March 4, 2022

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4192-P
Mail Stop: C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

Dear Administrator Brooks-LaSure:

On behalf of the 28 member organizations of the Diabetes Advocacy Alliance (DAA), we are writing to express our concern about obesity and its relationship to type 2 diabetes and prediabetes, and of the need for Medicare beneficiaries to have access to the full continuum of obesity treatments, which includes anti-obesity medications.

The DAA is diverse in scope, with our members representing patient, professional and trade associations, other non-profit organizations, and corporations, all united to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked with legislators and policymakers to increase awareness of, and action on, the diabetes epidemic. The DAA organizational members share a common goal of elevating diabetes on the national agenda so we may ultimately defeat this treatable, but also potentially deadly chronic disease. We are committed to advancing person-centered policies, practical models, and legislation that can improve the health and well-being of people with diabetes and prediabetes. An essential component to our goal is combatting health disparities and addressing social determinants of health. Our advocacy to policymakers highlights key strategies to prevent, detect and manage diabetes and care for those affected by it. Our educational outreach also illustrates the health equity implications of existing or new policies, regulations, and legislation, and provides alternatives to address the drivers of these inequities.

The Obesity-Diabetes Connection

Overweight and obesity are the key risk factors for identification of asymptomatic people with prediabetes and undiagnosed type 2 diabetes, and there is clear evidence that weight loss is associated with prevention or delay of onset of type 2 diabetes. Also, there are serious negative health outcomes associated with overweight and obesity among people with both type 1 and type 2 diabetes.

Additionally, the COVID-19 pandemic has demonstrated a strong association of overweight and obesity with hospitalization and mortality. These facts underscore the DAA's support for Medicare coverage of the full spectrum of treatments for overweight and obesity, including FDA-approved anti-obesity medications.

Primary and Secondary Prevention. The U.S. Preventive Services Task Force (USPSTF), in its most recent review of the evidence for screening for diabetes and prediabetes in asymptomatic adults published in August 2021, is clear about the obesity-diabetes connection from a primary prevention perspective for identifying adults with prediabetes, and from a secondary prevention perspective, for identifying asymptomatic adults with undiagnosed type 2 diabetes. Based on strong evidence, **the Task Force recommends that physicians and other health care professionals use overweight or obesity as the key indicators for deciding which asymptomatic patients they should screen:**

- The U.S. Preventive Services Task Force (USPSTF) recommends general screening for prediabetes and diabetes in adults ages 35-70 with overweight or obesity.

Additionally, the Task Force recommends that clinicians "offer or refer patients with prediabetes to effective preventive interventions," such as the CMS Medicare Diabetes Prevention Program and CDC's National Diabetes Prevention Program, where weight loss is the key desired outcome.

For people with type 2 diabetes, the American Diabetes Association (ADA) is clear, in its Standards of Medical Care in Diabetes – 2022, about the obesity-diabetes connection, and the association of obesity with other serious chronic diseases in people with diabetes:

- "Most, but not all, patients with type 2 diabetes have overweight or obesity. Excess weight itself causes some degree of insulin resistance." (pp. S23-24)
- "The importance of addressing obesity is further heightened by numerous studies showing that both obesity and diabetes increase risk for more severe coronavirus disease 2019 (COVID-19) infections." (p. S113)
- The ADA also points out that "diabetes is associated with increased risk of cancers of the liver, pancreas, endometrium, colon/rectum, breast and bladder" and that "the association may result from shared risk factors between type 2 diabetes and cancer" with obesity being listed as one of these risk factors, which also include older age and physical inactivity. (p. S53)
- Additionally, the ADA mentions that "rates of obstructive sleep apnea, a risk factor for cardiovascular disease, are significantly higher with obesity" and "the presence of obstructive sleep apnea in the population with type 2 diabetes may be as high as 23%." (p. S56)

There are many medical benefits of chronic weight management in people with diabetes who have overweight or obesity:
The ADA states that "for many individuals with overweight and obesity with type 2 diabetes, 5% weight loss is needed to achieve beneficial outcomes in glycemic control, lipids, and blood pressure" but adds that "it should be noted, however, that the clinical benefits of weight loss are progressive, and more intensive weight loss goals (i.e., 15%) may be appropriate to maximize benefit depending on need, feasibility, and safety." (p S64)

- One study published in Morbidity and Mortality Weekly Report estimated that 85.2% adults with diagnosed diabetes have overweight or obesity and could benefit from weight loss that would

help reduce not only their blood glucose levels, but also their blood pressure and cholesterol levels.

- Deleterious effects of overweight and obesity are not seen in just the population with type 2 diabetes. The ADA points out that "overweight and obesity are also increasingly prevalent in people with type 1 diabetes and present clinical challenges regarding diabetes treatment and CVD risk factors."
- The ADA also notes that "among patients with both type 2 diabetes and overweight or obesity who have inadequate glycemic, blood pressure, and lipid control and/or other obesity-related medical conditions, modest and sustained weight loss improves glycemic control, blood pressure, and lipids and may reduce the need for medications to control these risk factors. Greater weight loss may produce even greater benefits." (p. S115)

Physicians and other health care professionals who can prescribe medication should have the option of prescribing anti-obesity medications to patients who fit FDA recommendations for use and for whom they believe could benefit from their use. The DAA supports the American Medical Association's 2013 recognition of obesity as a chronic disease and believes patients should have access, as appropriate for each patient as an individual, to the full continuum of treatments for overweight and obesity, in consultation with their health care providers. This continuum includes evidence-based behavior change interventions, medications, medical devices, and weight loss surgery.

- For medications, the ADA notes that the FDA "has approved medications for both short-term and long-term weight management as adjuncts to diet, exercise, and behavioral therapy" and adds that "nearly all FDA-approved medications for weight loss have been shown to improve glycemic control in patients with type 2 diabetes and delay progression to type 2 diabetes in patients at risk." (p. S116).
- The ADA also notes that "five weight loss medications are FDA approved for long-term use (>12 weeks) in adult patients with BMI $\geq$27 kg/m^2 with one or more obesity-associated comorbid condition (e.g., **type 2 diabetes**, hypertension, and/or dyslipidemia) who are motivated to lose weight." (p. S116)

Health Equity, Diabetes, and Obesity

According to the most recent National Center for Health Statistics Data Brief on Obesity (February 2020), the percentage for obesity in all U.S. adults is 42.4%, with 42.8% of adults aged 60 and older classified as obese. Adult obesity rates are higher among non-Hispanic black (49.6%) and Hispanic (44.8%) populations, compared with a rate of 42.2% for the non-Hispanic white population. The prevalence rate among adult non-Hispanic black women, at 56.9%, is higher than all other groups. With obesity and type 2 diabetes disproportionately affecting communities of color, the DAA believes that expanding CMS coverage of obesity treatments to include medications is also a health equity issue. This is another important reason that the DAA urges CMS to amend its Part D Final Rule to add coverage for anti-obesity medications that have been approved by the FDA. Such an addition would offer physicians and other prescribers an important expansion of options in the available armamentarium for treating overweight and obesity in their patients with prediabetes and type 2 diabetes.

Finally, we want to share an analogy from comments submitted by the Obesity Care Advocacy Network (OCAN). Several members of the DAA are also members of OCAN, and support the arguments made by OCAN about when, in July 2005, CMS reversed policy that appeared in the January 28, 2005, Medicare Part D Final Rule. We agree that CMS's interpretation of the statutory exclusion of weight loss drugs is too narrow and that CMS, in July 2005, was not appropriately distinguishing ''cosmetic'' weight loss

from those clinical circumstances in which drugs are being specifically prescribed for an indication of obesity or chronic weight management. OCAN states in its comments:

- "The basis for CMS' policy is even less clear given the agency's language surrounding prescription drug products being used to treat AIDS wasting and cachexia. In past Part D rulemakings, CMS stated that 'given the clinical complexities associated with AIDS wasting and cachexia, and the documented therapeutic action of these drugs to work beyond weight gain and prevent associated morbidity and mortality, the use of these products cannot be excluded from Part D…' Such a statement would also be true if you inserted the words 'obesity' in place of 'AIDS wasting and cachexia' and 'weight gain,' in place of 'weight loss.' We view the refusal to apply the same interpretation to anti-obesity medications as effectively discriminating against beneficiaries with obesity, and we request that CMS revisit its interpretation in light of the agency's recently enhanced focus on health equity."

We appreciate the opportunity to comment on the Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, and we would be happy to make ourselves available if you have any questions.

Sincerely,

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