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Game Beyond The Game

January 27, 2025

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted via electronic submission

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 (CMS-4208-P)

Dear CMS:

The Color of Gastrointestinal Illnesses (COGI) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the 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.

COGI is a national patient advocacy organization whose mission is to improve the quality of life for populations disproportionately affected by Inflammatory Bowel Disease (IBD), digestive disorders, and associated chronic illnesses; through community engagement, research, education, and advocacy. We work to spread awareness about the day-to-day challenges of living with digestive illnesses and advocate on behalf of policy changes that eliminate barriers for access to care.

COGI supports CMS taking the step of expanding coverage for anti-obesity medications when used to treat obesity in the Medicare Part D and Medicaid programs. Doing so will ensure all Americans living with obesity are able to access the care they need. COGI is also supportive of CMS's assertion that broad access to biosimilars is a necessary component of an appropriate utilization management program for Part D programs.

COGI strongly agrees with CMS's proposal to identify obesity as a chronic disease and cover obesity medications, an important step towards curbing our nation's chronic disease epidemic and promoting good health.



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Gastrointestinal illness and obesity are often co-existing diseases.

It is not well understood that many people have co-existing gastrointestinal (GI) diseases such as IBD and obesity. As the founder and CEO of COGI, I have personal experience. After the birth of my daughter, my IBD medication no longer worked. I was technically classified as obese and worked hard to address it through diet and exercise. The experience confused me because I already had a very healthy diet. Therefore, I started exercising more, walking between 5 to 8 miles a day and working out at least five days a week. Yet, I was gaining about a quarter of a pound a week. After tracking my lack of progress over 3 months, I sought help from a physician specializing in weight loss and nutrition. I learned that my metabolism was running and operating at a pace for a woman that was 60 years old, not at the pace of a woman that was my age of 41. I was prescribed a medication to slowly boost metabolism that allowed me to lose weight at a pace that was natural and sustainable, as opposed to losing the weight quickly. In the end, my physical and mental health improved with medication, allowing me to focus on managing my gastrointestinal health challenges, education, and advocacy. We work to spread awareness about the day-to-day challenges of living with digestive illnesses and advocate on behalf of policy changes that eliminate barriers for access to care.

Rising prevalence of obesity and gastrointestinal disease are costly.

The prevalence of obesity in the United States has risen in recent years, having a negative impact on our nation's health and economy. Also, overweight and obesity are well known risk factors for GI disorders such as inflammatory bowel disease (IBD), pancreatitis, and GI cancer. We now know that obesity presence increases the risk of developing gastrointestinal diseases and is associated with more severe disease and a lower response to treatments. The result are less favorable outcomes and increased economic burden of disease.¹

Coverage for anti-obesity medications will reduce obesity prevalence and address rising rates of gastrointestinal illnesses.

The prevalence of obesity among individuals over age 60 is 42.8%, similar to the level among younger and middle-aged adults. The prevalence of severe obesity among those over age 60 is 5.8%, contributing to higher rates of gastrointestinal disease. By 2030, more than 20% of the population will be 65 years of age or older, up from 15% today, underscoring the importance of addressing obesity among older Americans as a tactic for preventing co-existing conditions such as gastrointestinal disease and cancer. According to a study published in The Lancet, 213 million American adults are expected to have overweight or obesity by 2050 in the absence of any major policy changes.²

1 Emerenziani S, Guarino MPL, Trillo Asensio LM, Altomare A, Ribolsi M, Balestrieri P, Cicala M. Role of Overweight and Obesity in Gastrointestinal Disease. *Nutrients*. 2019 Dec 31;12(1):111. doi: 10.3390/nu12010111. PMID: 31906216; PMCID: PMC7019431.

2 [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(24\)01548-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)01548-4/fulltext)



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Obesity is a progressive disease. Medicare beneficiaries that go untreated with overweight or obesity risk an increased likelihood of co-existing conditions such as gastrointestinal disease, cancer, liver disease, diabetes, and end stage renal disease. For example, an³ increase in abdominal pressure from obesity can lead to hemorrhoids and colonic diverticulitis. Obesity is highly associated with increased risk of Crohn's disease and ulcerative colitis.

We are also very concerned about the rising incidence of colorectal cancer among people over age 50, which could be⁴ linked to rising rates of obesity. Yet, adults with no obesity have lower mortality rates for appendicitis, diverticulitis, pancreatitis and chronic liver diseases than adults with severe obesity. These numbers clearly convey that treating the disease of obesity by providing coverage for medications will help reduce both obesity and its many co-existing conditions.

Coverage for anti-obesity medications will help address chronic illness in underserved and rural populations.

Obesity has a disproportionate impact on individuals that already struggle to access care. Obesity, like gastrointestinal illnesses disease, is significantly more prevalent among rural adult populations than urban ones. Adults living in the most rural counties have a 34.7% obesity prevalence compared to a 29% prevalence for those living in metropolitan counties.⁵ The highest rates of digestive diseases, exacerbated by obesity, are found in rural communities and among Native populations and other minority populations.⁶ Rural Americans already often lack accessible health care, which exacerbates this problem Coverage of highly effective anti-obesity medications is one tool to address this issue.

Supporting coverage of obesity drugs will ultimately save the Medicare program money, reducing chronic disease and the cost of advanced disease.

CMS' decision to cover anti-obesity medication in the Medicare Part D and Medicaid programs will result in cost savings to both the government and to patients and their families. A study conducted by the University of Southern California Schaeffer Center estimates that coverage for anti-obesity treatments could generate approximately \$175 billion in cost offsets to Medicare in the first 10 years alone, and, by 30 years, cost offsets could increase to \$700 billion.⁷ These savings would be a result of reduced health care spending and reduced disability if all Americans were able to access effective obesity treatments.

COGI agrees with CMS's proposal asserting that broad access to biosimilars and generics is a necessary component of an appropriate utilization management program, including in relation to tier placement and utilization management practices.

3 <https://obesitymedicine.org/blog/obesity-and-gastrointestinal-impact/>

4 Patel, A., Krishna, S.G., Patel, K. et al. Rising Rates of Severe Obesity in Adults Younger Than 50 Correspond to Rise in Hospitalizations for Non-malignant Gastrointestinal Disease. *Dig Dis Sci* 68, 554–563 (2023). <https://doi.org/10.1007/s10620-022-07589-3>

5 https://norc.org/content/dam/norc-org/pdfs/Adult%20Obesity%20in%20Rural%20America_Final%20White%20Paper.pdf

6 <https://newsnetwork.mayoclinic.org/discussion/magnifying-u-s-gastrointestinal-disease-mortality-reveals-health-disparities/>

7 <https://healthpolicy.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/>



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Patients should have broad access to the treatments that they and their doctors decide best to meet the patient's needs. For this reason, COGI is very supportive of CMS's proposal to ensure that biosimilar and generic drugs are equally accessible to patients as their branded counterparts, which has historically not been the case.

COGI supports CMS's proposal to ensure that biosimilars and generics are available on formularies and do not have access limited due to tier placement or other utilization management restrictions. COGI is also supportive of CMS's proposal to include an additional step in its formulary review process to ensure that plans are complying and providing broad access to generics and biosimilars.

This policy will take needed steps to ensure that lower cost treatments are available to patients and that patients are able to access whichever treatment they and their doctor have decided is best for their individual needs.

Conclusion

In conclusion, COGI strongly supports CMS's proposals to provide coverage of anti-obesity medications and to ensure patients can access all treatments prescribed by their physicians, including biosimilars and generics. We look forward to these proposals being finalized and hope to be a resource to CMS in its ongoing work. Thank you for your consideration and action to reduce the incidence of chronic illness in America.

Sincerely,

Melodie Narain-Blackwell
President,
Color of Gastrointestinal Illnesses