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Anti-Obesity Medications as Medicare Part D Drugs

Legal and Health Policy Rationales

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Table of Contents

Executive Summary

Obesity is a complex, multifactorial disease that has serious health consequences, affects millions of Americans and drives hundreds of billions of dollars in annual health care spending. Scientific understanding of the nature of obesity has evolved over the course of the past several decades. It is now clinically recognized that obesity is a *disease*, not simply a cosmetic concern or issue of personal behavior. We now have a much greater understanding of obesity's various metabolic implications and direct links to cardiovascular disease, type 2 diabetes, liver disease and certain types of cancer, among other diseases. Multiple prescription medications have been developed, approved and recognized as safe and effective for long-term use in treating obesity. However, the Centers for Medicare & Medicaid Services (CMS) has historically prohibited coverage of these drugs under Medicare Part D, citing a decades-old federal statute excluding "agents when used for anorexia, weight loss, or weight gain" (the Statutory Exclusion). A new generation of drugs, commonly referred to as "GLP-1 agonists" (GLP-1s) have demonstrated significant efficacy in treating the disease of obesity and its well-known comorbidities. These are not the "weight loss drugs" of the past; instead, this class of drugs should be referred to as "anti-obesity medications" (AOMs). This paper summarizes the legal and policy rationales for CMS to alter its interpretation and concludes that the Statutory Exclusion does not prevent Part D coverage of AOMs. Put simply, obesity treatment, including use of AOMs, is not treatment solely for weight loss and the Statutory Exclusion need not prevent Part D coverage of AOMs on the basis of their weight loss properties. By both recognizing obesity as a complex chronic disease and describing AOMs as agents targeting obesity, rather than describing each solely in terms of effect on weight, CMS could interpret the Statutory Exclusion to reflect modern clinical understanding and not to preclude Part D coverage of AOMs. Doing so would align CMS policy with advances in pharmacology, clinical treatment guidelines and the Biden Administration's policy priorities.

Revising CMS's Interpretation to Characterize Obesity More Accurately as a Disease Would Provide CMS With Flexibility to Cover AOMs Under Part D

CMS characterizes obesity predominantly in terms of an individual's weight and maintains that drugs for obesity treatment are not covered by Medicare because they remain "agents…used for weight loss" subject to the Statutory Exclusion.[1] In contrast, various federal agencies, including the U.S. Centers for Disease Control and Prevention (CDC), in addition to leading professional medical societies, agree that obesity should be treated as an independent disease state, which is characterized by adipose tissue buildup and other metabolic implications (see Figure 1).[2] In conflating all drugs for obesity treatment with drugs for "weight loss," CMS disregards the metabolic implications of obesity and the ability of AOMs to treat obesity, unnecessarily rendering AOMs as non-covered under Part D. In addition, to reflect the current scientific and medical consensus around obesity as an independent disease state, the U.S. Food and Drug Administration (FDA) should update its governing 2007 guidance document on obesity drug development,[3] which uses outdated and stigmatizing language focusing on "weight management," even though the guidance's conceptual and scientific principles reflect the need to assess obesity and all of its metabolic implications

and comorbidities. In July 2023, FDA announced its intention to update this guidance.[4] In recognition of the roadblock to addressing obesity posed by CMS's interpretation, Congress has repeatedly expressed support for reinterpreting the Statutory Exclusion not to preclude Part D coverage of AOMs, thereby improving access to obesity care.

Figure 1: Federal Agencies Indicating a Modern Understanding of Obesity

Agency	Guidance/Position
U.S. Centers for Disease Control and Prevention	"Obesity is a common, serious, and costly chronic disease of adults and children."
National Institutes of Health	"Obesity is a complex multifactorial chronic disease that develops from an interaction of genotype and the environment."
U.S. Office of Personnel Management	"Long recognized as a disease that impacts children and adults in the U.S., obesity is a complex, multifactorial, common, serious, relapsing, and costly chronic disease that services as a major risk factor for developing conditions such as cardiovascular disease, type 2 diabetes, renal disease, non-alcoholic steatohepatitis, and certain types of cancer."
U.S. Department of Defense and U.S. Department of Veterans Affairs	"The epidemic of overweight and obesity is one of the most significant problems facing the United States (U.S.) healthcare system today. …Overweight and obesity are associated with increased prevalence and worsening of several obesity associated conditions, including type 2 diabetes mellitus (T2DM), hypertension (HTN), dyslipidemia, metabolic syndrome, osteoarthritis, and obstructive sleep apnea (OSA)."
U.S. Social Security Administration	"Obesity is a complex, chronic disease characterized by excessive accumulation of body fat. Obesity is generally the result of a combination of factors (e.g., genetic, environmental, and behavioral)."

Changing CMS's Interpretation of the Statutory Exclusion Would Be Consistent With CMS's Precedents

CMS has previously modified its interpretation of the Statutory Exclusion to permit coverage of Serostim, a drug used to treat wasting/cachexia resulting from acquired immunodeficiency syndrome (AIDS) by increasing the patient's weight but has, to date, declined to interpret the Statutory Exclusion to permit coverage of AOMs under analogous circumstances. Serostim is indicated to treat HIV patients with wasting or cachexia—a contributing factor in the death rate of patients with AIDS—"to increase lean body mass and body weight, and improve physical endurance."[5] CMS initially considered Serostim as subject to the Statutory Exclusion, only later declaring that drugs used to treat AIDS wasting/cachexia were not considered agents used for weight gain.[6] Consistent application of the Serostim coverage precedent would enable Part D coverage of AOMs by recognizing that these drugs treat the life-threatening disease of obesity, both by producing significant weight loss and with top-line results demonstrating reduction in risk of major

adverse cardiovascular events.[7] Especially with recently announced evidence of cardiovascular benefit, CMS can directly apply the same rationale for reinterpretation of coverage for anti-obesity medications that it applied to Serostim.

Significant Improvements in Safety and Effectiveness of New Generation of AOMs Distinguish Them From Previous Weight Loss Drugs

A new class of medicines to treat obesity, GLP-1s, has emerged that improves upon the previous generation of weight loss therapies, many of which were developed prior to 1990 and had been withdrawn due to safety concerns. In addition to producing significant weight loss, these new GLP-1s have been demonstrated to result in improvements in metabolic processes affected by obesity and demonstrable reduction in risk associated with other linked diseases, including diabetes and heart disease.[8] FDA Commissioner Robert Califf has characterized this class of medicines as "the beginning of a revolution in the way that we control weight, not just with the pills, but because we'll understand the biological mechanisms better."[9] Coverage of and reimbursement for this new generation of AOMs prescribed for medically necessary treatment can help patients achieve better health outcomes and produce savings to health care systems. In light of evidence supporting AOMs' clinical impact and detailing barriers to accessing obesity treatment, there is little clinical basis to single out this class of drugs for exclusion from the Part D program.

CMS's Formal Recognition of Obesity as a Disease and Its Coverage of AOMs Would Allow Medicare Beneficiaries to Access Clinical Guidelines-Recommended Treatment

Clinical guidelines recommend the use of AOMs adjunctively to lifestyle, behavioral and surgical obesity interventions, depending on a patient's personalized obesity treatment plan.[10] Incorporation of AOMs into clinical practice is attributable, at least in part, to research demonstrating that adding AOMs to such interventions produces greater weight loss and maintenance of weight loss than non-pharmacologic interventions alone.[11] FDA's guidance for drug developers recognizes the complexity of obesity as chronic and relapsing and urges manufacturers to study drugs to treat it not only for their impact on reduction in weight but also on other metabolic parameters, such as blood pressure and lipid levels.[12] In recognition of such advances, Congress has urged CMS to clarify that the Statutory Exclusion does not include AOMs approved by FDA.[13] However, AOMs remain non-covered, and the scope of lifestyle, behavioral and surgical obesity interventions covered by Medicare remains narrow; Medicare does not cover these treatment modalities unless beneficiaries satisfy various preconditions, and contrary to clinical guidelines, Medicare does not allow for the use of AOMs to supplement covered interventions.[14] This has led to substantially limited uptake of such treatment modalities and indicates the need for expanded access to them and to AOMs as additional covered obesity treatment options.[15] The exclusion of AOMs from Part D supplants the judgment of medical professionals, stripping providers of their ability to prescribe appropriate treatments consistent with clinical guidelines.

Removing Prohibitions on Part D Coverage of AOMs Would Aid in Achieving the Goals of the President's "National Strategy on Hunger Nutrition, and Health," Health Equity, and the Cancer Moonshot

In September 2022, President Biden issued the "Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health," which set forth a bold goal of "ending hunger and increasing healthy eating and physical activity by 2030 so fewer Americans experience diet-related diseases—while reducing related health disparities."[16] Earlier in 2022, President Biden also relaunched the 2016 Cancer Moonshot with a goal of reducing the cancer death rate by half within 25 years and improving the lives of people with cancer and cancer survivors.[17] Ending Part D's exclusion of AOMs from coverage is a critical step to take in meeting these goals. Obesity and its related comorbidities disproportionately affect Black, Latino and socioeconomically disadvantaged populations. Furthermore, obesity increases the risk of certain cancers, with disparate impacts by race and ethnicity.[18] Ending Part D's exclusion of AOMs from coverage would enable providers to better tailor obesity treatments to patient needs, resources and preferences. This would improve Medicare beneficiaries' access to effective obesity treatments, helping address health disparities and combat obesity-linked cancers.[19]

Cost-Related Policy Challenges in Covering AOMs Can Be Addressed with Utilization Management

Even if CMS interprets the Statutory Exclusion to permit coverage of AOMs, state Medicaid programs and Medicare prescription drug plan sponsors would still be able to employ various cost containment measures, including but not limited to prior authorization and medical necessity determinations, to ensure that beneficiaries are able to access AOMs when appropriate, while restricting inappropriate utilization.

I. Introduction

Obesity is a serious chronic disease caused by multiple biological, genetic, behavioral and environmental factors. One of the most significant barriers to accessing effective obesity treatments is the lack of coverage for pharmacologic interventions. Federal health care program coverage for obesity treatments is severely limited, and most notably, Medicare outpatient drug coverage (Part D) of drugs to treat obesity is nonexistent. In contrast, some states' Medicaid programs and various federal agencies, including the U.S. Office of Personnel Management, the U.S. Department of Defense and the U.S. Department of Veterans Affairs (VA), have used their discretion to provide partial or full coverage of certain pharmacologic interventions for the treatment of obesity.[20]

Rates of both adults and children living with obesity in the United States have grown significantly over the past two decades, resulting in substantial economic impacts and excess health care spending. The prevalence of American adults with obesity increased from 30.5% of adults in 1999 to 41.9% of adults in 2020, and the prevalence of American adults with severe obesity has also increased, from 4.7% to 9.2%, during the

same period.[21] According to the CDC, obesity affects 100.1 million adults (41.9%) and 14.7 million children (19.7%) and accounts for $147 billion in health care costs annually.[22] Obesity affects certain racial groups more than others; non-Hispanic Black adults (49.9%) had the highest age-adjusted prevalence of obesity, followed by Hispanic adults (45.6%), non-Hispanic White adults (41.4%) and non-Hispanic Asian adults (16.1%).

Among the Medicare fee-for-service population, approximately 21% of beneficiaries had a diagnosis of obesity in 2019, up from 6.2% in 2010.[23] These trends are especially worrisome because obesity has long been recognized as negatively impacting individual health in a variety of ways, such as by causing heart disease and stroke, type 2 diabetes, certain cancers and various digestive problems.[24] The economic cost of obesity-linked chronic diseases was an estimated $1.72 trillion in 2016 (9.3% of the gross domestic product), including $480.7 billion in direct health care costs and $1.24 trillion in indirect costs resulting from lost economic productivity.[25] Recent estimates of the annual direct cost of obesity alone to the U.S. health care system range from $147 billion to over $260 billion.[26] However, improving access to more effective treatments for obesity has the potential to save the federal government roughly $66 billion over ten years and $293 billion over 75 years.[27]

Improving access to the full array of obesity treatments would allow providers and patients to better adhere to clinical guidelines for treating obesity, which embrace a combination, as necessary, of behavioral and other lifestyle, pharmacologic and surgical interventions.[28] The recent emergence of GLP-1s, with striking data demonstrating their superior effectiveness and safety over previous generations of drugs used to treat obesity, represents a revolution in how we understand and treat the disease of obesity. Such drugs are properly conceived of as "anti-obesity medications" (AOMs) and not simply drugs for "weight management." This terminology recognizes that the disease of obesity is characterized by a range of causes and symptoms, and not exclusively weight. These recent and substantial advances in developing effective and safe AOMs have led to clinical consensus on incorporating AOMs as a key tool for personalized obesity treatment. One study estimates that widespread adoption of AOMs, facilitated by increased payor coverage, could save the United States approximately $750 billion over 75 years, with substantial savings accruing to both the Medicare and Medicaid programs.[29] Nevertheless, CMS has resisted calls from researchers, clinicians, advocates, patients and manufacturers to treat coverage of AOMs differently than that of "drugs for weight loss." This policy runs counter to the recommended care guidelines for treating obesity, which recognize the value of recently developed AOMs in treating obesity.

CMS has opted to interpret a statutory provision that excludes from Part D coverage "agents when used for anorexia, weight loss, or weight gain" (the Statutory Exclusion) to foreclose coverage of AOMs.[30] This white paper will present both legal and policy arguments in favor of CMS reconsidering its interpretation of the Statutory Exclusion. First, CMS has administrative flexibility to adopt an alternative interpretation of the statute that would not preclude Part D coverage of AOMs. Such an interpretation should be rooted in recognition of obesity as a multifaceted chronic disease and of AOMs as agents that target that disease. Obesity is not characterized solely by weight and AOMs are not "weight loss" agents as contemplated under the Statutory Exclusion. Second, reinterpreting the Statutory Exclusion to permit coverage of AOMs would align with advances in pharmacology, clinical recommendations for comprehensive obesity treatment and the Biden Administration's current health policy priorities.

II. Legal Basis for CMS to Reconsider Its Interpretation of the Statutory Exclusion

CMS could recognize that AOMs for the treatment of obesity are legally distinct from agents used for weight loss subject to the Statutory Exclusion. In light of (i) today's widespread scientific and medical consensus that obesity itself is a disease state with multiple physiological components and effects, and that AOMs represent a revolution in treatment of the disease of obesity, and (ii) CMS's interpretation of the Statutory Exclusion in other contexts, the current interpretation of the Statutory Exclusion as precluding Part D coverage of AOMs is best viewed as a *policy* choice, not a statutory mandate.

A. More Accurately Characterizing Obesity as a Disease State Would Permit CMS to Cover AOMs Under Part D

In categorizing AOMs as subject to the Statutory Exclusion for Part D coverage purposes, CMS contends that the categorization is controlled by the fact that AOMs cause weight loss, not that they treat the disease of obesity. Focusing on the metabolic, pathological and physiologic effects of obesity would more accurately describe the disease and its treatment and distinguish AOMs from "agents…when used for…weight loss."

Numerous federal agencies and medical experts consider obesity to be an independent, complex disease state. However, CMS characterizes obesity almost exclusively in terms of weight and considers AOMs uniformly as "agents…used for…weight loss" necessarily subject to the Statutory Exclusion. Accordingly, CMS has resisted making corresponding changes both to its description of obesity and to Part D coverage of AOMs validly prescribed to treat obesity. By refusing to align its interpretation of the Statutory Exclusion with medical and scientific consensus and with the consensus of other federal agencies, CMS relies on an outdated conception of obesity as justification for its Part D coverage policy.

Several federal agencies have expressly recognized obesity as a complex disease not merely characterized by an individual's weight. The National Institutes of Health (NIH) has recognized obesity as a disease since 1998, when NIH Clinical Guidelines first stated that "obesity is a complex, multifactorial chronic disease developing from interactive influences of numerous factors—social, behavioral, physiological, metabolic, cellular, and molecular" and outlined related clinical recommendations for the treatment of obesity.[31] This pronouncement was followed in 2002 by an Internal Revenue Service ruling that permitted programs that are part of the treatment for obesity to be tax deductible, noting that "obesity is medically accepted to be a disease in its own right," citing the NIH guidelines and distinguishing obesity treatments from weight control programs intended "to improve the taxpayer's appearance, general health and sense of well-being, and not to cure a specific ailment or disease."[32] In the same year, the Social Security Administration (SSA) stated that "obesity is a complex, chronic disease characterized by excessive accumulation of body fat" and deemed it

a medically determinable impairment (MDI) for the purpose of evaluating Social Security disability claims.[33] These federal policies lent credence to the now-predominant view that obesity is a disease characterized not only by an individual's weight but also by metabolic and physiologic functions.

Conversely, CMS has only tacitly recognized obesity as a disease and has refused to end Part D's prohibition on coverage of AOMs proven effective in treating obesity because CMS views AOMs as "agents…used for weight loss." In 2004, CMS removed the statement that "obesity is not an illness" from its Coverage Issues Manual (for coverage under Medicare Parts A and B) but maintained that "treatments for *obesity alone* remained non-covered" and "program payment may not be made for treatment of obesity unrelated to…a medical condition since treatment in this context has not been determined to be reasonable and necessary."[34] CMS viewed treatment for obesity as only reasonable and necessary when such treatment targeted medical conditions such as hypothyroidism, Cushing's disease, hypothalamic lesions, cardiac and respiratory diseases, diabetes, or hypertension; treatments for obesity alone were not reasonable or necessary because CMS still conceived of obesity as a condition of weight rather than a disease in its own right with metabolic and physiologic causes and effects.

CMS's position on AOMs was crystalized in 2006 with implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which authorized coverage of outpatient prescription drugs through Part D but excluded from Part D coverage certain classes of drugs. The Part D statute, in defining a "covered Part D drug," states that "[s]uch term does not include drugs or classes of drugs, or their medical uses, which *may be excluded* from coverage or otherwise restricted under section 1927(d)(2)…."[35] Section 1927(d)(2) is a provision within the Medicaid statute that was enacted in 1990 and permitted states to exclude certain drugs from coverage under their outpatient prescription drug benefit. In 1990, that category of drugs included only "agents when used for anorexia or weight gain."[36] In 1993, that same provision was amended to add "weight loss" to the list of potential, but not mandatory, exclusions.[37] Thus, the Part D statutes make mandatory the exclusion of certain classes of drugs that states' Medicaid agencies are given the option to exclude. Leveraging this mandatory exclusion language, CMS elaborated on its interpretation of the Statutory Exclusion in a 2007 proposed rule by clarifying that even drugs used "for the treatment of [severe] obesity are not Part D drugs…because…they nevertheless remain agents for anorexia, weight loss, or weight gain."[38]

As described by the Cleveland Clinic, severe obesity, formerly called "morbid" obesity, "is considered a disease and is often associated with other chronic health conditions."[39] Nonetheless, CMS's black-and-white Part D coverage policy precludes coverage of AOMs even when they are used for purely medical purposes, such as treating severe obesity.[40] By refusing to affirmatively recognize obesity as a disease, and by characterizing obesity treatments solely in terms of their weight loss effects, CMS mischaracterizes both the true nature of the disease of obesity and the role of AOMs.

Treating obesity as a disease would permit CMS to distinguish AOMs from agents used for cosmetic weight loss. Supported by substantial medical evidence regarding the health effects of adipose tissue buildup associated with obesity, CMS could leverage this differentiation as a basis for reinterpreting the Part D prohibition to permit coverage of AOMs.

Experts agree that what is reflected in CMS's current policies fails to focus on obesity as a serious disease that causes adipose tissue buildup and other metabolic effects. The American Medical Association's (AMA) 2013 declaration summarized the medical community's understanding of obesity by "recogniz[ing] obesity as a disease state with multiple pathophysiological aspects requiring a range of interventions to advance obesity treatment and prevention."[41] This declaration came after decades of gradual inclusion of obesity-related conditions and obesity treatments into medical, public health and coverage guidelines.

Following the AMA's statement, some professional societies began to use the term Adiposity-Based Chronic Disease (ABCD), which characterizes obesity more precisely in terms of the total amount, distribution and function of adipose tissue, and their associated health complications. Public embrace of this approach to describing obesity's features beyond those dictated by weight, if not the term "ABCD" itself, helped improve recognition of obesity as a true health concern rather than a cosmetic issue.[42] In 2017, the American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) stated that the diagnostic term ABCD "explicitly identifies a chronic disease, alludes to a precise pathophysiologic basis and avoids the stigmata and confusion related to the differential use and multiple meanings of the term 'obesity.'"[43] The CDC also called attention to the physiologic effects of obesity, stating that "obesity can cause changes in the body…includ[ing] long-lasting inflammation and higher than normal levels of insulin, insulin-like growth factor, and sex hormones. The risk of cancer increases with the more excess weight a person gains and the longer a person is overweight."[44]

Using such detailed descriptors of obesity illuminates the differences between cosmetic weight loss and treatment of obesity as a disease, and goes to the core of how AOMs have been developed and the clinical indications for which AOMs are used.[45] Adipose tissue is dynamic and metabolically active; it can stimulate endocrine and immune responses.[46] AOMs concentrate their effects on various metabolic processes causing or impacted by adipose tissue buildup, not just on weight loss; in particular, GLP-1s stimulate adipose tissue and regulate hormone imbalances that contribute to and are further impacted by obesity.[47]

CMS can heed the advice of NIH, SSA, AMA, AACE/ACE and the CDC, among other interest groups, professionals, and health and medical societies, by distinguishing between the use of a drug for treating the disease of obesity and a drug "*used for*…weight loss" without targeting a disease state. By adopting descriptors focusing on pathological and metabolic impacts of obesity, CMS could interpret the Statutory Exclusion not to apply to AOMs. This would align CMS's Part D coverage policies with the prevailing medical understandings of obesity and the actual role of AOMs in comprehensive, evidence-based obesity treatment.

FDA Is Reconsidering Its 2007 Draft Guidance for Industry, "Developing Products for Weight Management"

Federal guidance from FDA describes how AOMs should be part of a comprehensive obesity treatment strategy that extends beyond mere weight loss. FDA guidance to the pharmaceutical industry titled "Developing Products for Weight Management" recommends that manufacturers evaluate the effectiveness of AOMs on "[s]econdary efficacy endpoints" (i.e., changes in metabolic parameters), in addition to weight loss, in order for drugs to be considered for "chronic weight *management*" clinical indications.[48] "Secondary efficacy endpoints" refer to, at a minimum, "changes in the following metabolic parameters: [b]lood

pressure and pulse[, l]ipoprotein lipids[, f]asting glucose and insulin[,] HbA1c (in type 2 diabetics)[, and w]aist circumference,"[49] measurements of which evaluate AOMs' favorable impact on cardiometabolic parameters and thereby distinguish such AOMs from mere cosmetic weight loss drugs.

FDA announced in July 2023 it intends to update this guidance,[50] which was issued more than 15 years ago and does not fully reflect the scientific consensus that obesity is an independent disease, and take into account the newest generation of AOMs. This 2007 guidance uses outdated terminology by describing the products under the guidance as drugs for "weight management." Additionally, the guidance refers to obesity as a "chronic, relapsing health risk" instead of as a disease, which would be more consistent with the views of other federal agencies and the broader scientific community. The 2007 guidance also relies heavily on the body mass index (BMI) measurement to describe the target population for inclusion in clinical trials for such "weight management" products. BMI has recently been acknowledged by the AMA to have a "problematic history" and to be an "imperfect way to measure body fat in multiple groups" as it fails to account for "differences across race/ethnic groups, sexes, genders, and age-span."[51] The AMA's position is supported by a growing body of evidence demonstrating the numerous limitations of using BMI as a measurement to determine obesity.[52]

The use of the language of "weight management" also contributes to obesity stigma based on the misconception that the disease is one that is easily controlled simply by making changes to diet and physical activity and faulting individuals for failing to "manage" their "weight."[53] At a time when more than 40% of the U.S. population has obesity, FDA should ensure that its guidance documents reflect the latest science and disease terminology. Although not required to facilitate CMS action, FDA's updating the 2007 guidance would also help demonstrate to CMS that the latest generation of anti-obesity drugs are far more than drugs for "weight loss" and can save lives by treating the disease of obesity.[54]

B. CMS's Current Interpretation of the Statutory Exclusion Conflicts With Its Prior Decisions

In a coverage decision involving the AIDS wasting drug, Serostim, CMS previously interpreted the Statutory Exclusion to permit coverage of an agent that treated a disease but impacted weight. Engaging in a similar reinterpretation of the Statutory Exclusion in the context of AOMs used to treat obesity would both more accurately characterize AOMs and be more consistent with CMS's historical approach to the statutory text.

Prior to 1999, the Texas Medicaid program had opted to deny Medicaid coverage for Serostim on the basis of the U.S. Health Care Financing Administration's (HCFA, now called CMS) determination that is was a cosmetic treatment used for weight gain.[55] Serostim is a drug that is indicated to treat AIDS wasting/cachexia—the involuntary, unplanned loss of weight that is associated with increased morbidity and mortality[56]—by increasing "lean body mass and body weight."[57] Under Section 1927 of the Social Security Act, the Medicaid statute that serves as the basis for the Statutory Exclusion, state Medicaid agencies could (and still have flexibility to) choose whether or not to cover "agents when used for…weight gain."[58] After significant public pressure by AIDS advocacy groups and "discussions with the [FDA],"[59] which included a letter from FDA

affirming approval of Serostim for the treatment of AIDS wasting,[60] HCFA recognized Serostim's clinical benefits against AIDS wasting and revised its coverage policy to *require* state Medicaid programs to cover Serostim.[61]

This coverage decision is significant because, as noted above, Serostim is indicated for the treatment of AIDS patients with wasting or cachexia "to increase…body weight"[62]—or in the words of the Statutory Exclusion, to cause "weight gain." Yet CMS definitively declared in the Medicare Prescription Drug Benefit Manual that drugs "used to treat AIDS wasting and cachexia are *not considered agents used for weight gain*,"[63] taking into account the context in which Serostim has that effect—"increas[ing] lean body mass…and improv[ing] physical endurance." Thus, in the context of Serostim, CMS exercised its interpretive authority in determining that a drug with an indication "to increase…body weight" was not deemed an "agent…used for…weight gain."

Consistent application of the Serostim coverage precedent in light of the Statutory Exclusion would enable Part D coverage of AOMs. Like Serostim and similar drugs used to treat AIDS wasting/cachexia, AOMs impact weight as part of treatment of a condition that is not characterized solely by weight. Whereas Serostim increases lean body mass in treating a weight disorder related to a chronic disease, AOMs cause weight loss in the process of treating the disease of obesity. In addition, top-line results from a major clinical study suggest that AOMs also significantly reduce the risk of major adverse cardiovascular events (MACEs).[64] In its decision to cover Serostim, CMS concluded that the fact that weight gain was one characteristic of Serostim usage was not determinative; it should likewise not focus exclusively on the fact that AOMs result in weight loss incident to the treatment of obesity. Similar to the covered use of Serostim to treat wasting/cachexia caused by the chronic disease of AIDS, use of AOMs should not be precluded from Part D coverage when treating the chronic disease of obesity.

Simply put, CMS's coverage policy for AIDS wasting/cachexia drugs, and the 1999 changes to that policy, demonstrate that CMS has used its interpretive authority to cover under Part D drugs that, while impacting weight, are indicated for chronic disease that is characterized by more than simply their impact on weight.

III. Covering AOMs Under Part D Would Align Medicare Drug Coverage Policy With Both Prevailing Medical Science and Current Health Care Policy Imperatives

Interpreting the Statutory Exclusion not to prohibit Part D coverage of AOMs would (i) cohere with both biomedical advances in the safety and efficacy of such drugs, (ii) reduce stigma surrounding obesity and address access barriers to obesity treatment, and (iii) further the Biden Administration's priorities in addressing current health care policy imperatives. Further, states and Part D plan sponsors have tools and authority necessary to manage utilization in government programs.

A. Significant Improvements in Safety and Effectiveness of New Generation of Anti-Obesity Drugs Distinguish Them From Previous Weight Loss Drugs

Modern AOMs Are Proven to Be Safe and Effective for Long-Term Use to Treat Obesity, in Contrast to First-Generation Weight Loss Drugs

First-generation weight loss drugs—those sold between 1940 and 1980—were primarily used for cosmetic weight loss and have been largely withdrawn from the market due to significant side effects that rendered the associated drugs unsafe for long-term use.[65] These drugs (and side effects) included but were not limited to aminorex (pulmonary hypertension), fenfluramine (cardiac valvulopathy), dexfenfluramine (valvulopathy), phenylpropanolamine (stroke), rimonabant (suicidal ideation and behavior), sibutramine (myocardial infarction and stroke), and most recently, lorcaserin (cancer).[66] However, scientific advances over the past 30 years have produced a modern generation of AOMs, in particular the GLP-1s, with profiles that are safe and effective for long-term treatment of obesity.[67]

Currently available AOMs include lipase inhibitors that reduce absorption of dietary fats (e.g., orlistat), anorectic-anticonvulsant combinations (e.g., phentermine-topiramate) and opioid antagonist-antidepressant combinations (e.g., naltrexone-bupropion).[68] GLP-1s are an even newer class of AOMs; they differ from the medicines from the 1980s in both their molecular composition and the metabolic processes they stimulate or suppress. GLP-1s mimic naturally occurring hormones to stimulate insulin secretion and inhibit glucagon release (both of which are mechanisms effective at treating type 2 diabetes), reduce the rate of gastric emptying, and signal to the brain to control appetite and energy intake as well as increase satiety.[69] In addition, current evidence demonstrates that the most common side effects are gastrointestinal, including nausea, diarrhea, vomiting and constipation, most of which are noted as "transient and of mild-to-moderate severity."[70]

AOMs are increasingly being evaluated based on weight management efficacy *and* cardiovascular safety (including ability to lower the risk of cardiovascular disease), providing a more comprehensive treatment option that reflects appreciation for the "complex, chronic, and relapsing nature of obesity."[71] Substantial scientific and medical research and various systematic reviews affirm the efficacy of GLP-1s in producing significant weight loss, with some studies showing loss of up to a fifth of body mass and demonstrable improvements in metabolic processes affected by obesity, as well as other linked diseases and conditions, such as diabetes and cardiovascular disease.[72]

For instance, recently announced headline results from a recent landmark study (SELECT) bolster the evidence supporting GLP-1s' clinical efficacy by specifically evaluating semaglutide's effect on preventing MACEs. The SELECT study found that semaglutide produced "a statistically significant and superior reduction" in three MACEs—cardiovascular death, nonfatal myocardial infarction and nonfatal stroke−—of 20% for people with obesity and cardiovascular disease who did not have diabetes.[73] This builds on the preceding OASIS 1 study, which found that, in addition to significantly reducing body weight, an oral GLP-1 (semaglutide) produces "consistent improvements" in cardiometabolic risk factors, such as "hyperglycaemia, hypertension, elevated lipids and high-sensitivity C-reactive protein."[74] Multiple cardiovascular outcome trials in people with type 2 diabetes have shown that GLP-1 receptor agonists can reduce both weight and the risk of MACEs.[75] These results (and results of other clinical studies) have led researchers to conclude that GLP-1s have the potential to translate over time to reduced cardiovascular disease, chronic kidney disease, and non-alcoholic fatty liver disease, among other outcomes (see Appendix A).[76]

These recent milestone studies are further supported by numerous other clinical trials, meta-analyses and systematic reviews demonstrating that in addition to reducing body weight,[77] GLP-1s have a "class effect" in improving cardiometabolic functioning and reducing rates of MACEs.[78] The substantial and growing scientific evidence supports GLP-1s as consistently and reliably producing "superior weight loss effects" and maintaining patient safety, which in addition to better controlling blood pressure, plasma levels of LDL, HDL, triglycerides and glycemic levels, make GLP-1s ideal for treatment of obesity.[79]

FDA Commissioner Robert Califf has characterized the class of GLP-1s as "the beginning of a revolution in the way that we control weight, not just with the pills, but because we'll understand the biological mechanisms better."[80] As recognized by the Labor, Health and Human Services Subcommittee of the House of Representatives Appropriations Committee, "[o]besity is associated with over 200 comorbid conditions and is a driver of health care costs and poor health outcomes for patients with heart disease, Alzheimer's, diabetes, cancer, among many others, and is a top modifiable risk factor for serious COVID-19 outcomes."[81]

One recent study noted that "as there is growing evidence that these drugs can delay the onset of obesity-related complications and improve metabolic and cardiovascular parameters, they should be considered in a timely manner"—referring to consideration in earlier stages of obesity treatment.[82] Part D coverage of this new generation of AOMs would significantly improve Medicare patients' access to these medicines, thereby enabling the earlier and more effective treatment of obesity as well as the prevention or mitigation of associated diseases.

B. CMS's Formal Recognition of Obesity as a Disease and Its Coverage of AOMs Would Cohere With Clinical Guidelines for Comprehensive Treatment

The overwhelming clinical consensus is that providers should be able to use their medical judgment to devise the most effective treatment solutions for their patients. CMS's continued imposition of Part D coverage prohibitions on AOMs supplants the judgment of a treating provider with the judgment of regulators. CMS's reinterpretation of the Statutory Exclusion would give providers the flexibility necessary to comprehensively care for their patients with obesity.

Clinical Guidelines Recommend the Use of AOMs Adjunctive to Lifestyle, Behavioral and Surgical Interventions

In addition to AACE/ACE clinical guidelines, published clinical guidelines from researchers and physicians[83] and from the VA and the U.S. Department of Defense (DoD)[84] recommend that treatment for obesity include AOMs alongside lifestyle, behavioral and/or surgical interventions to maximize the effectiveness of the regimen. For Medicare patients, such nonpharmacologic interventions are limited to three covered treatments: bariatric surgery, intensive behavioral therapy for obesity (IBT) and the Medicare Diabetes Prevention Program.[i] Notably, adding AOMs to intensive lifestyle interventions, such as IBT, produces greater weight loss than does lifestyle therapy alone[85] and is effective at increasing weight loss maintenance.[86] Accordingly, AACE/ACE clinical guidelines recommend that clinicians consider all approved medications to allow for the safe and effective individualization of appropriate pharmacotherapy, enabling clinicians and patients to determine the most effective and least disruptive regimen, accounting for clinical presentation, contraindications and comorbidities.[87]

C. Ending Part D's Exclusion of AOMs Would Aid the Biden Administration in Achieving Goals Related to the "National Strategy on Hunger Nutrition, and Health," Health Equity, and the Cancer Moonshot

President Biden has recently identified key health policy priorities that directly touch on the need for covering AOMs under Part D. The "Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health," (National Strategy) was issued with a goal of reducing Americans' diet-related diseases, as well as reducing health disparities.[88] In the "reignition" of the 2016 Cancer Moonshot, the President also renewed his commitment to making strides in reducing cancer deaths and improving the experience of living with and surviving cancer.[89] All of these goals are furthered by reducing barriers to accessing obesity treatment and enabling providers to implement comprehensive obesity treatments. One key action that would help accomplish such aims would be CMS's reinterpretation of the Statutory Exclusion to eliminate exclusion of AOMs from Part D coverage.

[i] Use of each of these interventions is also subject to the beneficiary meeting various preconditions, such as a certain BMI level, having certain comorbidities, and having previously and unsuccessfully tried alternative obesity treatments. Such conditions are further described below.

Advancing Health Equity Requires Evaluating and Addressing Access Barriers Encountered by Beneficiaries Disproportionately Impacted by Obesity

The National Strategy was issued to help address the "health crisis" relating to "the rising prevalence of diet-related diseases such as type 2 diabetes, obesity, hypertension, and certain cancers" and specifically cites the fact that "historically underserved communities" are "disproportionately" impacted.[90] As the National Strategy notes:

> *Moreover, diet-related diseases are some of the leading causes of death and disability in the U.S. New data show that 19 states and two territories have an obesity prevalence at or above 35%, more than double the number of states from 2018. One in 10 Americans have diabetes. One in 3 people will have cancer in their lifetime. And, more than 4 in 10 Americans have hypertension (high blood pressure), which is linked to the leading causes of death for Americans: heart disease and stroke.*

Indeed, obesity disproportionately affects racial and ethnic minorities and socioeconomically disadvantaged populations,[91] which also historically have fewer healthy nutrition options,[92] lower levels of insurance coverage,[93] more fragile provider relationships (especially with regard to obesity treatment)[94] and more limited access to obesity treatment.[95] Obesity is also a significant health risk factor for many comorbidities and is associated with treatment complications, increased mortality, reduced quality of life, lost productivity and absenteeism.[96] Black adults have the highest prevalence of obesity, followed by Hispanic adults, White adults and Asian adults, meaning such consequences of obesity are disproportionately borne by minority populations.[97]

CMS has recently commenced numerous initiatives to reduce health disparities and improve equity in health care.[98] As part of CMS Fiscal Year 2024 Budget, President Biden proposed additional resources to provide increased access to "nutrition and obesity counseling services" for beneficiaries with "nutrition or obesity-related chronic diseases."[99] Ending CMS's refusal to allow AOMs to qualify as Part D-eligible medicines can augment both the President's and CMS's health equity initiatives, or spur new ones, helping address access barriers that prevent those most impacted by obesity from receiving necessary evidence-based care.

As stated in the bill report produced by the Labor, Health and Human Services Subcommittee of the House of Representatives Appropriations Committee for the most recent appropriations legislation, "it is a matter of health equity and key to reducing modifiable risk factors for cancer and Alzheimer's disease, to ensure that seniors have access to obesity treatments under Medicare Part D to complement coverage of intensive behavioral therapy and bariatric surgery under Medicare Part B."[100] By removing barriers to Part D coverage of AOMs, CMS can enable providers to better tailor comprehensive obesity treatments to beneficiary needs, resources and preferences. This can help reduce rates of obesity among minority beneficiaries, address their comorbidities, and thereby reduce rates of morbidity and mortality. Reinterpreting the Statutory Exclusion can also establish a path for improving access to obesity treatments that other payors can follow, further scaling the positive impact AOMs have on individual health.[101]

Realizing the Cancer Moonshot Requires Decreasing the Prevalence of Obesity and Targeting Treatments Earlier in the Disease State

At the start of his term, President Biden relaunched the Cancer Moonshot, which aims to reduce the death rate from cancer by at least 50% over the next 25 years.[102] According to the CDC, obesity increases the risk of cancer, specifically with respect to 13 different types of cancers that make up 40% of all cancers diagnosed in the United States annually.[103] These cancers are also linked to racial, ethnic and socioeconomic disparities, disproportionately affecting individuals in minority and less affluent communities.[104] If not addressed through preventive and prophylactic measures, cancers linked to obesity are expected to rise in prevalence over the coming decade.[105] Addressing obesity, including by eliminating the practice of excluding AOMs from Part D, would be another tool in the fight to reduce the prevalence of such cancers.

D. Cost-Related Policy Challenges in Covering AOMs Can Be Addressed with Utilization Management

Part D Plans and Other Payors Can Use Commonly Employed Cost Containment Strategies as Tools to Help Address Costs Associated With Coverage and Use of AOMs

Part D plans have a wide array of utilization management tools that can be used to ensure appropriate use of AOMs if the prohibition on coverage were to be lifted. As they do with any other Part D-eligible medicine, plans could use formulary tiering strategies and/or impose prior authorization or step therapy requirements on AOMs. Part D plans would also be able to negotiate discounts from manufacturers, particularly as competition in this therapeutic category grows and more options are approved by FDA.[ii]

IV. Conclusion

The Statutory Exclusion is currently narrowly construed by CMS in a way that fails to acknowledge the widespread recognition of obesity as a complex disease that is not characterized solely by weight, and that impedes access to comprehensive treatment for obesity. Under this interpretation, CMS categorizes AOMs used for valid medical purposes in the same way as weight loss agents used solely for cosmetic purposes. AOMs are intended to be used for those with a clinical diagnosis of the disease of obesity. However, as a bipartisan 2020 letter to CMS notes, Congress did not intend the Statutory Exclusion to mandate noncoverage of AOMs under Part D.[106] Furthermore, CMS's interpretation of the Statutory Exclusion as excluding Part D coverage of AOMs is inconsistent with other positions CMS has taken; CMS has interpreted the same provision in the past to not apply to drugs used to treat certain conditions, even when the effect of

[ii] As noted in Section II(A), *supra*, the Statutory Exclusion references Social Security Act § 1927(d)(2)(A), which governs coverage of certain drugs (including agents for weight loss) under Medicaid. Reinterpreting the Statutory Exclusion could remove AOMs from consideration as drugs that "may be excluded from coverage or otherwise restricted under [Social Security Act § 1927(d)(2)(A)]." Such a reinterpretation would mean that state Medicaid programs would, similarly to Part D plan sponsors, be limited in their ability to exclude AOMs from coverage. But, like Part D plan sponsors, Medicaid agencies would be permitted to impose prior authorization and other utilization management controls on such medicines.

such pharmacotherapy was a change of weight that, using the interpretation CMS applies to AOMs, would otherwise cause such drugs to fall within the Statutory Exclusion. Despite clinical evidence that AOMs treat the disease of obesity, CMS continues to apply the Statutory Exclusion to AOMs as if the fact that they result in weight loss incident to treating obesity is controlling. CMS has not heeded the accepted medical consensus regarding treatment of obesity and the significant advances made in developing safe and effective AOMs since first-generation weight loss drugs were marketed. Put simply, obesity treatment, including use of AOMs, is not treatment solely for weight loss and the Statutory Exclusion need not prevent Part D coverage of AOMs on the basis of their weight loss properties.

By reinterpreting the Statutory Exclusion, CMS can enable more appropriate, comprehensive and patient-centered treatment of obesity and related comorbidities while reducing stigma and access barriers faced by beneficiaries. Doing so would also support three key goals announced by President Biden: reducing diet-related disease, promoting health equity, and addressing the prevalence and severity of cancer. Congress has even expressly encouraged CMS to reinterpret the Statutory Exclusion to not apply to FDA-approved AOMs.[107] To make progress in addressing the obesity epidemic and the various comorbidities associated with obesity, it is essential to remove obstacles to coverage of AOMs and promote access to comprehensive obesity treatments, of which AOMs are a core part. This makes CMS's reinterpretation of the Statutory Exclusion to remove prohibitions on Part D coverage of AOMs a necessary step in combating obesity in the United States.

Appendix A: Key (non-SELECT) Studies of GLP-1s

Study/Clinical Trial ID (Medication)	Description	Topline Results
OASIS 1 (semaglutide oral)[1] *June 25, 2023*	Phase 3, double-blind, randomized, placebo-controlled, 68-week trial of once-daily oral semaglutide (50mg) that assessed efficacy and safety for treatment of obesity in 667 adults with either a BMI of 30 or more or of 27 to 30 with at least one weight-related condition, and without type 2 diabetes.	**Body Weight** • Reductions in body weight of 15.1% (compared with 2.4% in the placebo group), and clinically meaningful reductions of at least 5% of body weight for 85% of participants (compared with 26% of participants in the placebo cohort). • 2/3 of participants had bodyweight reductions of at least 10%, more than 1/2 had reductions of at least 15%, and 1/3 had reductions of at least 20%, all more than with placebo cohort **Secondary Endpoints** • "Substantial improvements" in cardiometabolic risk factors, such as waist circumference, HbA1c, blood pressure, and lipid profiles
SURMOUNT-2 (tirzepatide subcutaneous)[2] *June 26, 2023*	Phase 3, double-blind, randomized, placebo-controlled, 72-week trial of once-weekly tirzepatide (10mg or 15mg) that assessed dose-specific efficacy and safety for weight management in 1514 adults living with obesity (BMI of 27 or higher) and type 2 diabetes.	**Body Weight** • Mean bodyweight reduction of 14.7% with approximately 80% of participants reaching weight reduction of 5% or more • 65%, 48%, and 31% of participants had bodyweight reductions of 10% or higher, 15% or higher, and 20% or higher, respectively **Secondary Endpoints** • Weight reductions were coupled with improvements in cardiometabolic risk factors such as waist circumference, systolic and diastolic blood pressure, fasting triglycerides, HDL-cholesterol, and non-HDL-cholesterol

Study/Clinical Trial ID (Medication)	Description	Topline Results
NCT04881760 (retatrutide subcutaneous)[3] *August 10, 2023*	Phase 2, double-blind, randomized, placebo-controlled, 48-week trial of once-weekly retatrutide (1 mg, 4 mg, 8 mg, or 12 mg, with variable initial doses of 2mg or 4mg) that assessed dose-specific efficacy and safety for weight loss in 338 adults with either a BMI of 30 or more or of 27 to 30 with at least one weight-related condition (except type 2 diabetes).	**Body Weight** • Mean bodyweight reduction at 24 weeks of 7.2% (1 mg), 12.9% (4 mg), 17.3% (8 mg), and 17.5% (12 mg), as compared with 1.6% in the placebo cohort • Mean bodyweight reduction at 48 weeks of 8.7% (1 mg), 17.1% (4 mg), 22.8% (8 mg), and 24.2% (12 mg), as compared with 2.1% in the placebo cohort • At 48 weeks, weight reduction of at least 5%, 10%, and 15%, respectively, in 92%, 75%, and 60% of the 4 mg cohort; in 100%, 91%, and 75% of the 8 mg cohort; and in 100%, 93%, and 83% of the 12 mg cohort (27%, 9%, and 2% of placebo cohort) **Secondary Endpoints** • Improvements in cardiometabolic measures, including systolic and diastolic blood pressure, triglycerides, LDL-cholesterol, total cholesterol, HbA1c, and fasting glucose and insulin at 24 weeks and 48 weeks
NCT05051579 (orforglipron oral)[4] *September 7, 2023*	Phase 2, double-blind, randomized, placebo-controlled, 36-week trial of once-daily orforglipron (12 mg, 24 mg, 36, or 45 mg) that assessed dose-specific efficacy and safety for weight reduction in 272 adults with obesity, or with overweight and at least one weight-related condition, and without diabetes.	**Body Weight** • At 26 weeks, mean body weight reduction from baseline ranged from 8.6% to 12.6% across dose cohorts, compared to 2.0% in the placebo cohort • At 26 weeks, mean body weight reduction from baseline ranged from 9.4% to 14.7% across dose cohorts, compared to 2.3% in the placebo cohort • Bodyweight reduction of at least 10% by week 36 occurred in 46% to 75% of participants (compared with 9% of the placebo cohort) **Secondary Endpoints** • Improvement in all specified cardiometabolic measures

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2. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)01200-X/fulltext.

3. https://www.nejm.org/doi/full/10.1056/NEJMoa2301972; https://investor.lilly.com/news-releases/news-release-details/lillys-phase-2-retatrutide-results-published-new-england-journal#:~:text=Treatment%20with%20retatrutide%20was%20associated,at%20weeks%2024%20and%2048.

4. https://www.nejm.org/doi/full/10.1056/NEJMoa2302392; https://investor.lilly.com/news-releases/news-release-details/lillys-phase-2-results-published-new-england-journal-medicine.

[1] Social Security Act § 1927(d)(2)(A), 42 U.S.C. § 1396r-8(d)(2)(A); Social Security Act § 1860D-2(e)(2)(A), 42 U.S.C. § 1395w-102(e)(2).

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[4] Food and Drug Administration (FDA), *CDER Guidance Agenda New & Revised Draft Guidance Documents Planned for Publication in Calendar Year 2023* (July 2023), https://www.fda.gov/media/134778/download.

[5] Food and Drug Administration (FDA)-approved Serostim label (online at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020604s078lbl.pdf).

[6] See National Library of Medicine (NIH), *After Protests, HCFA Requires Coverage of Anti-Wasting Drug*, 14(8) AIDS Policy & Law 11 (1999), https://pubmed.ncbi.nlm.nih.gov/11366530/; National Library of Medicine (NIH), *HCFA Reverses Ruling on AIDS Wasting Treatment*, 14(6) AIDS Alert 69 (June 1999), https://pubmed.ncbi.nlm.nih.gov/11366412/; Centers for Medicare & Medicaid Services (CMS), Medicaid Drug Rebate Program Release #88 (Mar. 5, 1999), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-088.pdf.

[7] Novo Nordisk, *Company Announcement: Semaglutide 2.4 mg reduces the risk of major adverse cardiovascular events by 20% in adults with overweight or obesity in the SELECT trial* (Aug. 8, 2023), https://www.novonordisk.com/news-and-media/news-and-ir-materials/news-details.html?id=166301#:~:text=Novo%20Nordisk%20A%2FS%3A%20Semaglutide,the%20SELECT%20cardiovascular%20outcomes%20trial.

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