Administration

The Obesity Care Advocacy Network (OCAN) is a diverse group of organizations that have come together with the purpose of changing how we perceive and approach the obesity epidemic in this nation. As part of this effort, we strive to prevent disease progression, improve access to evidence-based treatments for obesity, improve standards of quality care in obesity management, eliminate weight bias, and foster innovation in future obesity treatments.

In less than 20 years, the rate of obesity in the United States has gone up almost 50%, with no less than 42% of Americans currently affected by obesity -- with severe obesity nearly doubling over the same period of time. The pervasiveness of obesity and our failure to adequately prevent and treat it has resulted in an increased severity in COVID-19 infections, with obesity being the second leading indicator after older age of severe COVID-19 outcomes.

Despite these facts, there is a bias and stigma that pervades the obesity conversation, with terrible results for those who suffer from this disease. Many policymakers continue to view obesity as a lifestyle choice or personal failing. Others acknowledge that obesity is a chronic and complex disease, but they believe that all that's needed is more robust prevention. These negative, muddled perceptions and attitudes have resulted in health insurance plans taking vastly different approaches in determining what and how obesity treatment services are covered for their members. It's time for a paradigm change and for all public and private health plans to adopt a comprehensive benefit approach toward treating obesity.

OCAN's Blueprint for Action stresses the immediate need for coverage of obesity care during the COVID-19 public health emergency; and highlights administrative action that could be taken in the first 100 days of the Biden-Harris Administration to ensure obesity treatment parity for all Americans who are affected by this complex and chronic disease.

Evidence-Based Obesity Treatment Avenues

Numerous evidence-based treatments (intensive behavioral therapy, anti-obesity medications and bariatric surgery) exist for people with obesity that mitigate the impacts of the disease and improve health outcomes. Despite this fact, the present landscape of obesity care coverage remains piecemeal, inadequate and laden with arbitrary hurdles to comprehensive care. The coming Biden-Harris Administration must move to eliminate these unscientific barriers to care – both for the long term and for the immediate health of those affected by obesity.

The Convergence of Three Pandemics: COVID-19, Obesity and Racial Inequity

COVID-19 has made it clear that the obesity epidemic is an immediate and deadly threat to our country. Since the pandemic began, dozens of studies have reported that many of the sickest COVID-19 patients have been people with obesity. That link has come into sharper focus as large new population studies have cemented the association and demonstrated that even people with overweight are at higher risk.

For example, in the first meta-analysis of its kind, published on August 26th an international team of researchers found that people with obesity who contracted COVID-19 were 113% more likely than people of healthy weight to be hospitalized, 74% more likely to be admitted to an ICU, and 48% more likely to die.[1] These tragic numbers are being driven by the major biological factors associated with obesity -- including impaired immunity, chronic inflammation, and blood that's prone to clot, all of which can worsen COVID-19.

The COVID-19 pandemic has also magnified the health inequities experienced by racial and ethnic minority communities. Data show that the same communities disproportionately impacted by COVID-19 also experience high rates of obesity and diabetes. Among African American adults, 48% have obesity and 13% have diabetes. Meanwhile, people of color and low-income households are disproportionately living in communities with comparably less access to health care, healthy food, and opportunities to be active. Further complicating the risks, these individuals are more likely to hold "frontline" jobs that increase their risk of exposure to COVID-19.

Opportunities for Administrative Action

Medicare Coverage Policy

The obesity community has worked for a nearly a decade with Congress to pass the Treat and Reduce Obesity Act (TROA) to enhance Medicare beneficiaries' access to IBT and by allowing Medicare Part D to cover FDA-approved anti-obesity medications (AOMs). The genesis for TROA resulted partly from current regulations, which do not permit coverage for drugs that treat obesity under Part D -- on the grounds that such drugs are excluded under the Medicare statute as agents "used for anorexia, weight loss, or weight gain."[2]

190 bipartisan Members of Congress are currently on record supporting the Treat and Reduce Obesity Act - a strong signal to CMS that nearly half the Congress believe that CMS should apply its administrative authority and precedent to interpret the statute to include weight management treatments.

In fact, CMS' current interpretation runs counter to FDA Guidance, as well as Congressional intent which wanted to prohibit cosmetic weight loss products. The FDA distinguishes drugs used for weight *management* from drugs used for weight *loss*. FDA explains that weight management incorporates weight loss and weight maintenance but also includes the "goal of reduced morbidity and mortality through quantifiable improvements in biomarkers such as blood pressure, lipids, and HbA1c."[3] Further, the modern generation of AOMs have profiles that are safe and effective for long-term therapy compared to some of the older generation short-term therapies.

CMS has used its administrative authority in the past to broadly interpret the statutory language surrounding the Part D exclusion for weight management. The agency did so when it allowed Medicare Part D coverage of Serostim®, for the treatment of HIV patients with wasting or cachexia "to increase lean body mass and body weight and improve physical endurance." Despite this, CMS currently provides coverage under Part D for prescription drug products that otherwise satisfy the definition of a Part D drug, when used for AIDS wasting and cachexia due to a chronic disease, if these conditions are medically-accepted indications as defined by section 1927(k)(6) of the Act for the particular Part D drug.

OCAN believes that CMS coverage of Serostim® suggest that the agency could allow coverage of AOMs under Part D. There are many similarities (albeit inverse) in indications and treated-disease definitions across anti-obesity medications and Serostim®. While one promotes weight management (or weight loss) to treat obesity, the other promotes weight gain to treat AIDS wasting/cachexia. These two product types seemingly represent mirror images of treatments that suggest CMS could (and should) readily interpret the statutory exclusion provision consistently across both drugs.

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[1] August 26, 2020 Obesity Reviews: Individuals with obesity and COVID-19: A global perspective on the epidemiology and biological relationships

[2] *See* SSA § 1860D-2(e)(2); SSA§1927(d)(2).

[3] FDA, *Draft Guidance for Industry: Developing Products for Weight Management*, February 2007, at 1.

We are also concerned about the outdated interpretation taken by CMS of the U.S. Preventive Services Task Force (USPSTF) recommendation related to adult obesity in developing its Intensive Behavioral Therapy for Obesity coverage determination.[4,5] Specifically, we question the decisions by CMS to continue to only cover services provided in a primary care setting and only allow primary care providers to bill for these services.

Recommendations from the USPSTF for IBT for obesity[6,7] are based on systematic reviews of interventions conducted primarily by providers other than primary care providers and in a variety of settings beyond a primary care office. In fact, the 2018 recommendation noted, "few interventions [included in the systematic review] included a primary care clinician as the primary interventionist over 3 to 12 months of individual counseling. In the trials not involving a primary care clinician, the interventionists were highly diverse and included behavioral therapists, psychologists, registered dietitians, exercise physiologists, lifestyle coaches, and other staff."

Since 2012, USPSTF has specifically recommended referral out of the primary care setting for IBT as an evidence-based treatment option and yet CMS requires patients with obesity to pay entirely out of pocket for IBT provided in this manner. CMS has not reconsidered the National Coverage Determination for IBT for obesity in nearly a decade, leaving the Medicare benefit woefully behind the science. We urge the administration to begin the process of revising this coverage determination to provide adequate care for patients with obesity.

OCAN applauds CMS for taking a number of actions during this pandemic to ensure that patients continue to have access to care through increasing access to telehealth and enhancing state flexibility under Medicaid. We believe the Biden-Harris Administration should update Medicare's coverage policies surrounding the aforementioned obesity treatment avenues as these services are just as critical.

HHS Guidance Declaring Obesity a Chronic Disease

While the ACA has established numerous patient protections and essential health benefits (EHB), millions of Americans affected by obesity continue to be denied access to evidence-based treatment. Despite broad EHB categories for hospital services, prescription drugs and chronic disease management, public and private health plans often exclude coverage for bariatric surgery, FDA-approved AOMs and intensive behavioral therapy.

OCAN looks forward to working with the Biden-Harris Administration to develop clear regulatory guidance acknowledging that obesity is a complex and chronic disease. Such guidance would reaffirm the decades-old findings of the National Institutes of Health as well as mirror the strong support from the medical and scientific communities for recognizing obesity as a chronic disease.

Should you have any questions or need additional information, please contact OCAN Washington Coordinator Chris Gallagher via email at chris@potomaccurrents.com or telephone at 571-235-6475.

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[4] Centers for Medicare and Medicaid Services. November 29, 2011. National Coverage Determination (NCD) for Intensive Behavioral Therapy for Obesity (210.12). Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=353

[5] Centers for Medicare and Medicaid Services. November 29, 2011. Decision Memo for Intensive Behavioral Therapy for Obesity (CAG-00423N). Available at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=253&NCDId=353&ncdver=1

[6] Moyer VA, U.S. Preventive Services Task Force. Screening for and Management of Obesity in Adults: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2012;157:373-8.

[7] U.S. Preventive Services Task Force. Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults US Preventive Services Task Force Recommendation Statement. *JAMA*. 2018;320(11):1163-1171. doi:10.1001/jama.2018.13022