January 27, 2025

SUBMITTED ELECTRONICALLY

The Honorable Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: ITEM Coalition Comments in Response to the Contract Year 2026 Medicare Advantage and Medicare Part D Drug Benefit Proposed Rule (CMS-4208-P)

Dear Acting Administrator Wu:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition appreciate the opportunity to provide comments to the Centers for Medicare and Medicaid Services ("CMS") in response to the Contract Year ("CY") 2026 Medicare Advantage ("MA") and Medicare Part D Prescription Drug Benefit Programs Proposed Rule ("proposed rule").[1] Our comments below focus exclusively on CMS's proposal to expand access to and coverage of transformative anti-obesity medications ("AOMs") under the Medicare Part D and Medicaid programs and the important positive impact this coverage could have on enrollees with disabilities.

The ITEM Coalition is a national consumer- and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including limb loss and limb difference, multiple sclerosis, spinal cord injury, brain injury, stroke, paralysis, cerebral palsy, spina bifida, hearing, speech, and visual impairments, myositis, and other life-altering conditions. Many of the constituents represented by the ITEM Coalition have mobility impairments that significantly reduce their ability to ambulate, exercise, and regulate their weight in a manner taken for granted by their non-disabled peers.

[1] Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (Nov. 26, 2024) (to be codified at 42 CFR 417, 422, 423, and 460) https://www.federalregister.gov/public-inspection/2024-27939/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare

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Proposed Coverage of Anti-Obesity Medication

A lack of mobility in the disability population contributes to obesity and the chronic illnesses that often accompany obesity. The ITEM Coalition firmly believes that individuals living with obesity should have equal access to the full continuum of obesity treatment options available to those living with chronic diseases such as diabetes and cardiovascular conditions.

The incoming Trump Administration's Make America Healthy Again initiative is aligned with this coverage proposal for AOMs. The policy focus of this initiative is to implement a comprehensive national strategy to combat the chronic disease epidemic in the United States, which includes addressing the root causes such as poor diet, sedentary lifestyles, environmental toxins, and inadequate healthcare. This policy goal will be further strengthened if the proposed rule is finalized. Make America Healthy Again supports policies that promote preventative healthcare and reduce the environmental factors contributing to chronic illness like diabetes, cancer, and heart disease, all of which are closely tied to a common disease state—obesity.

From the ITEM Coalition's perspective, we view access to AOMs as a critical tool for people with disabilities, who often struggle with maintaining a healthy weight, to fight the obesity epidemic and every tool should be at our disposal to combat this increasing risk of death and disability from chronic illnesses. While we support holistic and healthy lifestyles, proper diet, and exercise, as well as programs to encourage these behaviors, we believe that sometimes this is not enough, or even an option for people with disabilities to remain fit and manage their weight. Far too often, people with disabilities encounter barriers when it comes to accessible weight loss activities. For example, many fitness facilities are inaccessible for people with disabilities. When fitness facilities are accessible, they often lack features such as accessible weight scales and mobility-related exercise equipment that is useful to encourage and facilitate exercise within this population. Health insurance coverage also often precludes access to prostheses, orthoses, and mobility-related equipment that would enable people with disabilities to participate in and benefit from exercise and fitness programs. Many of these barriers to fit and healthy lifestyles for people living with disabilities could be reduced if this proposal is finalized by the incoming Administration.

Obesity is a serious chronic disease that effects more than 100 million Americans today.[2] The Centers for Disease Control and Prevention ("CDC") has stated that obesity is an epidemic in the United States and because living with obesity and being overweight are major risk factors for a broad range of chronic illnesses, including diabetes, the increase in prevalence of obesity has major implications on the health and well-being of the nation. Given the alarming rise of obesity and obesity-related comorbidities in the United States, the ITEM Coalition commends CMS for taking the necessary steps to address this growing issue by expanding coverage for AOMs under both the Medicare and Medicaid programs.

[2] Stierman B, Afful J, Carroll MD, et al. National Health and Nutrition Examination Survey 2017–March 2020 prepandemic data files development of files and prevalence estimates for selected health outcomes. Natl Health Stat Report. 2021;158.

Since the inception of the Part D program in 2006, the statutory definition of a covered Part D drug excludes certain drugs and uses—specifically those that may be excluded by Medicaid under section 1927(k)(2) of the Social Security Act, namely, "agents when used for…weight loss…". Since 2006, CMS has interpreted this statutory exclusion to mean that when a drug is used for weight loss, even when not used for cosmetic purposes, it is excluded from the definition of a covered Part D drug.[3] This historical interpretation has meant that all drugs used for weight loss have been excluded from the definition of covered Part D drugs and considered to be an optional benefit under the Medicaid program, at the state's discretion, regardless of their use to treat the chronic disease of obesity.

Therefore, under current policy, anti-obesity medications are only coverable under Medicare Part D if the drug is being used to treat another condition that is a medically accepted indication other than weight loss (e.g., type 2 diabetes or to reduce the risk of major adverse cardiovascular events in adults with established cardiovascular disease and either obesity or overweight). However, in this proposed rule, CMS has re-evaluated the exclusion and considered changes in the prevailing medical consensus towards recognizing obesity as a disease and the increasing prevalence of obesity in the U.S. population generally, and in the Medicare and Medicaid populations more specifically.

The proposed rule reinterprets the statute to permit coverage of anti-obesity medications for the treatment of obesity when such drugs are indicated to reduce excess body weight and maintain long-term weight reduction for individuals living with obesity. CMS believes that, in doing so, the agency would be aligned with existing policies under which CMS permits Part D coverage of drugs that would otherwise be excluded when they are being used to treat certain specific diseases (e.g., drugs used to treat acquired immunodeficiency syndrome ("AIDS") wasting and cachexia).

The ITEM Coalition fully supports this proposal. This proposed revised interpretation would recognize obesity to be a chronic disease based on changes in medical consensus, consistent with the CDC's designation. However, it is important to note that CMS would not consider that interpretation to extend to individuals who are living with higher body mass but are not living with obesity, as the Agency does not consider being overweight a disease. Accordingly, CMS would continue to exclude anti-obesity medications from Part D coverage when being used in individuals living with overweight but not living with obesity or another condition that is a medically accepted indication.

<u>Obesity's Impact on Disability</u>

It is well known that living with obesity is a primary risk factor for many chronic illnesses, including type 2 diabetes. In a 2017 study published by the American Diabetes Association,

[3] 73 FR 20489-20490 in "Medicare Program; Policy and Technical Changes to the Medicare Prescription Drug Benefit" published April 15, 2008 (73 FR 20486). However, CMS's longstanding interpretation of the phrase "[a]gents when used for…weight gain …" (emphasis added) in the same section of the Act has not included drugs used to treat acquired immunodeficiency syndrome (AIDS) wasting and cachexia (73 FR 20490).

researchers found that treating obesity could reduce the incidence of diabetes by 58%.[4] There are several major comorbidities associated with type 2 diabetes, including limb amputation. Obesity management is important not only for the prevention of diabetes but also for the delay of diabetes-related complications including peripheral artery disease ("PAD") which often leads to lower limb amputation. Glucagon-like peptide-1 ("GLP-1") receptor agonists ("GLP-1Ras") are a class of drugs that are used to treat type 2 diabetes and obesity.

In a study conducted in Denmark in 2023, patients on GLP-1 treatment experienced a notable reduction in the risk of limb amputation due to diabetes compared to those without the treatment.[5] This risk reduction was consistent across different age groups, but notably most pronounced among middle income patients. Analysis from the study revealed compelling evidence of a reduced risk of amputation among patients receiving GLP-1 medications, compared to those without the treatment, even after adjusting for various socio-economic factors. *Id.*

Achieving or maintaining a target weight is often more difficult for individuals with mobility disabilities, such as limb loss and limb difference, than it is for the general population living without a disability. When patients are adjusting to a new lifestyle post-injury and adapting to using wheelchairs, prosthetic limbs or orthotic braces, maintaining a target weight is typically more difficult to achieve. There are many challenges for individuals living with obesity in the orthotic and prosthetic community, including proper fitting and alignment of prostheses and orthoses, higher risk of skin breakdown, impaired mobility, potential complications during surgery or fitting, and increased energy expenditure needed to walk, all of which can significantly impact functional ability and quality of life. Expanded coverage of AOMs will assist in addressing all of these clinical realities.

Obesity is also associated with increased risk of 13 types of cancer. Women and minorities are disproportionately impacted by cancer types associated with obesity. Fifty-five percent of all cancers diagnosed in women and 24 percent of those diagnosed in men are associated with obesity.[6] Unfortunately, obesity may be the most under-treated chronic disease in the United States—just 2% of U.S. adults eligible for obesity medications receive it.[7]

Weight Bias and Weight Stigma

Lack of mobility, especially for individuals living with a disabling condition, can contribute to weight gain. Weight bias and weight stigma, which is defined as negative, prejudicial, or

[4] Bramante, Carolyn T. "Treatment of Obesity in Patients With Diabetes" Diabetes Spectrum 2017; 30(4):237–243, https://doi.org/10.2337/ds17-0030

[5] Sundström, J., & Collaborators. Glucagon-like peptide-1 treatment reduces the risk of diabetes-type 2 related amputations: A cohort study in Denmark. *Journal of Hepatology*, Volume 202, 110799 (August 2023) https://doi.org/DOI

[6] Cancers associated with overweight, and Obesity make up 40 percent of cancers diagnosed in the United States. (2017, October 03). Retrieved May 05, 2021, from https://www.cdc.gov/media/releases/2017/p1003-vs-cancer-obesity.html

[7] Velazquez A, Apovian CM Updates on obesity pharmacotherapy. Ann N Y Acad Sci 2018

stereotypical beliefs and attitudes toward individuals based on their size, has been cited as the fourth most common form of discrimination among U.S. adults.[8] Weight bias and stigma exist in healthcare settings, increasing risks for individuals who have a higher body weight. Patients with higher weight face bias and stigma from physicians, nurses, psychologists, dietitians, medical students, and even professionals who specialize in obesity. Some healthcare professionals perceive individuals with higher weight to be lazy, lacking in willpower, unmotivated to improve health, and noncompliant with treatment. When patients feel judged or stigmatized about their weight, this can lead to lower trust of their healthcare providers, poorer quality of care, and avoidance of healthcare altogether.

Experiencing weight bias can also lead to feelings of shame, decreased self-esteem, and reduced motivation to engage in physical exercise and rehabilitation therapy. The ITEM Coalition believes that CMS's proposal to expand coverage of AOMs under Medicare and Medicaid would provide, for the first time, individuals with greater access to the anti-obesity care they may need to improve their health and lower the chances of developing associated chronic conditions. For individuals with disabilities, coverage of these medications can lead to improvements in function and independence, which can help motivate individuals to regulate their weight and achieve greater benefit from rehabilitation therapies and assistive devices and technologies.

Costs Benefit of AOM Coverage: Expanding Medicare and Medicaid coverage of AOMs for those living with obesity would not only provide greater access to healthier lives for millions of beneficiaries and enrollees who desperately need it, but it would also result in significant reductions in healthcare costs for both patients and the federal government. Studies demonstrate the cost benefit of AOM coverage.[9] The cumulative social benefits from Medicare coverage for new obesity treatments over the next 10 years was estimated in a recent study to reach almost $1 trillion, or roughly $100 billion per year. Furthermore, this study also found that Medicare coverage of weight-loss therapies would save federal taxpayers as much as $245 billion in the first 10 years of coverage alone if private insurers were to follow Medicare's lead.

These savings represent a reduction in healthcare spending from fewer hospitalizations, surgeries, doctors' visits, drugs, nursing home stays, and other medical needs associated with a healthier Medicare population. The study found that a majority of the projected cost offsets to Medicare (60%) occur in Medicare Part A spending, with the rest coming from savings to outpatient care under Medicare Parts B and Medicare Part D. According to the study, Medicare Part A spending will fall by $846 billion after 30 years of Medicare and private insurance coverage for weight-loss therapies. *Id.*

The ITEM Coalition's mission is to advocate for greater access to and coverage of assistive devices and technologies for people with disabilities under the Medicare and Medicaid programs. Proper diet and exercise is not always feasible or effective for weight loss, especially for

[8] Puhl RM, Andreyeva T and Brownell KD (2008) Perceptions of weight discrimination: prevalence and comparison to race and gender discrimination in America. International Journal of Obesity (London) 32, 992–1000.
[9] Alison Sexton Ward, PhD, *The Benefits of Medicare Coverage for Weight Loss Drugs*, DOI: 10.25549/4rf9-kh77 (April 18, 2023) https://healthpolicy.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/

individuals living with a mobility disability. As such, we believe that providing expanded access to anti-obesity medications that would help reduce body mass and, in turn, improve quality of life and health outcomes is squarely in line with the ITEM Coalition mission. Accordingly, we are fully supportive of CMS's proposal to expand coverage of AOMs under Medicare and Medicaid as indicated for treatment of obesity. We encourage CMS to finalize this proposal as expeditiously as possible.

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We appreciate your consideration of these comments. Should you have any further questions regarding this letter, please contact the ITEM Coalition Co-Coordinators at Peter.Thomas@PowersLaw.com and Michael.Barnett@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready, Inc.
ACCSES
Alexander Graham Bell Association for the Deaf and Hard of Hearing
American Association on Health and Disability
American Congress of Rehabilitation Medicine
American Macular Degeneration Foundation
American Music Therapy Association
American Occupational Therapy Association
Amputee Coalition*
Association of Assistive Technology Act Programs
Association of Rehabilitation Nurses
Autistic Women & Nonbinary Network
Center for Medicare Advocacy
Center on Aging and DIS-Ability Policy
Christopher & Dana Reeve Foundation*
Clinician Task Force
International Eye Foundation
International Registry of Rehabilitation Technology Suppliers
Lakeshore Foundation
Lighthouse Guild
Long Island Center for Independent Living
The Miami Project to Cure Paralysis
National Association for the Advancement of Orthotics and Prosthetics
National Multiple Sclerosis Society
Perkins School for the Blind
Prevent Blindness
RESNA
Rifton Equipment
Spina Bifida Association*

Team Gleason*
United Cerebral Palsy
United Spinal Association*
VisionServe Alliance

**** ITEM Coalition Steering Committee Member***