CMS Has the Legal Authority to Cover Anti-Obesity Medications (and Should)

A Legal, Regulatory and Policy Assessment

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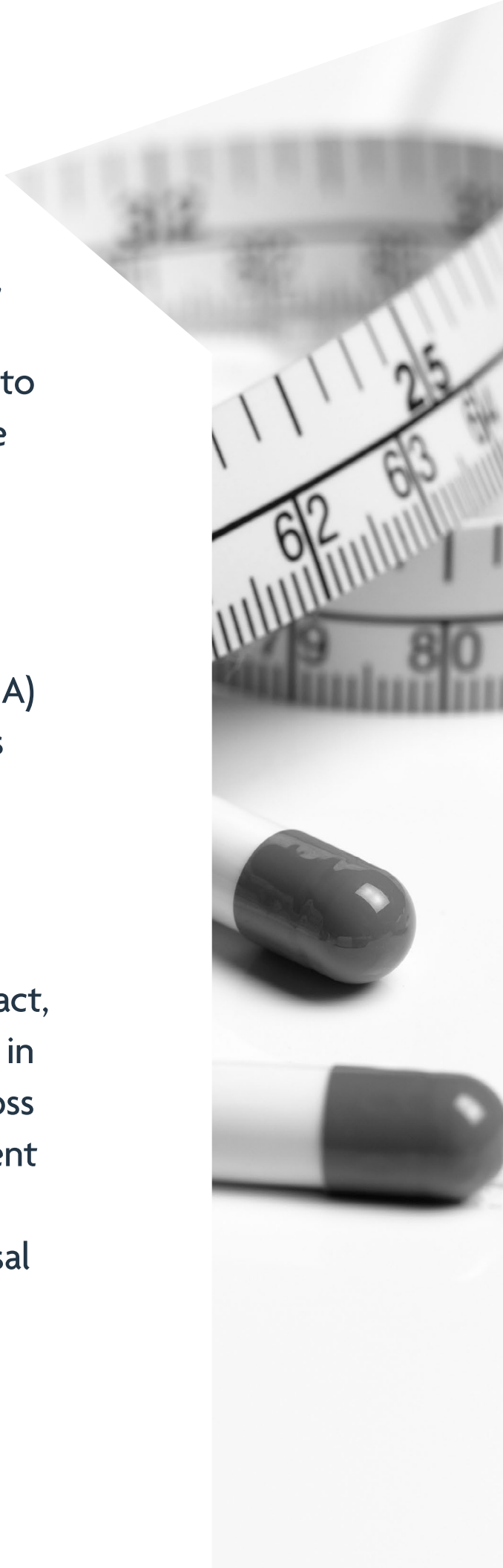
Contents

Obesity is a public health crisis, affecting nearly half of all Americans and significantly increasing the risk of cardiovascular disease, type 2 diabetes, musculoskeletal disorders and cancer. Although medications are now proven to help people with obesity, the Medicare program currently does not cover Anti-Obesity Medications (AOMs).

The Centers for Medicare & Medicaid Services (CMS) recently interpreted a provision of the Social Security Act (SSA) to mean that CMS cannot cover AOMs under the prescription drug benefit (Part D). However, the SSA provision does not prohibit coverage of weight loss medications for obesity, which is a serious, widely recognized disease. In fact, when CMS implemented the provision in 2005, the agency stated that "weight loss agents may be covered for the treatment of morbid obesity."

This paper analyzes CMS's policy reversal and argues that CMS has the existing authority to and must cover AOMs for obesity.



I. Introduction

The United States has a well-documented obesity epidemic.[1] According to the Centers for Disease Control and Prevention (CDC), about 41% of adults aged 60 and over had obesity in the period of 2015 through 2016, representing more than 27 million people.[2] In the United States, the prevalence of obesity had risen to 42.4% in 2017 through 2018[3] and predictive models now suggest that the prevalence will grow to one in two adults by 2030.[4] Obesity is a major risk factor in the development of cardiovascular disease, type 2 diabetes, musculoskeletal disorders and several cancers.[5] Fortunately, a relatively new type of drugs are highly effective for weight loss for individuals with obesity. This class of drugs, Glucagon-like peptide-1 (GLP-1) drugs, such as Ozempic (semaglutide) and Mounjaro (tirzepatide) were initially developed to treat type 2 diabetes, but their effectiveness as anti-obesity medications (AOMs) has generated skyrocketing demand. For example, in clinical trials, people on Wegovy (semaglutide) typically lost 15% or more body weight,[6] and people on Zepbound (tirzepatide) lost over 20%.[7] Yet another GLP-1 medication still in clinical development, retatrutide, demonstrated 24% weight loss.[8] The U.S. Food and Drug Administration (FDA) has also approved non-GLP-1 drugs for obesity treatment, including Xenical, Qsymia, Contrave, Plenity and Imciveree.[9] FDA recently approved a new use for Wegovy to reduce the risk of cardiovascular death, heart attack and stroke in adults with cardiovascular disease and either obesity or overweight.[10]

The Centers for Medicare & Medicaid Services (CMS) recently incorrectly interpreted the Medicare statute to mean that Medicare coverage under its prescription drug benefit (Part D) is prohibited. In fact, the provision upon which CMS relies to deny coverage for AOMs does not prohibit coverage. Indeed, in 2005, CMS stated that under that law, coverage for morbid obesity would be possible. Given the urgent need for the Medicare population to obtain coverage for AOMs, CMS should reconsider its position and implement a policy that ensures access for those beneficiaries who truly need these life-saving medications.

1 Cynthia L. Ogden et al., *Prevalence of Obesity Among Adults and Youth: United States, 2011-2014*, NCHS Data Brief. 2015(219):1-8, **https://pubmed.ncbi.nlm.nih.gov/26633046/**; Beverly G. Tchang, M.D. et al., Pharmacologic Treatment of Overweight and Obesity in Adults (Aug. 20, 2024), **https://www.ncbi.nlm.nih.gov/books/NBK279038/**.

2 Chris M. Hales, M.D. et al., Dep't of Health & Human Servs., CDC, *Prevalence of Obesity Among Adults and Youth: United Stated, 2015-2016* (Oct. 2017), **https://www.cdc.gov/nchs/data/databriefs/db288.pdf**.

3 CDC, *Overweight & Obesity: Adult Obesity Facts*, Vol. 20212020, **https://pubmed.ncbi.nlm.nih.gov/31851800/**.

4 Zachary J. Ward et al., *Projected U.S. State-Level Prevalence of Adult Obesity and Severe Obesity*, N. Engl. J. Med. 2019;381(25):2440-2450.

5 World Health Organization (WHO). Overweight and Obesity. Vol. 20202020.

6 Wegovy (semaglutide) injection 2.4 mg, Prescribing Information, **https://www.novo-pi.com/wegovy.pdf**.

7 Zepbound (tirzepatide) injection, Prescribing Information, **https://pi.lilly.com/us/zepbound-uspi.pdf?s=pi**.

8 Emily Harris, *Triple-Hormone Combination Retratrutide Induces 24% Body Weight Loss*, JAMA. 2023;330(4):306. doi:10.1001/jama.2023.12055.

9 Beverly G. Tchang, M.D. et al., *Pharmacologic Treatment of Overweight and Obesity in Adults* (Aug. 20, 2024), **https://www.ncbi.nlm.nih.gov/books/NBK279038/**.

10 FDA, *FDA Approves First Treatment to Reduce Risk of Serious Heart Problems Specifically in Adults with Obesity or Overweight* (Mar. 8, 2024), **https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-reduce-risk-serious-heart-problems-specifically-adults-obesity-or**.

II. Background

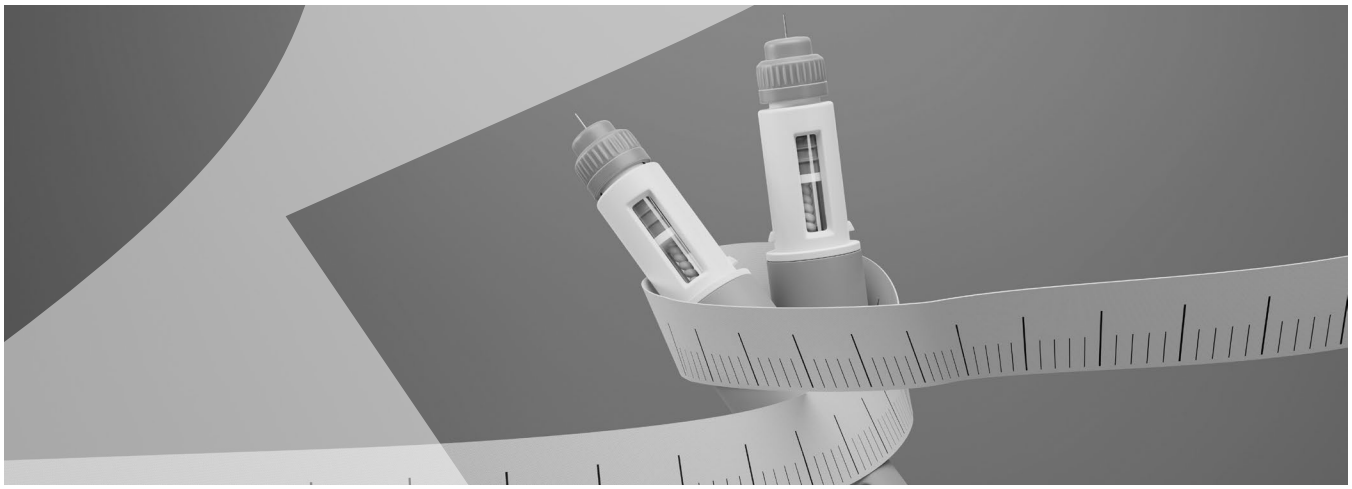
CMS has taken the position that statutory restrictions do not allow Medicare to cover AOMs, such as GLP-1 medications. The context of this statutory restriction is critical to understand why it does not, in fact, prohibit Medicare coverage of AOMs.

Because currently approved AOMs are self-administered, they are only eligible for coverage under Medicare Part D, Medicare's outpatient drug benefit offered by private stand-alone drug plans and Medicare Advantage plans, not Part B, which covers physician-administered drugs.

Section 1927(d)(2) of the Social Security Act (SSA) provides that drugs or classes of drugs when used for "anorexia, weight loss, or weight gain" may be excluded from coverage or otherwise restricted from Medicare Part B coverage.[11] In addition to weight loss drugs, this section excludes a select number of other medicines, including those used for "cosmetic purposes" or "symptomatic relief of cough and cold."[12] Congress relied on this Section regarding exclusions for Part B drugs when it established prescription drug coverage under Medicare (Part D), providing that a covered Part D drug does not include those which may be excluded or otherwise restricted under Part B.[13] During implementation of the Part D program, CMS stated in preamble to rulemaking that weight loss agents may be covered for the treatment of morbid obesity:

> Drugs that are excluded from coverage under Part D when used as agents for certain conditions may be considered covered when used to treat other conditions not specifically excluded by section 1927(d)(2) of the Act, provided they otherwise meet the requirements of section 1860D–2(e)(1) of the Act and are not otherwise excluded under section 1860D–2(e)(2)(B) of the Act. To the extent this is the case, and a drug is dispensed for a 'medically accepted indication' as described in the statute, weight loss agents may be covered for the treatment of morbid obesity...[14]

11 42 U.S.C. § 1396r—8(d)(2).
12 *Id.*
13 42 U.S.C. § 1395w-102.
14 CMS, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,194, 4,230 (Jan. 28, 2005, **https://www.govinfo.gov/content/pkg/FR-2005-01-28/pdf/05-1321.pdf 9** (emphasis added).



III. Landscape of Current Coverage Policies

Medicare Part D

In March 2024, CMS issued a memorandum (Part D AOM Guidance) stating that AOMs that receive FDA approval for an additional medically accepted indication can be considered for Part D coverage for that specific use.[15] As an example, the memorandum cites that a GLP-1 agonist that receives approval to treat diabetes or reduce the risk of a major cardiovascular event (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight, would then be considered a Part D drug for those specific uses only. However, CMS also stated that Part D coverage is still not available for AOMs when used for chronic weight management in patients who do not have the additional medically accepted indication.[16] This policy runs contrary to the statute, and to CMS's own acknowledgement that obesity is "not specifically excluded by Section 1927(d)(2) of the [Social Security] Act".[17]

Medicaid

States can decide to cover AOMs under Medicaid, leading to variation in coverage policies across states, and between Medicaid and Medicare beneficiaries. Under the Medicaid Drug Rebate Program, Medicaid programs must cover nearly all of a participating manufacturer's FDA-approved drugs for medically accepted indications. However, due to the provision in the SSA noted above, Medicaid programs may exclude or limit coverage for drugs when used for weight loss. According to a 2023 survey conducted by the Kaiser Family Foundation (KFF), 16 states provide coverage for some sort of AOMs.[18] Although state coverage of weight-loss drugs in Medicaid is limited, GLP-1 agonists that are approved to treat type 2 diabetes would typically be covered by Medicaid for treatment of type 2 diabetes.[19] According to another study, of 47 states with publicly available lists of preferred drugs, nine had Medicaid programs that covered Wegovy in the first quarter of 2023.[20]

Private Payors

Private payor coverage for AOMs also varies. A recent survey from the Pharmaceutical Strategies Group (PSG) found that 33% of health plans and employers provide coverage for GLP-1 medications for obesity and 91% cover them for type 2 diabetes.[21] An additional 19% of respondents said they were considering covering the drugs for obesity.[22] A recent survey conducted by the Business Group on Health found that a majority of the 125 large, self-insured employers surveyed reported that they would cover GLP-1 drugs for obesity in 2025.[23]

15 *See* CMS, HPMS E-Mail, *Part D Coverage of Anti-Obesity Medications with Medically Accepted Indications* (March 20, 2024), **https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-march-18-22**.
16 *Id.*
17 CMS, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,194, 4,230 (Jan. 28, 2005, **https://www.govinfo.gov/content/pkg/FR-2005-01-28/pdf/05-1321.pdf**.
18 Kaiser Family Foundation, *Medicaid Utilization and Spending on New Drugs Used for Weight Loss* (Sept. 8, 2023), **https://www.kff.org/policy-watch/medicaid-coverage-of-and-spending-on-new-drugs-used-for-weight-loss/**.
19 *Id.*
20 Benjamin Y. Liu and Benjamin N. Rome, *State Coverage and Reimbursement of Antiobesity Medications in Medicaid*, JAMA, vol. 331, no. 14, at pp. 1230–1232 (March 14, 2024), **https://doi.org/10.1001/jama.2024.30733**.
21 Pharmaceutical Strategies Group, *PSG Publishes Annual Drug Benefit Design Report for 2024* (June 11, 2024), **https://www.psgconsults.com/press-release/psg-publishes-annual-drug-benefit-design-report-for-2024/**; AIS Health, *PSG Survey Finds 33% of Health Plans, Employers Cover GLP-1s for Obesity* (July 3, 2024), **https://www.mmitnetwork.com/aishealth/spotlight-on-market-access/psg-survey-finds-33-of-health-plans-employers-cover-glp-1s-for-obesity-2/**.
22 *Id.*
23 Cathy Kelly, Pink Sheet, Citeline Regulatory, *Obesity Drugs Will Get Broad Commercial Coverage in 2025 Despite Cost Concerns, Survey Says* (Sept. 5, 2024).

IV. Costs Remain a Barrier to Coverage

Despite the clear benefits of covering AOMs for Medicare beneficiaries, concerns regarding high costs remain a barrier to coverage. Legislators and payors have expressed concern regarding the cost associated with covering AOMs for obesity. At a March 2024 presentation at the National Academies' Roundtable on Obesity Solutions, the Congressional Budget Office (CBO) estimated that at the current prices, AOMs would cost the federal government more than it would save from reducing other health care spending—which would lead to an overall increase in the deficit over the next 10 years.[24] However, the presentation acknowledged that the future price trajectory of AOMs is "highly uncertain."[25] CBO noted that the price of AOMs is likely to decrease because: (1) generic competition will be introduced into the market for semaglutide and tirzepatide; (2) new AOMs are expected to become available, which may improve upon existing formulations, such as by reducing side effects; and (3) CBO expects that semaglutide will be selected for price negotiation, which would lower its price (and potentially the prices of other drugs in the AOM class).[26]

In its October 8, 2024 Report to Congress, "How Would Authorizing Medicare to Cover Anti-Obesity Medications Affect the Federal Budget?" CBO explained that beyond 2034, the AOM policy's net federal costs to the Medicare program "would probably be lower on a per-user basis than in the first decade" because the costs of these drugs will fall over time, and the savings from improved health will grow over time.[27] CBO acknowledged that its estimates regarding potential savings were limited. Because "research about the effects of newer AOMs on health care spending is not yet available, given the recent approval of those drugs for weight-management indications," [28] CBO utilized sources with notable limitations to inform its predictions. To estimate savings from improved health stemming from AOM use, CBO reviewed evidence from observational studies that looked at the effects of bariatric surgery on health care related to spending and evidence of health care savings from AOM use by looking at microsimulation studies that have linked Body Mass Index (BMI) and health care spending.[29] CBO stated that "[o]ne limitation of the evidence from observational studies is that AOMs and bariatric surgery may have different effects on health."[30] For example, bariatric surgery patients can receive significant health benefits, but they can also develop both short- and long-term (and even lifelong) complications that may affect health care costs[31] (and obviously, their quality of life).

To determine the budget impact of AOMs, CBO relied, in part, on data that reference Quality-Adjusted Life Years (QALY) metrics.[32] However, the Affordable Care Act (ACA) explicitly prohibits the Medicare program from using QALYs or similar discriminatory measures to determine coverage, reimbursement, or incentive programs.[33] The QALY is a traditional health economics metric used to determine how "cost-effective" a drug is based on its success at lengthening and/or improving patient's lives.[34] The National Council on

24 Congressional Budget Office, *The Federal Perspective on Coverage of Medications to Treat Obesity; Considerations from the Congressional Budget Office* at 11 (Mar. 20, 2024), **https://www.cbo.gov/system/files/2024-03/60116-Duchovny.pdf**.
25 *Id.* at 14.
26 *Id.*
27 Congressional Budget Office, *How Would Authorizing Medicare to Cover Anti-Obesity Medications Affect the Federal Budget?* (Oct. 2024), **https://www.cbo.gov/system/files/2024-10/60441-medicare-coverage-obesity.pdf** [hereinafter "CBO October 2024 Report"].
28 *Id.* at 9.
29 *Id.* at 9-10.
30 *Id.* at 10.
31 *Id.*
32 *Id.* at 10-11.
33 42 U.S.C. § 1320e-1(e).
34 Institute for Clinical & Economic Review, *Cost-Effectiveness, the QALY, and the evLYG*, **https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/#:~:text=The%20quality%2Dadjusted%20life%20year,for%20more%20than%2030%20years**.

Disability, an independent federal agency, published a report on QALYs[35] that describes how QALY-type measurements place less value on the lives of people who are disabled, chronically ill or elderly than on the lives of those in good health, making them inherently biased.

A separate study estimated that the cost of treating obesity related conditions range from $147-$210 billion dollars per year.[36] It went on to state that obesity treatment has been shown to reduce morbidity and mortality "therefore, preventing or treating obesity would be very beneficial on both an individual and societal basis."[37] On average, a Medicare beneficiary with obesity incurs costs $2,505 more per year than a normal-weight beneficiary. Spending is higher for people with a higher BMI, in part because of their greater likelihood of having other chronic conditions. The prevalence of obesity among older individuals in the United States is growing at a linear rate and, if nothing changes, nearly one in two (47%) Medicare beneficiaries aged 65 and over will have obesity in 2030, up from slightly more than one in four (28%) in 2010.[38]

The KFF found that 3.6 million people with Medicare could be eligible for Wegovy, now that the FDA has approved its use to reduce the risk of heart attacks and stroke in certain patients and because CMS is allowing coverage for this indication.[39] This change in coverage would allow access to Wegovy for approximately 1 in 4 of the 13.7 million people on Medicare diagnosed with obesity or overweight, based on data from 2020.[40] Of these 3.6 million beneficiaries, 1.9 million also had diabetes (other than type 1) and may already have been eligible for Medicare coverage of GLP-1s as diabetes treatments prior to the FDA's approval of the new use of Wegovy.[41] Based on KFF's estimates, Medicare Part D spending could amount to $2.8 billion for one year for Wegovy alone.[42]

KFF notes that Medicare spending associated with expanded coverage of Wegovy depends on several unknown factors: plan utilization management restrictions; how many people who qualify will take it; and negotiated prices.[43] KFF has also stated that: "To the extent that access to medications reduces obesity rates among Medicaid enrollees, there could also be longer-term reductions in Medicaid spending on chronic diseases associated with obesity, such as heart disease, type 2 diabetes, and types of cancer."[44]

However, a study published by USC Schaeffer demonstrated that Medicare coverage of AOMs would result in a net savings to the program of $175-$245 billion in the first 10 years, assuming private insurers also cover AOMs, by reducing hospital inpatient care costs and the costs of skilled nursing care.[45] Further, because more patients would enter Medicare with fewer comorbidities if AOMs are available through private insurance, USC Schaeffer's model estimates that over 30 years the savings for Medicare would be approximately $1.5 trillion.[46]

Although it appears that coverage of AOMs will be a net economic benefit to the Medicare program, the SSA does not require a return on investment for CMS to cover a medication that beneficiaries need. CBO was merely charged with evaluating the costs of various illustrative policies related to coverage of AOMs—not what these policy decisions would mean for the health and quality of life of the Medicare beneficiaries. With this information in mind, the government should spend money on treatment of obesity through coverage of AOMs that improve beneficiary health outcomes, rather than spend what is estimated to be a similar amount of money on treating complications that arise as beneficiary health outcomes worsen.

35 National Council on Disability, *Quality-Adjusted Life Years and the Devaluation of Life with Disability* (Nov. 6, 2019), **https://www.ncd.gov/assets/uploads/reports/2019/ncd_quality_adjusted_life_report_508.pdf**.
36 Howard Rosen, *Is Obesity A Disease or A Behavior Abnormality? Did the AMA Get It Right?* Mo Med. 2014 Mar-Apr;111(2):104-108. PMID: 30323513; PMCID: PMC6179496, **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6179496/**.
37 *See id.*
38 Alison S. Ward, et al., *Benefits of Medicare Coverage for Weight Loss Drugs* (April 18, 2023), U.S.C. Schaeffer Center White Paper Series, DOI: 10.25549/4rf9-kh77, **https://healthpolicy.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/** (citing John Cawley, et al., *Direct Medical Costs of Obesity in the United States and the Most Populous States*, Journal of Managed Care and Specialty Pharmacy, 27 (3): 354-66 (2021)). *See also*, Etienne Gaudette et al., *Health and Health Care of Medicare Beneficiaries in 2030*, Forum Health Econ Policy. 2015 Dec;18(2):75-96. doi: 10.1515/fhep-2015-0037. Epub 2015 Nov 28. PMID: 27127455; PMCID: PMC4845680. *See also* CBO October 2024 Report, Fig. 1
39 Kaiser Family Foundation, *A New Use for Wegovy Opens the Door to Medicare Coverage for Millions of People with Obesity* (Apr. 24, 2024), **https://www.kff.org/medicare/issue-brief/a-new-use-for-wegovy-opens-the-door-to-medicare-coverage-for-millions-of-people-with-obesity/**.
40 *Id.*
41 *Id.*
42 *Id.*
43 *Id.*
44 Kaiser Family Foundation, *Medicaid Utilization and Spending on New Drugs Used for Weight Loss* (Sept. 8, 2023), **https://www.kff.org/policy-watch/medicaid-coverage-of-and-spending-on-new-drugs-used-for-weight-loss/**.
45 Alison S. Ward, et al., *Benefits of Medicare Coverage for Weight Loss Drugs* (April 18, 2023), U.S.C. Schaeffer Center White Paper Series, DOI: 10.25549/4rf9-kh77, **https://healthpolicy.usc.edu/research/benefits-of-medicare-coverage-for-weight-loss-drugs/**.
46 *Id.*

Cost Models Do Not Consider the Implications of the Inflation Reduction Act (IRA)'s Mandatory Coverage Provisions

The IRA Drug Price Negotiation Program allows CMS to negotiate prices for qualifying medications. There are two ways that the IRA could significantly affect pricing for AOMs soon. For example, CMS may select semaglutide for price negotiation that would be effective as early as 2026, based on the first FDA approval date of semaglutide. If CMS selects Wegovy for price negotiation on the basis of its approved indication to reduce the risk of cardiovascular disease, the IRA will require the drug to be added to all plan formularies. Specifically, the IRA provides that for 2026 and each subsequent year, Part D sponsors that offer a prescription drug plan must include each covered Part D drug that is a "selected drug" for price negotiation for which a maximum fair price is in effect with respect to the year.[47] This is to say, **selection of a GLP-1 for IRA price negotiation would automatically require Part D sponsors to add the drug to its formularies, in all of its formulations and across separate New Drug Application (NDA) filings including versions approved for obesity pursuant to CMS's own interpretation of the IRA. The IRA would therefore require coverage of all obesity indications of a "selected drug": there is no carve-out provision in the statute**. Part D sponsors still could apply utilization management restrictions to ensure compliance with labeling requirements, or place AOMs on nonpreferred tiers, but the drug must be available for coverage for its FDA-approved uses, and the price would be subject to CMS's negotiated price.

None of the published cost models for AOMs to date consider the impact of the IRA's impending price reductions. Keeping in mind that IRA's minimum reductions are a 25% reduction[48] of the drug's already discounted Non-Federal Average Manufacturer's Price (NFAMP)[49], the cost-benefit analysis will only improve over time in favor of coverage. Price reductions under IRA can go up to 40% of NFAMP and higher depending on the timing of the drug's initial approval by FDA and additional statutory factors that can be applied by CMS in further lowering the drug's price.

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47 42 U.S.C. § 1395w-104(b)(3)(I).
48 Inflation Reduction Act, codified at 42 U.S. Code § 1320f–3(c)(3)(A).
49 NFAMP is the average price paid by wholesalers for drugs that are distributed only to non-Federal purchasers, taking into account rebates, discounts or other price concessions. 38 U.S.C. § 8126(h)(5).

V. CMS May Currently Cover AOMs Under Medicare Part D

Although CMS has interpreted the SSA to prohibit Medicare Part D coverage for AOMs, CMS does—in fact—have the regulatory flexibility to cover AOMs under Medicare Part D without legislation. CMS could cover AOMs for the purpose of treating the medical condition of obesity, not for weight loss for cosmetic purposes. When Congress allowed medicines for weight loss to be excluded from Part B, and excluded them from Part D, the legislators intended to target the use of prescription medicines for weight loss for cosmetic purposes—not for treatment of obesity, which is a medical condition. Thus, CMS has now denied coverage for AOMs for obesity based on a false premise and an incorrect statutory interpretation.

CMS itself has taken this position. In 2005, CMS stated that: "[D]rugs are excluded from coverage under Part D when used as agents for certain conditions may be considered covered when used to treat other conditions not specifically excluded by section 1927(d)(2) of the Act" provided that they meet other requirements for coverage.[50] Critically, CMS went on to state that: "To the extent this is the case, and a drug is dispensed for a 'medically accepted indication' as described in the statute, weight loss agents may be covered for the treatment of morbid obesity..."[51]

Since the 1927(d)(2) statutory exclusion for weight loss was implemented, the understanding of obesity has significantly evolved in the medical community. The fact that obesity is a medical condition, which should be managed with medication, is now well-documented. Human genetics studies have found that DNA predisposes some individuals to develop obesity.[52] In 2004, the Department of Health & Human Services (HHS) recognized obesity as an illness.[53] Following the agency's reassessment of obesity in 2004, CMS issued a National Coverage Determination providing coverage for bariatric surgery under Medicare in 2006.[54] The American Medical Association (AMA) also recognized obesity as an illness in 2013,[55] and in 2023, affirmed its recognition of obesity as a disease that involves genetic, metabolic and behavioral aspects that require medical support.[56] There are numerous International Classification of Diseases (ICD) codes related to the treatment of obesity and BMI.[57]

A 2019 study concluded that "obesity may be viewed as a multifactorial pathology and chronic low grade inflammatory disease."[58] Further, it found that people affected by obesity had a greater risk of developing comorbidity and morbidity.[59] A 2014 study described obesity as a "significant public

50 CMS, Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,194, 4,230 (Jan. 28, 2005, **https://www.govinfo.gov/content/pkg/FR-2005-01-28/pdf/05-1321.pdf**.
51 *Id.*
52 Ruth J. F. Loos & Giles S.H. Yeo, *The Genetics of Obesity: From Discovery to Biology*, Nature Review Genetics (Sept. 23, 2021), **https://www.nature.com/articles/s41576-021-00414-z**.
53 CMS removed language stating that "obesity is not an illness" from its *Coverage Issues Manual*, which removed a significant obstacle to further progress coverage for obesity-related medical services. CMS, National Coverage Analysis (NCA) Tracking Sheet for Obesity as an Illness (CAG-00108N) (2004), **https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=57&TAId=23&IsPopup=y&bc=AAAAAAAAAgAAAA%3D%3D&**.
54 CMS, Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity (CAG-00250R) (2006), **https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=160&ver=32&NcaName=Bariatric+Surgery+for+the+Treatment+of+Morbid+Obesity+(1st+Recon)&bc=BEAAAAAAEAgA**.
55 American Medical Association, Recognition of Obesity as a Disease (Resolution 420) (2013), **https://media.npr.org/documents/2013/jun/ama-resolution-obesity.pdf**.
56 American Medical Association, Recognition of Obesity as a Disease H-440.842 (2023), **https://policysearch.ama-assn.org/policyfinder/detail/obesity?uri=%2FAMADoc%2FHOD.xml-0-3858.xml**.
57 E.g., ICD-10-CM E66.01 (morbid (severe) obesity caused by excess calories); ICD-10-CM E66.8 (other obesity); ICD-10-CM E66.9 (obesity, unspecified); ICD-10-CM E663 (overweight).
58 Antonio De Lorenzo, et al. *Why primary obesity is a disease*? J. Transl. Med. 17 169 (2019), **https://doi.org/10.1186/s12967-019-1919-y**.
59 *Id.*

health hazard" which increases the risks for diseases such as type 2 diabetes, cardiovascular disease, hyperlipidemia, hypertension, stroke, breast and colon cancer, and degenerative arthritis.[60]

Congress excluded drugs for "anorexia, weight gain, or weight loss" in the context of high rates of use of certain medicines for cosmetic weight loss. CMS coverage of GLP-1 medications for cosmetic weight loss would not be permissible or appropriate. However, treatment for obesity, in accordance with the FDA-approved label for GLP-1 medications, falls outside the scope of the statutory exclusion, and may be covered. For example, Wegovy is a GLP-1 receptor agonist indicated, in part, to reduce excess body weight and maintain weight reduction long term in: (1) adults and pediatric patients aged 12 years and older with obesity; and (2) adults with overweight in the presence of at least one weight-related comorbidity.[61] **Wegovy and other AOMs are not indicated for use for cosmetic purposes**, and do not carry the same health risks as those medications that initially spurred Congress to allow for exclusion of weight loss medications. **Use of AOMs for cosmetic purposes to "lose a few pounds," would be an off-label use of the drug and would continue to be excluded from coverage by CMS.**

60 Howard Rosen, *Is Obesity A Disease or A Behavior Abnormality? Did the AMA Get It Right?* Mo Med. 2014 Mar-Apr;111(2):104-108. PMID: 30323513; PMCID: PMC6179496, **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6179496/**.
61 Wegovy, Highlights of Prescribing Information (Initial U.S. Approval: 2017; Revised: 2024), **https://www.novo-pi.com/wegovy.pdf**.

VI. Following the *Loper Bright* Decision, CMS Must Revert to Its Original Interpretation of the SSA and Allow for Coverage of AOMs

On June 28, 2024, the United States Supreme Court decided *Loper Bright Enterprises v. Raimondo*, overturning the longstanding doctrine known as "*Chevron* deference."[62] *Chevron* deference provided that so long as an agency's interpretation of an ambiguous or unclear statutory provision was "reasonable," it was "entitled to deference."[63] This doctrine only applied in the narrow situation in which a court disagreed with an agency's statutory interpretation that the court determined was nevertheless "reasonable." In the *Loper Bright* decision, the Supreme Court held that even when a "statute [is] ambiguous, there is a best reading all the same."[64] The reviewing court must adopt the reading that the court "concludes is best" "after applying all relevant interpretive tools."[65] Contrary to *Chevron*, *Loper Bright* found that resolving statutory ambiguities requires only expertise in textual interpretation (which courts do have), not expertise in a specialized subject matter. As such, *Loper Bright* tightens the reins on agency flexibility and authority to interpret statutes that are "silent or ambiguous" regarding certain issues.

In light of *Loper Bright*, CMS must revert to the interpretation the agency originally provided in 2005 during implementation of the SSA provision. CMS's interpretation at that time considered the purpose and context of the exclusions—for such things as cosmetic uses—and reasoned that coverage of medications for uses such as morbid obesity would be permissible. This interpretation is arguably the "best reading" of the statute, and the one that remained in place until AOMs ushered in a new wave of policy considerations and potential costs for the Medicare program. In the face of this change, CMS reversed its stance and issued a new statutory interpretation—that the provision prohibits coverage of AOMs. The statute and the use that CMS analyzed (obesity) did not change during this time. The only change is that now, at last, there are medications that can treat obesity. The agency's assumed flexibility to reverse policies is impermissible under *Loper Bright*.

62 *Loper Bright Enters. v. Raimondo*, No. 22-4751, 2024 WL 3208360 (U.S. June 28, 2024) [hereinafter "*Loper Bright*"].
63 *Chevron, U.S.A. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 865-66 (1984).
64 *Loper Bright* at 16.
65 *Id.*

VII. CMS Should Issue Updated Guidance to Allow Part D Plans to Cover AOMs

Keeping this regulatory flexibility in mind and the requirements of the statute, CMS should issue updated guidance regarding coverage for AOMs. Issuance of sub-regulatory guidance such as the Part D AOM Guidance did not require notice-and-comment rulemaking, and CMS could exercise its discretion to update its policy and revert to its 2005 interpretation of the law as set forth in the preamble to its formal regulations.

As noted in CMS's Part D AOM Guidance, CMS can direct Part D sponsors to require coverage of AOMs for obesity and prohibit any off-label use for cosmetic weight loss.[66]

66 *Id.*

VIII. Proposed Legislation

While the agency has the authority and discretion to cover AOMs without legislation, Congressional action to clarify intent around Medicare coverage of AOMs can both expand access and ensure the agency is operating on firm legal ground. Several legislators understand that Medicare coverage for AOMs for obesity is urgently needed in the interest of the Medicare population's health and have proposed legislation to explicitly permit CMS to cover AOMs.

For example, The Treat and Reduce Obesity Act of 2023 (H.R. 4818) (TROA) would amend the SSA by providing that drugs used for the treatment of obesity or for weight loss management for an individual who is overweight and has one more related comorbidities may not be excluded from coverage under Medicare Part B, and thus would not be excluded under Medicare Part D.[67]

The House Ways and Means Committee cleared a trimmed down version of TROA which would authorize Medicare Part D plans to cover obesity drugs for new enrollees who had commercial coverage for the treatments in the year prior to aging into the program.[68] While commercial coverage for AOMs is increasing, it is certainly not guaranteed. This version of TROA would narrow the window for Medicare Part D coverage significantly compared to the original version and set a precedent for potentially limiting future prescription drug coverage predicated on pre-Medicare use.

67 Treat and Reduce Obesity Act of 2023, H.R. 4818, Sec. 4.

68 House of Representatives, Ways & Means Committee, Explanation of Changes Reflected in the Chairman's Amendment in the Nature of a Substitute to H.R. 4818, *Treat and Reduce Obesity Act* (June 27, 2024), **https://waysandmeans.house.gov/wp-content/uploads/2024/06/Ways-and-Means-Description-of-the-AINS-to-H.R.-4818-Green-Sheet.pdf**.

IX. Conclusion

The approvals of AOMs for the treatment of obesity have transformed medical care for those who struggle with obesity and related conditions. The Medicare population deserves equitable access to these potentially life-saving medications, and this report clearly outlines that CMS has the authority to cover AOMs for beneficiaries who need them. Although there is much discussion of these types of medicines for cosmetic weight loss, CMS coverage of AOMs would only be for on-label uses (i.e., obesity) and have the potential to vastly transform the long-term health and quality of life for millions of Americans. It is true that the estimated costs of coverage of these medicines are significant, but use of traditional cost-effectiveness measures is banned in the Medicare program and cost is also not a statutory prerequisite for Medicare coverage. There are additional significant gaps in the literature that make calculating the true costs and cost-savings resulting from AOM coverage challenging to determine. These costs also do not dwarf amounts spent on other chronic conditions. CMS should prioritize the health of the Medicare population by spending money on treating the root cause of obesity and other related conditions, rather than spending those funds on treatment for health complications for those suffering from obesity as they age. Fortunately, CMS already has the statutory authority to implement this policy.

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