AIMEDALLIANCE

January 27, 2025

Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Re: 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

Dear CMS Administrator:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We appreciate the opportunity to comment on the proposed changes to expand Medicare and Medicaid coverage of treatments for obesity. Aimed Alliance urges Centers for Medicare & Medicaid Services (CMS) to swiftly finalize the proposed rule as it represents an important step toward addressing the obesity epidemic and improving health equity. To maximize the potential benefits of this rule, we urge the CMS to ensure:

(1) Health plans are prohibited from requiring patients to step through off-label medications;
(2) CMS monitors the short and long-term implications on Medicare Part B spending; and
(3) Providers have discretion in treatment duration to ensure appropriate continuity of care decisions.

I. Prohibit Health Plans from Imposing Off-Label Step Therapy Policies

Health plans use a variety of tools known as benefit utilization policies to influence and restrict how beneficiaries access their benefits. One such benefit utilization tool is step therapy. Step therapy requires patients to try-and-fail on alternatives before the health plan will cover the originally prescribed medication. Without appropriate guardrails and oversight, these policies may be inconsistent with clinical practice guidelines and can cause unnecessary delays in accessing effective treatments and irreversible disease progression. In some cases, health plans require patients to try and fail on one or more medications that are not FDA-approved for their condition before they can access their provider-prescribed medication. This is known as "off-label" stepping.

In 2024, the Food and Drug Administration recognized a growing concern for the use of non-FDA approved weightless drugs.[1] Specifically, the FDA recognized that compounded drugs

[1] U.S. Food and Drug Administration, *FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss*, FDA (Dec. 18, 2024), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

such as "semaglutide and tirzepatide . . . can be risky for patients, as unapproved versions do not undergo FDA's review for safety, effectiveness and quality before they are marketed."[2] While the FDA does recognize that compounded drugs may be appropriate in limited circumstances, such as when a drug is not available to treat a condition or not commercially available, it did not recognize off-label compounded drugs as alternatives to FDA-approved prescription drugs.

Therefore, when finalizing the proposed rule to include coverage for obesity treatments we urge CMS to clarify that plans cannot impose off-label stepping for anti-obesity medications.

II. Monitor the Impact on Medicare Part B Spending

Individuals living with obesity also often live with co-occurring conditions such as cardiovascular disease, respiratory disorders, arthritis, and gastrointestinal disorders.[3] These co-occurring conditions can be difficult to manage and costly to treat.[4] Many of these chronic diseases contribute to substantial expenditures within Medicare Part B, including hospitalizations, surgeries, and long-term management of multiple conditions. Fortunately, for many individuals, reducing weight and treating obesity can also help improve their other chronic conditions.[5] As such, it is critical to recognize that any initial costs attributable to the coverage of anti-obesity medications under Medicare Part D may generate substantial long-term savings for consumers and Medicare and Medicaid programs.

To ensure proper accounting for how anti-obesity medications reduce overall health care spending, Aimed Alliance urges CMS to monitor the effects of this policy on the overall Medicare spending, particularly Part B costs. Tracking the downstream effects of treating obesity can provide important insights on short and long-term health care savings.

III. Ensure Provider Discretion and Continuity of Care

Current FDA approvals have authorized anti-obesity treatments for individuals with a Body Mass Index (BMI) of 30 or greater. However, current guidelines and FDA approvals do not address treatment guidelines for individuals on anti-obesity treatments whose BMI decreases to 30 or less than 30 while on anti-obesity treatments.

Currently, coverage decisions rely on BMI as a criterion for eligibility. However, it is critical to ensure that healthcare providers retain discretion in their clinical decision-making to ensure the appropriate treatment of individuals with obesity who have reached a BMI below 30. Many individuals who have lost significant weight or are at risk of relapse may still require ongoing treatment to maintain their progress. Discontinuing treatment and denying coverage solely

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[2] *Id.*
[3] Yizhe Lim and Joshua Boster, *Obesity and Comorbid Conditions*, STATPEARLS (Jun. 27, 2024).
[4] Cother Hajat, et al., *Clustering and Healthcare Costs With Multiple Chronic Conditions in a US Study*, 8 FRONT PUBLIC HEALTH (Jan. 21 2021).
[5] Donna Ryan et al., *Prioritizing obesity treatment: expanding the role of cardiologists to improve cardiovascular health and outcomes,* 12 CARDIOVASCULAR ENDOCRINOLOGY & METABOLISM (Feb. 7, 2023).

because a patient's BMI drops below 30 could undermine treatment progress and result in negative health outcomes.

As such, Aimed Alliance strongly urges CMS to ensure the final rule recognizes that provider's discretion and clinical decision making should be supported and upheld to allow health care providers to continue to prescribe anti-obesity medications below a BMI of 30 to support long-term weight management and treatment of obesity.

IV. Conclusion

In conclusion, the proposed rule represents a significant step forward in reducing stigma and improving access to anti-obesity treatments for Medicare and Medicaid beneficiaries. Moreover, Aimed Alliance urges CMS to prohibit off-label stepping, closely monitor the impact of covering anti-obesity treatments on Part B costs, and ensure healthcare providers retain discretion in their clinical decision-making. Please contact us at policy@aimedalliance.org if you have any questions regarding this comment.

Sincerely,

Olivia Backhaus
Staff Attorney
Aimed Alliance