March 28, 2025

SUBMITTED ELECTRONICALLY

Don Dempsey
Associate Director of Health Programs
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Re: Disability Community Support for Proposed Coverage Expansion of Anti-Obesity Medications ("AOMs") under Medicare and Medicaid

Dear Associate Director Dempsey:

On behalf of the undersigned national disability and rehabilitation organizations, we write to express our strong and continued support for the proposal included in the Contract Year ("CY") 2026 Medicare Advantage and Medicare Part D Prescription Drug Benefit Programs proposed rule[1] ("proposed rule") to expand coverage for anti-obesity medications ("AOMs") under the Medicare and Medicaid programs. This proposal, if finalized, would have a significant and positive impact on enrollees in the disability community and we strongly encourage the new Administration to move forward with finalizing this proposed coverage expansion as expeditiously as possible.

The national organizations represented in this letter represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including limb loss and limb difference, visual impairments, spinal cord injury, stroke, paralysis, cerebral palsy, spina bifida, hearing, speech, and, and other life-altering conditions. Many of the constituents represented by the undersigned organizations have mobility impairments that significantly reduce their ability to ambulate, exercise, and regulate their weight in a manner taken for granted by their peers without disabilities.

Proposed Coverage of Anti-Obesity Medications

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, the Centers for Medicare and Medicaid Services ("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.[2] This historical interpretation has meant that all drugs used for

[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

[2] 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

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 discretion of the state Medicaid program, regardless of their use to treat the 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 or weight management (for example, 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 the 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.

In the rule under consideration by the Office of Management and Budget, CMS proposes to reinterpret 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 with obesity. CMS believes that, in doing so, the agency would be aligned with existing policies under which CMS permits Part D coverage for 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).

This proposed revised interpretation would recognize obesity to be a chronic disease based on changes in medical consensus. Because this proposal reinterprets the Medicaid statute, this proposed reinterpretation would also apply to the Medicaid program. As a result, anti-obesity medications, when used to reduce excess body weight and maintain long-term weight reduction to treat obesity, could not be excluded from Medicaid coverage and would therefore be considered covered outpatient drugs.

Alignment with Administration's Make America Healthy Again Initiative

The undersigned organizations believe that the Trump Administration's Make America Healthy Again initiative is fully aligned with this expanded coverage proposal for AOMs. The policy focus of the Make America Healthy Again initiative is to implement a comprehensive national strategy to combat the chronic disease epidemic in the United States, which includes addressing root causes such as poor diet, sedentary lifestyles, environmental toxins, and inadequate healthcare. Finalizing this proposed AOM coverage expansion would further advance this policy objective. This initiative 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. By expanding coverage for AOMs, this proposal reinforces the Administration's commitment to proactive, preventative healthcare and represents a critical step toward reducing the burden of chronic illness nationwide.

"[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).

From the disability perspective, we view expanded access to AOMs as a critical tool for people with disabilities who often struggle with maintaining a healthy weight. To meaningfully combat the obesity epidemic, every tool should be at the medical community's disposal to combat the 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 there is a limit to what these strategies alone can accomplish, particularly for the disability community.

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. Access to AOMs to address obesity is an important tool that can help people with disabilities augment whatever fitness activities they are able to engage in, even with these barriers in place.

Obesity's Impact on Disability

A lack of mobility in the disability population contributes to obesity and the chronic illnesses that often accompany obesity. The undersigned national organizations firmly believe 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. Pharmacotherapy is an important component of treatment to address the risk of death and disability from chronic illnesses.

It is well known that obesity is a primary risk factor for type 2 diabetes. In a 2017 study published by the American Diabetes Association, researchers found that treating obesity could reduce the incidence of diabetes by 58%.[3] 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.[4] This risk reduction was consistent across different age groups, but notably most pronounced among middle income patients. Analysis from the study revealed

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

[4] 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

compelling evidence of a reduced risk of amputation among patients receiving GLP-1 therapy, an effect dominated by liraglutide, compared to those without the treatment, even after adjusting for various socio-economic factors. *Id.*

Obesity's Impact on Limb Loss and Limb Difference

Maintaining a healthy weight is important for everyone, but it holds particular significance for those at risk of limb loss or those who have experienced limb loss or limb difference. Coverage of AOMs would significantly improve the health and quality of life of the approximately 5.6 million people in the country who have limb loss or limb difference. People at risk for, or who have had a limb amputated due to infection, are discouraged from exercising as elevating their heart rate could spread the infection to other parts of their body.[5] Furthermore, when patients are adjusting to a new lifestyle post-amputation or injury and adapting to using wheelchairs, prosthetic limbs or orthotic braces, maintaining a consistent target weight is typically more difficult to achieve and may complicate the use of these devices.

For instance, variances in weight create challenges for patients living with obesity who use orthoses and prostheses, including proper fitting and alignment, 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. Health insurance providers also often deem access to prostheses, orthoses, and mobility-related equipment that would enable people to participate in and benefit from exercise and fitness programs as "not medically necessary." If finalized, this proposal would help alleviate some of these challenges by providing beneficiaries in the limb loss community with another treatment option, in addition to proper diet and exercise, to maintain their weight and benefit from the rehabilitation therapy services and assistive devices and technologies they need to thrive.

Obesity is also closely linked to insulin resistance and metabolic syndrome, which can significantly hinder the healing process after sustaining an injury, particularly in individuals with diabetes. Factors such as chronic inflammation and poor blood circulation due to excess body fat contribute to a higher risk of limb loss and prolonged healing times for amputation wounds, delaying or even prohibiting the reliable use of prosthetic limbs. Similarly, orthotic brace users may need to spend significantly more time in an orthosis compared to their non-obese peers before achieving noticeable benefits. The undersigned organizations strongly believe that greater access to AOMs for managing obesity and the clinical improvements that coincide with decreasing body mass would offer substantial benefits and lead to sustainable, positive health outcomes for the limb loss and limb difference population.

Obesity's Impact on Low Vision

There are many challenges for individuals living with obesity in the vision impaired community that intersect across physical, psychological, and social domains. From a chronic disease management perspective, obesity is a major risk factor for a number of systemic and sight-

[5] "Should you exercise when sick: Dr. Montero," YouTube, uploaded by Mayo Clinic, March 22, 2020, https://youtu.be/ftaqIXk2Bho?si=VdO2WxdmoFmb-4Ru.

threatening comorbidities.[6] Increasing evidence shows that obesity significantly increases the risk of developing various eye conditions, including increased inflammation, glaucoma, cataracts, age-related macular degeneration ("AMD"), diabetic retinopathy, and microvasculature of the eyes.[7] The undersigned organizations believe that expanded coverage of AOMs to treat obesity will assist in meaningfully decreasing the incidence of these eye-related conditions that often accompany obesity.

From a physical health and mobility perspective, achieving or maintaining a target weight is often more difficult for individuals with vision-related disabilities than it is for the general population living without a disability. Obesity can limit physical mobility, and when combined with vision impairment, navigating physical spaces becomes more challenging and can lead to increased risk of falls, injuries, and reduced physical activity. Access to mobility aids or assistive technologies and devices may also be limited due to weight restrictions on medical equipment such as wheelchairs, prosthetic limbs, walkers, and scooters. Physical activity is critical for maintaining one's weight; however, vision impairment creates additional barriers to participating in exercise, such as difficulty accessing fitness facilities, outdoor walking trails, or fitness programs designed for individuals with disabilities. Expanded coverage of AOMs will assist in addressing many of these physical and health challenges.

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 vision-related 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.

Obesity's Impact on Cancer

Obesity is also associated with increased risk of 13 types of cancer and 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.[8] Unfortunately, obesity may be the most under-treated chronic disease in the U.S.—just 2% of U.S. adults eligible for obesity pharmacotherapy receive it.[9] 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.

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[6] Cheung, N., & Wong, T. Y. (2007). Obesity and eye diseases. Survey of ophthalmology, 52(2), 180–195. https://doi.org/10.1016/j.survophthal.200

[7] GBD 2019 Blindness and Vision Impairment Collaborators. Global causes of blindness and distance vision impairment 1990–2020: a systematic review and meta-analysis. The Lancet Global Health, 2021.

[8] 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

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

Costs Benefit of AOM Coverage

Studies demonstrate the cost benefit of AOM coverage.[10] 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 per year 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 remainder 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.*

Proper diet and exercise is not always feasible or effective for weight loss, especially for individuals living with a mobility disability. As such, we believe that providing expanded access to anti-obesity medications that would help these individuals reduce body mass and, in turn, improve quality of life and health outcomes. Accordingly, we are fully supportive of CMS's proposal to expand coverage of AOMs under Medicare and Medicaid as proposed for treatment of obesity, and we strongly encourage OMB and CMS to finalize this proposal as expeditiously as possible.

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We thank you for your consideration of these comments and we look forward to working with you and your colleagues in the new Administration to ensure that individuals with disabilities are able to access the care they need to fully participate in their communities and live healthier, more fulfilling lives. Should you have any questions regarding this letter, please contact Peter Thomas at Peter.Thomas@PowersLaw.com or Michael Barnett at Michael.Barnett@PowersLaw or by calling 202-466-6550.

Sincerely,

The Undersigned National Rehabilitation and Disability Organizations

Access Ready, Inc.
ACCSES
ADVION
Alexander Graham Bell Association for the Deaf and Hard of Hearing
American Association for Homecare
American Association on Health and Disability
American Macular Degeneration Foundation
American Music Therapy Association

[10] 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/

American Occupational Therapy Association
American Orthotic & Prosthetic Association
American Therapeutic Recreation Association
Amputee Coalition
Association of Rehabilitation Nurses
Brain Injury Association of America
Center for Medicare Advocacy
Center on Aging and DIS-Ability Policy
Child Neurology Foundation
Christopher & Dana Reeve Foundation
Clinician Task Force
3DA
Falling Forward Foundation
International Eye Foundation
International Registry of Rehabilitation Technology Suppliers
Lakeshore Foundation
Lighthouse Guild
Long Island Center for Independent Living, Inc. (LICIL)
National Association for the Advancement of Orthotics and Prosthetics
National Association of Rehabilitation Providers and Agencies
National Disability Rights Network (NDRN)
National Multiple Sclerosis Society
Perkins School for the Blind
Prevent Blindness
RESNA
Spina Bifida Association
Team Gleason
The Vision Council
United Cerebral Palsy
United Spinal Association
VisionServe Alliance