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Report to Congressional Committees

August 2019

OBESITY DRUGS

Few Adults Used Prescription Drugs for Weight Loss and Insurance Coverage Varied

GAO-19-577

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GAO Highlights

Highlights of GAO-19-577, a report to congressional committees

Why GAO Did This Study

Obesity has been associated with an increased risk of developing conditions such as heart disease, stroke, diabetes, and certain types of cancer. Treatment options for individuals with obesity include lifestyle therapy, such as diet, exercise, and behavioral counseling; obesity drugs; surgery; or a combination of these efforts. The Bipartisan Budget Act of 2018 (P.L. 115-123) included a provision for GAO to review the prevalence of obesity and the use and insurance coverage of obesity drugs.

This report examines the prevalence of obesity in the United States, and what is known about the use and health insurance coverage of obesity drugs, among other objectives.

GAO examined data from agencies within the Department of Health and Human Services (HHS) on the prevalence of obesity (using estimates for 2013 through 2016) and the use, spending, and coverage of obesity drugs; conducted a literature review of relevant studies published from January 2012 through January 2019 in peer-reviewed and other publications; reviewed drug formularies for selected health plans; and reviewed documents and interviewed officials from federal agencies and stakeholder organizations (including medical associations, advocacy groups, pharmacy benefit managers, and insurers).

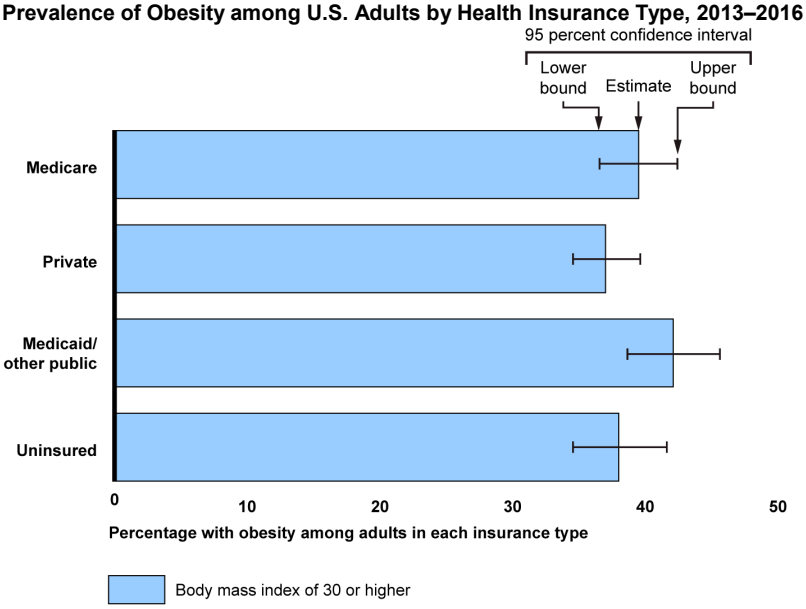
HHS provided technical comments on a draft of this report, which were incorporated as appropriate.

View GAO-19-577. For more information, contact John E. Dicken at (202) 512-7114 or dickenj@gao.gov.

What GAO Found

The prevalence of obesity—that is, body weight higher than what is considered a healthy weight for a given height—was about 38 percent among all U.S. adults, according to the latest available national estimates at the time of GAO's analysis. This prevalence was similar for adults with different types of health insurance.

Prevalence of Obesity among U.S. Adults by Health Insurance Type, 2013–2016



Source: Centers for Disease Control and Prevention's estimates from the National Health and Nutrition Examination Survey, 2013-2016. | GAO-19-577

Treatment for adults with obesity may include one or more of nine prescription drugs that the Food and Drug Administration has approved for weight management (i.e., obesity drugs), though relatively few adults have used these drugs. Of an estimated 71.6 million U.S. adults with obesity, an estimated 660,000 per year, on average, used an obesity drug from 2012 through 2016, according to national estimates. Among adults who reported trying to lose weight, about 3 percent reported that they took prescription medication for weight loss from 2013 through 2016, according to national estimates.

Coverage of obesity drugs varied across different types of health insurance, including Medicare and Medicaid. Plans cited factors such as low consumer demand and strong evidence supporting other treatments in their coverage decisions. GAO's analysis of Centers for Medicare & Medicaid Services' data indicates that some Medicare prescription drug plans and state Medicaid programs reimbursed for some obesity drugs in 2016 and 2017. Coverage for private health insurance plans also varied, and plans may require the patient to obtain prior authorization for the drugs to be covered, according to officials from insurers and pharmacy benefit managers GAO interviewed. For example, officials from one insurer said that some of their plans only cover obesity drugs after a patient has tried other treatment options such as behavioral counseling.

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
BMI	body mass index
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
HHS	Department of Health and Human Services
FEHBP	Federal Employees Health Benefits Program
FDA	Food and Drug Administration
MEPS	Medical Expenditure Panel Survey
NHANES	National Health and Nutrition Examination Survey

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Obesity—that is, body weight higher than what is considered a healthy weight for a given height—has been associated with an increased risk of developing heart disease, stroke, type 2 diabetes, certain types of cancer, and other conditions. It is also associated with an increased risk for death, particularly among adults younger than 65 years old.[1] Obesity and its associated health problems also have a significant economic effect on the U.S. health care system. The medical spending on obesity for adults in the United States was estimated to be about $342 billion in 2013, and the share of health care spending to treat obesity-related illness rose from about 21 percent in 2005 to about 28 percent in 2013, according to a 2017 study.[2]

In 2013, the American Medical Association classified obesity as a disease that requires a range of interventions for its treatment and prevention. Obesity is a complex health issue to address and results from a combination of causes and contributing factors, including individual factors such as behavior and genetics, according to the Centers for Disease Control and Prevention (CDC). Treatment options for individuals with obesity include lifestyle therapy (such as diet, physical activity, and behavioral counseling), bariatric surgery, prescription weight loss medications (i.e., obesity drugs), or a combination of these.[3] As of June 2019, there were nine prescription obesity drugs approved by the Food and Drug Administration (FDA); four of them are approved for short-term use and five are approved for long-term use.

[1]U.S. Preventive Services Task Force, "Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults: U.S. Preventive Services Task Force Recommendation Statement," *JAMA,* vol. 320, no. 11 (2018): 1163–1171.

[2]A. Biener, J. Cawley, and C. Meyerhoefer, "The High and Rising Costs of Obesity to the U.S. Health System," *The Journal of General Internal Medicine,* vol. 32 (Suppl 1), (2017): S6-S8.

[3]Bariatric surgery includes a variety of procedures to help individuals lose weight by reducing the size of the stomach and/or rearranging the small intestine. This can help individuals feel fuller sooner and can also lead to metabolic changes that cause weight loss.

The Bipartisan Budget Act of 2018 included a provision for us to review the prevalence of obesity and the use of obesity drugs, including spending for and insurance coverage of these drugs.[4] This report examines

1. the prevalence of obesity among adults in the United States;
2. what is known about the use of obesity drugs and the individuals who use them;
3. what is known about health insurance coverage of obesity drugs; and
4. what is known about spending on obesity drugs and about medical spending for adults who used obesity drugs compared to those who did not.

To examine the prevalence of obesity among adults in the United States, we examined nationally representative estimates calculated by CDC using data from the National Health and Nutrition Examination Survey (NHANES), which uses physical examinations of participants to measure height and weight to calculate body mass index (BMI).[5] CDC analyzed NHANES data from 2013 through 2016 to estimate the prevalence of obesity for all adults by age and health insurance coverage.

To examine what is known about the use of obesity drugs and the individuals who use them, we conducted a literature review, interviewed knowledgeable stakeholders, and examined federal agency data:

- **Literature review.** We identified relevant peer-reviewed studies published from January 2012 through January 2019 through a search of bibliographic databases, including ProQuest, Scopus, MEDLINE, and International Pharmaceutical Abstracts, using terms such as “obesity,” “weight loss,” and “prescriptions.” Of the 765 study citations we identified, we reviewed 220 full studies; of those, we determined there were 19 relevant studies, which we examined for information related to the use of obesity drugs and individuals who use them. We also examined available information on the clinical trials conducted to obtain FDA’s approval of the prescription obesity drugs for the U.S.

[4]Pub. L. No. 115-123, div. E, tit. III, § 50352, 132 Stat. 64, 212.

[5]BMI is a person’s weight in kilograms divided by the square of their height in meters, and is used as a screening tool for obesity.

market. These were either included in our literature review or, for publications prior to 2012, we obtained a copy of the study.

- **Stakeholder interviews.** We obtained information from officials from eight organizations—three medical associations and five advocacy groups for obesity research and treatment.[6] We reviewed information and studies obtained from these organizations on the use of obesity drugs, including any guidelines for using obesity drugs, and also obtained their perspectives on what physicians and other health care providers take into consideration when prescribing these drugs, among other things.
- **Federal agency data.** We reviewed data and documents, and interviewed officials from federal agencies within the Department of Health and Human Services (HHS), including CDC, FDA, the Agency for Health Care Research and Quality (AHRQ), the Centers for Medicare & Medicaid Services (CMS), and the National Institutes of Health. Data and documents we reviewed included AHRQ's nationally representative estimates of the use of obesity drugs from Medical Expenditure Panel Survey (MEPS) data from 2012 through 2016; CDC's estimates of adults who reported that they took prescription medications for weight loss from NHANES data from 2013 through 2016; and FDA's analysis of dispensings of the nine prescription obesity drugs using 2008 through 2017 data from the agency's Sentinel System.[7] These data were the most recently available data at the time of our review.

To examine what is known about the health insurance coverage of obesity drugs, we examined relevant laws and regulations and obtained

[6]The stakeholder organizations we contacted were the American Academy of Family Physicians, American Association of Clinical Endocrinologists, American College of Cardiology, American Heart Association, Obesity Action Coalition, Obesity Medicine Association, The Obesity Society, and the Strategies to Overcome and Prevent (STOP) Obesity Alliance. These stakeholders were selected because of their medical or scientific expertise, relevant publications, or familiarity with the treatment of obesity and obesity drugs.

[7]MEPS collects nationally representative data on health care use, expenditures (i.e., spending), sources of payment, and insurance coverage for the U.S. civilian, noninstitutionalized population.

Dispensing is the act of delivering a prescription drug to a patient or an intermediary who is responsible for administering the drug. FDA's analysis of its Sentinel System included data from populations with federal or commercial health insurance from 17 of 18 FDA data partners, including large insurers and Medicare.

information and policy documents from federal agencies, including from CMS (for Medicare and Medicaid) and the Office of Personnel Management [for the Federal Employees Health Benefits Program (FEHBP)].[8] For information on the number of claims for obesity drugs that were reimbursed and the number of plans that reimbursed these claims under the Medicare prescription drug program, known as Medicare Part D, we analyzed Prescription Drug Event data from CMS for 2016 and 2017.[9] For information on the number of state Medicaid programs that reimbursed claims for obesity drugs and the number of claims for obesity drugs that they reimbursed, we analyzed CMS's Medicaid State Drug Utilization data for 2016 and 2017.[10] For information on FEHBP guidance on coverage of obesity drugs as of May 2019, we examined documents and information from the Office of Personnel Management. In addition, we identified one study in our literature review relevant to insurance coverage of obesity drugs, and we obtained information from officials from the three largest pharmacy benefit managers and from four large insurers, as well as from two organizations knowledgeable about prescription drug benefits for employer-sponsored health plans.[11] We also reviewed drug formularies for selected private health insurance plans to determine if any of the prescription obesity drugs were included.[12]

To examine what is known about spending on obesity drugs and about medical spending for adults who used obesity drugs compared to those who did not, we examined the latest available AHRQ estimates, which are

[8]The Office of Personnel Management administers FEHBP—the largest employer-sponsored health insurance program in the United States—providing health insurance coverage to about 8 million federal employees, retirees, and their dependents in 2016 through contracts with private health insurance plans.

[9]Medicare Part D provides a voluntary outpatient prescription drug benefit for Medicare beneficiaries. In 2018, there were about 44 million enrollees covered by a Medicare Part D plan. CMS's Prescription Drug Event data contains cost and payment data submitted by plans to CMS for covered Part D drugs to enable CMS to make payments to plans and administer the Part D benefit.

[10]As of March 2019, there were 65.9 million enrollees covered by Medicaid.

[11]Pharmacy benefit managers administer prescription drug programs for health plans, including employer-sponsored health plans and Medicare Part D plans.

[12]A formulary is a list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits. A plan may cover drugs that are not included on the formulary if, for example, a patient has previously used other prescription drugs or therapies and the health care provider determines the prescription drug not included in the formulary is medically necessary for the patient.

based on 2012 through 2016 MEPS data on payments for obesity drugs and medical spending, and FDA's nationally projected estimates on the prescriptions dispensed for obesity drugs calculated using data from the 2017 IQVIA™ National Prescription Audit and IQVIA™ Total Patient Tracker.[13] In addition, for the amounts spent on obesity drugs by Medicare Part D plans and Medicaid, we analyzed CMS's Prescription Drug Event data and Medicaid State Drug Utilization data, respectively, for 2016 and 2017.[14] We also reviewed studies that we identified in our literature review or obtained from stakeholders.

To determine the reliability of the data we used for all four objectives, we reviewed documentation on data collection processes and discussed limitations of the data with the relevant federal agency officials. In addition, we conducted data reliability checks on the data, when appropriate. We determined the data used in this report were sufficiently reliable for our purposes. See appendix I for additional information on our scope and methodology.

We conducted this performance audit from April 2018 to August 2019 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[13]IQVIA™ is proprietary data that includes data for prescriptions dispensed at approximately 59,900 U.S. outpatient retail pharmacies. FDA analyzed these data and provided us with aggregated results for obesity drugs.

[14]This analysis did not include some reimbursement amounts for obesity drugs covered by Medicaid under a Medicaid managed care plan that received a capitated payment to cover medical costs, including prescription drugs, as those payments are not captured in CMS's Medicaid State Drug Utilization data.

Background

Body Mass Index (BMI) and Classes of Obesity

BMI is a person's weight in kilograms divided by the square of their height in meters.

Obesity (defined as a BMI of 30 or higher) is frequently subdivided into categories:

- Class 1: BMI of 30 to <35
- Class 2: BMI of 35 to <40
- Class 3: BMI of 40 or higher. Class 3 obesity is sometimes categorized as extreme or severe obesity.

Source: Centers for Disease Control and Prevention. | GAO-19-577

BMI is used as a screening tool for obesity. An individual with a BMI of 30 or higher is considered to have obesity.

Over the past two decades, both the prevalence of obesity and estimates of the medical spending associated with individuals with obesity have increased. For example, a 2018 study estimated that the percentage of national medical expenditures used to treat obesity-related illnesses in adults increased from 6.13 percent in 2001 to 7.91 percent in 2015, a 29 percent increase.[15] This study also found that the high medical costs of obesity are due to extremely high medical costs among a small percentage of the population who have severe obesity (those with a BMI of 40 or higher). In addition, a 2017 study found that medical expenditures rise most rapidly for individuals with a BMI of 40 or higher.[16]

One option for the treatment of obesity is the use of prescription obesity drugs.[17] As of June 2019, there were nine prescription drugs approved by FDA to treat obesity.[18] Four obesity drugs—benzphetamine, diethylpropion, phendimetrazine, and phentermine—were approved by FDA in 1961 or earlier for short-term use, which is generally about 12 weeks, and are available as generic drugs. The remaining five obesity

[15]This study presents estimates of the amount by which individuals with obesity have higher medical expenditures than individuals who do not have obesity. One important limitation noted in this study is that the estimates do not show a causal effect—that is, even if individuals with obesity have higher medical costs, it does not mean the obesity caused the higher medical costs. See A. Biener, J. Cawley, and C. Meyerhoefer, "The Impact of Obesity on Medical Care Costs and Labor Market Outcomes in the US," *Clinical Chemistry*, vol. 64, no.1 (2018): 108-117.

[16]Biener, Cawley, and Meyerhoefer, "The High and Rising Costs of Obesity," S6-S8.

[17]Obesity drugs are not for everyone with a high BMI; some people who are overweight or have obesity may lose weight with a lifestyle program that helps them change their behaviors and improve their eating and physical activity habits, according to the National Institutes of Health. See National Institutes of Health, *Prescription Medications to Treat Overweight and Obesity*, accessed May 2, 2019, https://www.niddk.nih.gov/health-information/weight-management/prescription-medications-treat-overweight-obesity. Also, see S.Z. Yanovski and J.A. Yanovski. "Long-term Drug Treatment for Obesity: A Systematic and Clinical Review." *JAMA,* vol. 311, no. 1 (2014): 74–86. In addition, the U.S. Preventive Services Task Force recommends intensive, multicomponent behavioral interventions as the primary focus of effective interventions for weight loss in adults. See U.S. Preventive Services Task Force, Recommendation Statement, pp. 1163–1171.

[18]There are two additional FDA-approved prescription obesity drugs, methamphetamine and amphetamine, that we excluded from our review because they were not recommended for use by any medical society guidelines we reviewed for the treatment of obesity. Appendix II provides more detail on the obesity drugs included in our review.

drugs were approved by FDA in 1999 or later for long-term use and are available as brand-name drugs— bupropion/naltrexone (Contrave), liraglutide (Saxenda), lorcaserin (Belviq), orlistat (Xenical), and phentermine/topiramate (Qsymia).[19] Each of these five brand-name obesity drugs underwent one or more randomized, controlled clinical trials for safety and efficacy prior to FDA approval of the drug—a total of 15 clinical trials across the five drugs. Obesity drugs work in different ways; some may help an individual feel full sooner or less hungry, while others may reduce fat absorption in the body. Results vary by medication and by person, but, according to the National Institutes of Health, on average, people who take obesity drugs as part of a lifestyle program lose between 3 and 9 percent more of their starting body weight than people in a lifestyle program who do not take obesity drugs. As with other prescription drugs, obesity drugs may have side effects such as headache, dizziness, dry mouth, nausea, and diarrhea.[20] And, as with other prescription drugs, health care providers may prescribe an obesity drug for off-label use—that is, for a different medical condition, in a different dosage, or for a different duration than for which the drug is FDA approved.[21]

Obesity drugs should be used as an adjunct to lifestyle therapy (e.g., diet, physical activity, and behavioral counseling), according to guidelines from several medical associations.[22] According to these guidelines, the use of obesity drugs is indicated for individuals with a BMI of 27 or higher with one or more obesity comorbidities (such as type 2 diabetes), or individuals with a BMI of 30 or higher who have a history of failure to achieve clinically meaningful weight loss (that is, weight loss of 5 percent

[19]These five obesity drugs are FDA approved for weight management as an adjunct to a reduced-calorie diet and, for four of the drugs, as an adjunct to increased physical activity.

[20]These side effects are some of the most common, but they may not apply to all nine obesity drugs as the different obesity drugs may have different side effects.

[21]Once FDA approves a drug, health care providers generally may prescribe the drug for an unapproved use when they determine that it is medically appropriate for their patient.

[22]These guidelines include: (1) American College of Cardiology and American Heart Association Task Force on Practice Guidelines and The Obesity Society, A Guideline for the Management of Overweight and Obesity in Adults, (2013); (2) C.M. Apovian et al., "Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline," *Journal of Clinical Endocrinology and Metabolism*, vol. 100, no. 2, (2015): 342-362; (3) W.T. Garvey et al., "American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity," *Endocrine Practice,* vol. 22, supp. 3, (2016): 1-203; and (4) Obesity Medicine Association, *Obesity Algorithm 2017-2018*, (Denver, CO: June 2018).

or more) or who are unable to sustain weight loss. In addition, the guidelines recommend evaluating the patient's weight loss after about 12 to 16 weeks of treatment with an obesity drug and discontinuing the drug if the patient has not lost a certain amount (e.g., at least 5 percent) of their initial body weight.

Although obesity is classified as a disease, some health care providers, including those who specialize in the care of patients with obesity, continue to stigmatize patients with obesity. For example, a 2018 study reported that health care providers may perceive patients with obesity as being less compliant and having less self-discipline than other patients.[23] Additionally, health care providers may not initiate discussions about weight loss with patients because of lack of time, other important issues or concerns, a belief that a patient is not motivated or interested in losing weight, or concern over a patient's emotional state, according to another 2018 study.[24]

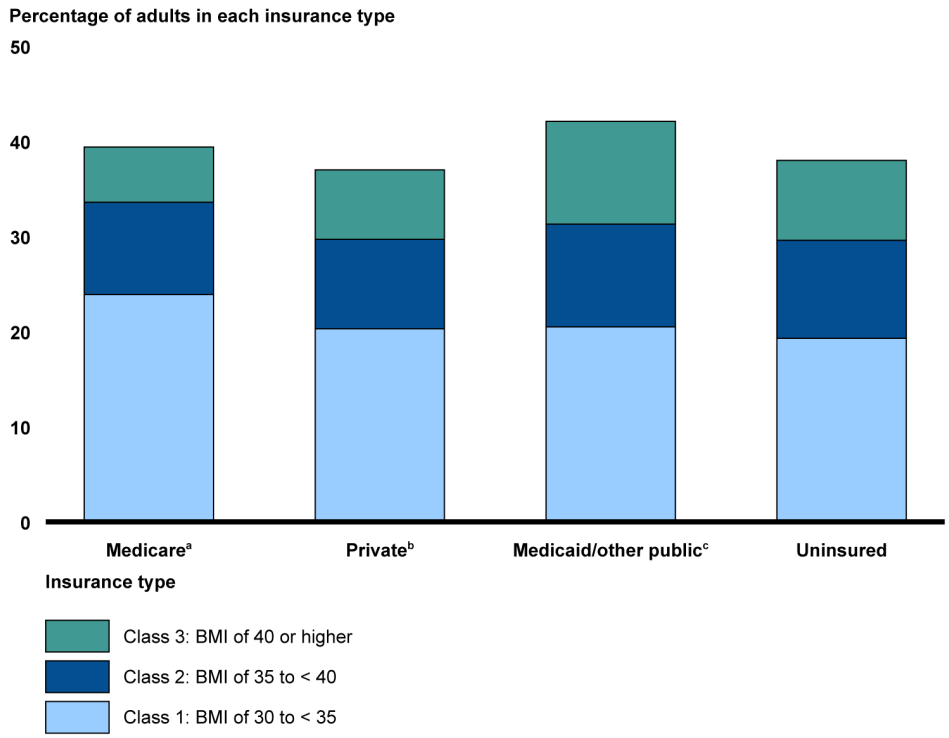
The Prevalence of Obesity Was Close to 40 Percent among All U.S. Adults from 2013 through 2016

The prevalence of obesity was about 38 percent among all U.S. adults (about four of every 10 adults) from 2013 through 2016, according to nationally representative estimates from CDC. The estimate of prevalence among adults covered by Medicare was about 40 percent, and among those with Medicaid or other public health insurance (excluding Medicare) it was about 42 percent. In addition, the prevalence of obesity among adults with private health insurance coverage and among the uninsured was similar, at about 37 percent and 38 percent, respectively. These national estimates also showed that about 24 percent of Medicare beneficiaries had Class 1 obesity, about 10 percent had Class 2 obesity, and about 6 percent had Class 3, or severe, obesity. (See fig. 1.)

[23]D.H. Bessesen and L.F. Van Gaal, "Progress and Challenges in Anti-obesity Pharmacology," *The Lancet Diabetes Endocrinology*, vol. 6 (2018): 237-248.

[24]L.M. Kaplan et al., "Perceptions of Barriers to Effective Obesity Care: Results from the National ACTION Study," *Obesity*, vol. 26, no. 1 (2018): 61-69.

Figure 1: Prevalence of Obesity among U.S. Adults by Insurance Type and Class of Obesity, 2013–2016



Source: Centers for Disease Control and Prevention's (CDC) estimates from the National Health and Nutrition Examination Survey (NHANES), 2013-2016. | GAO-19-577

Notes: Individuals with a body mass index (BMI) of 30 or higher are considered to have obesity. BMI is a person's weight in kilograms divided by the square of their height in meters and is used as a screening tool for obesity. The insurance categories are mutually exclusive. These estimates exclude coverage by a single service plan, such as a dental or vision plan.

[a]Medicare estimates include all adults who reported having Medicare, including adults who also reported having private health insurance or other public health insurance; if they reported having Medicare, they were counted in the Medicare category and not in the private insurance or other public insurance category.

[b]Adults who reported having private health insurance and another type of insurance, such as Medicaid, were counted in the private insurance category except if they had Medicare—in which case they were counted in the Medicare category.

[c]Medicaid accounted for about 46 percent of the Medicaid/other public insurance category in the NHANES analysis, according to CDC. Other public insurance also includes military health care, Indian Health Service; state-sponsored health plans, and other government programs. This excludes Medicare coverage.

According to CDC estimates, adults age 18 to 64 and adults age 65 and older had a similar prevalence of obesity, about 39 percent and 38 percent, respectively.[25] However, a higher percentage of adults age 18 to 64 than adults age 65 and older had Class 3 obesity. (See table 1.) Appendix III provides additional information on the prevalence of obesity among adults, as well as on the prevalence of adults who were overweight, which is defined as a BMI of 25 to <30, including 95 percent confidence intervals.

Table 1: Prevalence of Obesity in Adults by Age and Class of Obesity, 2013–2016

Age groups	All adults with body mass index (BMI) ≥30	Class 1 (BMI of 30 to <35)	Class 2 (BMI of 35 to <40)	Class 3 (BMI ≥40)
18–64	38.5	20.4	9.7	8.4
65 and older	37.6	23.6	10.0	4.0

Source: Centers for Disease Control and Prevention's estimates from the National Health and Nutrition Examination Survey, 2013-2016. | GAO-19-577

Few Adults Used Obesity Drugs and Limited Data Are Available on Individuals Who Have Used These Drugs

Relatively few U.S. adults, including adults with obesity and adults who reported trying to lose weight, used obesity drugs from 2012 through 2016, according to nationally representative estimates. Guidelines suggest prescribing obesity drugs as an adjunct to other diet and lifestyle changes, or when other approaches have not resulted in clinically significant weight loss. Those health care providers who prescribe obesity drugs consider several factors, such as whether there are any contraindications of the obesity drug for their patients and the cost of the drug. Some limited data are available on individuals who have used obesity drugs, including data on whether these individuals adhered to taking the prescribed obesity drug or maintained their weight loss over time.

[25]Of all U.S. adults with a BMI of 30 or higher, CDC estimated that about 81 percent were age 18 to 64 and about 19 percent were age 65 and older.

Relatively Few Adults Used Obesity Drugs

Available data indicate that relatively few U.S. adults, including those with obesity, used obesity drugs.[26] Specifically, of the estimated 233 million U.S. adults, fewer than a million used any of the nine obesity drugs, according to AHRQ's nationally representative estimates from MEPS data for 2012 through 2016.[27] Of the estimated 71.6 million U.S. adults with obesity, an estimated 660,000 per year, on average, used an obesity drug, according to these data.[28] Similarly, among those who reported trying to lose weight, relatively few of them (about 3 percent) reported that they took prescription medication for weight loss, according to CDC's nationally representative estimates from NHANES for 2013 through 2016.[29]

Additionally, six of the studies we reviewed examined this topic and found that few U.S. adults have used obesity drugs.[30] For example, one study reported that in 2011, 2,554 obesity drug prescriptions were filled per 100,000 people, with about 87 percent of those prescriptions for phentermine, a generic obesity drug.[31] Three other studies assessed the use of obesity drugs among veterans receiving care from the Veterans Health Administration and similarly found that few patients were

[26]We define use of obesity drugs as having an outpatient prescription filled or refilled for any of the nine obesity drugs.

[27]Not all of the nine obesity drugs were on the market during the entire period from 2012 through 2016; two were approved by FDA in 2012 and two were approved in 2014. The MEPS estimates are average annual estimates for the U.S. civilian, noninstitutionalized population.

[28]For these estimates, obesity was identified using a BMI of 30 or higher, calculated from individual's height and weight as reported by household respondents of MEPS. Because some individuals may self report higher than actual height and lower than actual weight, calculations of BMI from MEPS data may be lower than actual BMI.

[29]The national survey used to obtain these data did not specifically ask about the nine obesity drugs; however, it did ask about prescription medications for weight loss (i.e., diet pills prescribed by a doctor), and the nine obesity drugs are the FDA-approved prescription drugs specifically for weight management.

[30]See appendix IV for a list of selected studies we reviewed pertaining to the use of obesity drugs, as well as studies pertaining to physician considerations about obesity drugs, individuals who used obesity drugs, and insurance coverage of obesity drugs.

[31]C. Hampp, E.M. Kang, and V. Borders-Hemphill, "Use of Prescription Antiobesity Drugs in the U.S.," *Pharmacotherapy*, vol. 33 (2013): 1299-1307.

prescribed obesity drugs.[32] One of these studies found that about 1 percent of the 153,939 veterans who enrolled in the MOVE! Weight Management Program from 2013 through 2016 were prescribed an obesity drug (orlistat, phentermine, phentermine/topiramate, liraglutide, or bupropion/naltrexone) within 1 year of MOVE! initiation.[33]

Physicians May Have Concerns About Prescribing Obesity Drugs; Those Who Do Prescribe These Drugs Consider Multiple Factors

According to officials from groups representing physicians and advocacy groups we interviewed, and seven studies we reviewed, some physicians and other health care providers may not be open to or comfortable with prescribing obesity drugs.[34] For example, providers may not perceive obesity drugs to be safe or effective. According to officials from one advocacy and research group, concerns about the safety of obesity drugs may be related to the adverse consequences associated with past obesity drugs.[35] In addition, one medical association we contacted indicated physicians consider clinical preventive service recommendations from the U.S. Preventive Services Task Force on the use of obesity drugs.[36] The task force recommends that clinicians offer or refer adults with a BMI of

[32]T.P. Semla et al., "Pharmacotherapy for Weight Management in the VHA," *Journal of General Internal Medicine*, vol. 32 (2017): 70-73; A.C. Del Re, S.M. Frayne, and A.H.S Harris, "Antiobesity Medication Use Across the Veterans Health Administration: Patient-Level Predictors of Receipt," *Obesity*, vol. 22 (2014): 1968-1972; and D.D. Thomas et al., "Patient Characteristics Associated with Receipt of Prescription Weight-Management Medications Among Veterans Participating in MOVE!" *Obesity*, vol. 27, no. 7 (2019): 1168-1176.

[33]Thomas et al., "Patient Characteristics Associated with Receipt of Prescription Weight-Management Medications," pp. 1-9. The MOVE! Weight Management Program is a weight management, health promotion program that encourages healthy eating behavior, increased physical activity, and small weight losses, and is supported by the Veterans Administration's National Center for Health Promotion and Disease Prevention. MOVE! initiation was defined as having at least one MOVE! visit in the study period without having a MOVE! visit in the previous 6 months.

[34]The studies we reviewed were limited by, for example, small sample sizes and low responses rates; however, they provide information for those physicians or other health care providers who responded to a survey.

[35]Dexfenfluramine and fenfluramine are prescription obesity medications that were withdrawn from the market in 1997 because they were linked to heart valve abnormalities. These medications were used alone or off label in combination with phentermine, which was commonly known as fen-phen.

[36]The U.S. Preventive Services Task Force is an independent, volunteer panel of national experts in disease prevention and evidence-based medicine that makes evidence-based recommendations about clinical preventive services. See U.S. Preventive Services Task Force, Recommendation Statement, pp. 1163–1171.

30 or higher to intensive, multicomponent behavioral interventions. Further, a systematic review of evidence of the benefits and harms of behavioral therapy and use of obesity drugs conducted for the task force found that obesity drugs, but not behavior-based interventions, were associated with higher rates of harm.[37] The potential for harm (i.e., adverse events) may discourage physicians and other health care providers from prescribing these drugs. In addition, officials we interviewed and the studies we reviewed noted that a lack of insurance coverage, high out-of-pocket costs, and the patient's means to afford obesity drugs may also discourage physicians from prescribing obesity drugs.

The officials and studies also noted that physicians might have gaps in knowledge about obesity drugs. For example, officials from one medical association noted that lack of education is a barrier to physicians in prescribing obesity drugs for patients who would be candidates for them, and officials from another medical association said that many clinicians are not aware that there are FDA-approved drugs for obesity, and therefore they do not think about prescribing them. One study we reviewed found that, of the 111 primary care providers responding to a survey, most reported limited experience with obesity drugs as a barrier to prescribing them.[38] While guidelines on the use of obesity drugs suggest prescribing obesity drugs as an adjunct to other diet and lifestyle changes, or when other approaches have not resulted in clinically significant weight loss, physicians and other health care providers may not understand the recommendations outlined in the guidelines.[39] For example, one study found that many of the health care providers responding to a survey reported responses inconsistent with the

[37]See E.S. LeBlanc et al., "Behavioral and Pharmacotherapy Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults: Updated Evidence Report and Systematic Review for the U.S. Preventive Services Task Force," *JAMA,* vol. 320, no. 11 (2018): 1172-1191.

[38]This study was limited by a small sample size and low response rate, but it does provide information on the perspectives of the 111 responding primary care providers. See R. Simon and S.W. Lahiri, "Provider Practice Habits and Barriers to Care in Obesity Management in a Large Multicenter Health System," *Endocrine Practice*, vol. 24, no. 4 (2018): 321-328.

[39]Apovian et al., "Pharmacologic Management of Obesity," pp. 342-362; and Garvey et al., "Comprehensive Clinical Practice Guidelines," pp. 1-203.

guideline-recommended thresholds to initiate and continue use of obesity drugs.[40]

Physicians and health care providers who do prescribe obesity drugs take several factors into consideration. Specifically, before prescribing an obesity drug, these providers consider the likely benefits of weight loss, the drug's possible side effects, the patient's current health issues and other medications, family medical history, and the cost of the drug, according to the National Institutes of Health.[41] According to officials from an advocacy group, specific considerations include (1) the patient's other health conditions that may increase the risk from using a particular obesity drug (contraindications); (2) the ability of an obesity drug to treat both the patient's obesity and other health conditions; (3) the patient's ability to afford a particular obesity drug, given their insurance coverage and other financial resources; (4) patient preference regarding the dosage and form of the drug; and (5) the average efficacy (weight loss) of an obesity drug.[42] Further, when treating obesity, providers use the least invasive treatments, such as lifestyle-based therapies first, then escalate to obesity drugs if noninvasive treatments prove ineffective, according to officials from the same advocacy group.

Some Limited Data Are Available on Individuals Who Have Used Obesity Drugs

Some limited data are available on individuals who have used obesity drugs, including data on the distribution of BMI, the use of obesity drugs in conjunction with other items or services, whether these individuals adhered to using the prescribed obesity drug or maintained their weight loss over time, and the impact that using obesity drugs has on other medical services directly related to obesity. The following is a summary of available information on specific aspects of individuals who have used obesity drugs.

[40]M. Turner et al., "Current Knowledge of Obesity Treatment Guidelines by Health Care Professionals," *Obesity*, vol. 26, no. 4 (2018): 665-671.

[41]National Institutes of Health, *Prescription Medications to Treat Overweight and Obesity*, accessed May 2, 2019, https://www.niddk.nih.gov/health-information/weight-management/prescription-medications-treat-overweight-obesity.

[42]For example, phentermine is contraindicated for individuals with a history of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, and uncontrolled hypertension), and phentermine/topiramate (Qsymia) is contraindicated for people with glaucoma.

Distribution of BMI across individuals who have used obesity drugs. CDC's nationally representative estimates for 2013 through 2016 found that the BMI of adults who reported that they used obesity drugs ranged from 21 to 64, with a median BMI of 34. However, these data are limited because they do not indicate how long the individual used the drugs before their BMI was measured.[43]

Use of obesity drugs in conjunction with other items or services. Two studies we reviewed examined the use of obesity drugs in conjunction with other items or services. These studies found that participants who used an obesity drug in conjunction with other services, such as behavioral counseling, lost more weight than those who did not take the drug with the other services. For example, in one 2019 study, participants who received intensive behavioral therapy combined with an obesity drug, liraglutide, had nearly double the weight loss (an average of about 12 percent of their body weight) compared to the participants who received only intensive behavioral therapy (an average of about 6 percent of their body weight).[44] In addition, the 15 clinical trials for the brand-name obesity drugs that we reviewed generally found that a significantly higher percentage of participants who used the obesity drug combined with other items or services (such as a low-calorie diet or increased physical activity) achieved 5 percent or more weight loss compared to participants who used a placebo with the other items or services. One clinical trial that used an intensive behavior modification program (28 group sessions) found higher average weight loss (9 percent loss of initial body weight) for participants who used the obesity drug (bupropion/naltrexone) than for the placebo group.[45] This clinical trial also found that the placebo group with the intensive behavior modification had higher weight loss than

[43]These are the BMIs at the time of the physical examination, not necessarily when an individual started or stopped using the obesity drugs. These estimates are based on data from 166 NHANES participants who reported that they tried to lose weight and took diet pills prescribed by a doctor.

[44]The intensive behavioral therapy consisted of 21 visits of counseling. The participants who received intensive behavioral therapy combined with the obesity drug were divided into two groups, one group with a meal replacement diet and the other group without this diet. See T.A. Wadden et al., "Intensive Behavioral Therapy for Obesity Combined with Liraglutide 3.0 mg: A Randomized Controlled Trial," *Obesity*, vol. 27 (2019): 75-86.

[45]T.A. Wadden et al., "Weight Loss With Naltrexone SR/Bupropion SR Combination Therapy as an adjunct to Behavior Modification: The COR-BMOD Trial," *Obesity*, vol. 19, no. 1 (2011): 110-120.

placebo groups in the other clinical trials, none of which used intensive behavioral therapy.

Adherence to using the prescribed obesity drug. FDA's analysis of Sentinel System data of obesity drugs dispensed in 2008 through 2017 found that in the majority of patients using obesity drugs, cumulative treatment duration was 90 days or less. FDA analyzed data for 267,836 new users of obesity drugs and found that about 58 percent of patients who used any of the obesity drugs did so for 90 days or less; about 31 percent used any of the obesity drugs for 30 or fewer days.[46] The average duration for the first use of any of the nine obesity drugs was 69 days.[47] (See appendix V for more data from FDA's analysis.) FDA's findings are consistent with the findings of two of the three studies that we reviewed that measured adherence to using the prescribed obesity drug.[48] These studies reported that use of obesity drugs dropped significantly after 30 days. For example, one 2018 study that reviewed 1 year of data on 26,522 patients who had new prescription drug claims for one of four obesity drugs (liraglutide, lorcaserin, bupropion/naltrexone, and phentermine/topiramate) found that adherence to using any of the four

[46]A new user was defined as having no use of any obesity drug in the previous 183 days. FDA used a 14-day episode gap to estimate the duration of the first treatment episode (in days) of prescriptions filled for any of the nine obesity drugs. FDA defined an episode gap as the maximum allowable number of days between exhaustion of the supply of the previously dispensed medication and refilling the prescription. According to FDA, the purpose of the episode gap is to define how multiple dispensings of a medication are linked to estimate the total number of days patients were taking the medication during one treatment episode. Further, the episode gap may account for missed doses, late refills, and other sources of variability in adherence between dispensings. Although these data are not medication administration data, this analysis assumes that patients who obtained multiple dispensings took the dispensed doses of their obesity drugs prior to the last refill. In addition, FDA assessed all dispensed prescriptions to maximize the information captured. Because prescribers are not required to document the indication, it is possible that some drug dispensings were for indications that are not labeled, according to FDA. While some obesity drugs are FDA approved for short-term use and some are approved for long-term use, FDA's analysis found that the median duration for the first treatment episode for individual obesity drugs was 46 days for phentermine/topiramate (Qsymia); 42 days for liraglutide (Saxenda), and 30 days for each of the other obesity drugs.

[47]For individual obesity drugs, average duration for the first treatment ranged from about 47 days for benzphetamine to about 91 days for phentermine/topiramate (Qsymia). For phentermine, which was prescribed for 198,203 of the 267,836 patients in FDA's analysis, and which is approved for short-term use but used off label for longer durations, the average duration for the first treatment was about 68 days.

[48]The studies refer to this as (1) adherence to taking the obesity drugs, (2) duration of use, or (3) persistence with taking the drugs.

obesity drugs dropped markedly during the first month following the initial claim for the drug.[49] In addition, while the 15 clinical trials we reviewed were not designed to measure adherence to taking obesity drugs, they provide some information on whether or not study participants adhered to using these drugs during the trials. Participant dropout rates for these clinical trials ranged from 14 percent to 66 percent for the obesity drug treatment and the placebo groups, which could indicate difficulty in adherence to the study regimen; however, participants using the placebo generally had higher dropout rates than those using the obesity drug. The reasons for discontinuation among study participants in the clinical trials included side effects, such as headaches and nausea; being unavailable for follow up; and withdrawal of consent.

Maintaining weight loss over time by individuals who have used obesity drugs. The recent systematic review conducted for the U.S. Preventive Services Task Force noted that data on long-term weight loss with obesity drugs are limited. The review found that individuals using obesity drugs were more likely to maintain their weight loss over 12 to 36 months compared with placebo, but noted that the evidence was limited by the small number of trials for each medication, poor follow up with participants, and limited applicability (given that participants had to meet narrowly defined inclusion criteria), among other limitations.[50] We also identified six studies—each of which reviewed one of the FDA-approved obesity drugs—that examined weight loss maintenance, generally after about 1 year. For example, a 2018 study for one obesity drug (lorcaserin) found that while the obesity drug initially improved upon weight loss achieved with weight loss maintenance counseling, this advantage was

[49]Specifically, the study reviewed 26,522 patients that had new prescription drug claims for one of the four obesity drugs and found at month 12, about 28 percent of patients were still taking liraglutide compared to about 7 percent taking lorcaserin, 9 percent taking bupropion/naltrexone, and 11 percent taking phentermine/topiramate. One limitation noted in the study was that even though the obesity drugs were prescribed to patients, it does not necessarily mean that the drugs were used. See R. Ganguly et al., "Persistence of Newer Anti-Obesity Medications in a Real-World Setting," *Diabetes Research and Clinical Practice,* vol. 143 (2018): 348-356.

[50]The review examined 35 clinical trials that examined the effectiveness of or harms of medication for weight loss and weight loss maintenance for five obesity drugs: liraglutide, lorcaserin, bupropion/naltrexone, orlistat (both prescription strength and the over-the-counter dosage), and phentermine/topiramate. Other limitations included methodological variability and missing data regarding dispersion. The review noted that strength of evidence of medication-based weight loss maintenance was insufficient. See LeBlanc et al., "Behavioral and Pharmacotherapy Weight Loss Interventions," pp. 1172-1191.

not maintained at 1 year.[51] That is, after 1 year, there was no significant difference in weight loss maintenance between the participants treated with the obesity drug along with counseling, compared to those treated with placebo along with counseling. Another study that examined clinical trial data for one obesity drug (bupropion/naltrexone) concluded that participants who lost at least 5 percent of their body weight after 16 weeks were likely to maintain clinically significant weight loss (of at least 5 percent) after 1 year of treatment with the drug.[52]

The impact of using obesity drugs on medical services directly related to obesity. We did not identify any studies on the impact that the use of obesity drugs had on the utilization of medical services directly related to obesity. In terms of studies on the impact on health outcomes, the systematic review conducted for the U.S. Preventive Services Task Force concluded that health outcomes data for individuals receiving treatment with obesity drugs were limited.[53] The review reported that clinical trials of obesity drugs for weight loss examined few outcomes beyond quality of life measures, and that none of the drug-based maintenance trials reported the effects of the obesity drug interventions on health outcomes. The review noted that the trials included in the

[51]The study examined 137 adults who had lost at least 5 percent of initial weight during a 14-week low-calorie diet program before being put into the obesity drug or placebo groups. Participants were randomly assigned to the obesity drug (lorcaserin) or a placebo and were provided 16 group weight loss maintenance counseling sessions over 52 weeks. See J.S. Tronieri et al., "A Randomized Trial of Lorcaserin and Lifestyle Counseling for Maintaining Weight Loss Achieved with a Low-Calorie Diet," *Obesity,* vol. 26 (2018): 299-309.

[52]The study examined data for 1,310 participants who took the obesity drug (bupropion/naltrexone) in four clinical trials designed to evaluate the efficacy and safety of the drug over a 56-week period. See K. Fujioka et al., "The Relationship between Early Weight Loss and Weight Loss at 1 Year with Naltrexone ER/Bupropion ER Combination Therapy," *International Journal of Obesity*, vol. 40 (2016): 1369-1375.

In addition, one of the clinical trials examined weight loss maintenance over a 56-week period and found that more participants taking the obesity drug (liraglutide) with diet and exercise maintained their initial ≥ 5 percent weight loss than those taking a placebo with diet and exercise. This trial also noted that further study is needed of the frequency of medication usage required to facilitate weight loss maintenance. See T.A. Wadden et al., "Weight Maintenance and Additional Weight Loss with Liraglutide after Low-Calorie-Diet-Induced Weight Loss: The SCALE Maintenance Randomized Study," *International Journal of Obesity*, vol. 37 (2013): 1443-1451.

[53]The review examined 10 trials of medications for weight loss that examined health outcomes and concluded the strength of evidence was low for benefit for health outcomes from medication-based weight loss. See LeBlanc et al., "Behavioral and Pharmacotherapy Weight Loss Interventions," pp. 1172-1191.

review were of highly selected populations with multiple exclusions relevant to health outcomes (e.g., history of serious medical conditions). The review further noted that while it appears that weight loss interventions, including obesity drugs, can reduce diabetes incidence, larger studies with longer-term follow up are required to understand the full benefits of these interventions on health outcomes and whether those effects are long lasting.

Health Insurance Coverage for Obesity Drugs Is Limited and Varied across Types of Insurance

Health insurance coverage for obesity drugs is limited—that is, not all public and private health insurance provided coverage for obesity drugs or may have additional requirements to determine these drugs are medically necessary. Medicare Part D plans may opt to cover obesity drugs, and state Medicaid programs or Medicaid managed care plans within states may choose either to cover or exclude obesity drugs from coverage. We found that both Medicare Part D and Medicaid reimbursed for a relatively small number of prescriptions for obesity drugs in 2016 and 2017. For private health insurance—which includes employer-sponsored health insurance, individually purchased health plans, and FEHBP plans—we found that coverage varied and, when obesity drugs were covered, the coverage could have additional requirements such as prior authorization or determination that a drug is medically necessary for the patient.

Medicare. Under Medicare's prescription drug benefit, Medicare Part D plans may choose to cover obesity drugs—in these cases, obesity drugs are considered supplemental drugs under an enhanced alternative coverage plan.[54] Medicare beneficiaries who select a Part D plan that offers supplemental benefits, which may include coverage of excluded drugs such as obesity drugs, must pay the full premium cost for those

[54]Drugs for weight loss, even if used for a non-cosmetic purpose, are excluded from the definition of a Part D drug covered under Medicare Part D. See 42 U.S.C. § 1395w-102(e), 42 C.F.R. § 423.100 (2018), and 42 C.F.R. § 423.104(f)(ii)(A) (2018). Medicare Part D prescription drug plans include Medicare Advantage Prescription Drug plans and Medicare standalone prescription drug plans, which are collectively referred to as Medicare Part D plans in our report.

additional benefits (i.e., Medicare does not subsidize them).[55] Medicare Part D plans can choose whether or not to offer enhanced alternative coverage, and not all Medicare Part D plans that provide enhanced alternative coverage cover obesity drugs as supplemental drugs.[56] For example:

- Roughly half of the Medicare beneficiaries covered by one large insurer's Medicare Part D plans in one state have coverage for obesity drugs as a supplemental drug under enhanced alternative coverage, according to officials from that insurer.
- Officials at another large insurer told us that their Medicare Part D plans have historically covered supplemental drugs based on consumer demand, and obesity drugs do not typically meet their threshold for offering supplemental coverage. The officials noted that their plans have limited funds to cover supplemental drugs and that consumer demand is typically highest for other types of drugs, such as drugs to treat erectile dysfunction.

[55]For example, in 2017, average monthly premiums for beneficiaries in standalone Medicare Part D plans with enhanced benefits were $54 per month compared with an average premium of $31 for basic coverage. See Medicare Payment Advisory Commission, *June 2018 Data Book: Health Care Spending and the Medicare Program*, Section 10 (Washington, D.C.: July 2018), and Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, Chapter 14 (Washington, D.C.: March 2018).

[56]Once a Medicare Part D plan sponsor offers a plan with basic benefits in a region, it can also offer up to two plans with additional drug coverage that supplements the standard benefit, called enhanced plans. As of February 2017, 1,949 Medicare Part D plans provided enhanced alternative coverage to 18.9 million Medicare beneficiaries, according to the Medicare Payment Advisory Commission. These numbers include all of the plans that provided supplemental benefits. Plans may offer supplemental benefits, such as reductions in cost sharing, without covering any supplemental drugs, and plans choose which supplemental drugs they cover (so not all plans offering coverage of supplemental drugs choose to cover obesity drugs). For more information on Medicare Part D plans, see Medicare Payment Advisory Commission, *June 2018 Data Book: Health Care Spending and the Medicare Program*, Section 10 (Washington, D.C.: July 2018), and Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, Chapter 14 (Washington, D.C.: March 2019).

Enhanced Alternative Coverage and Supplemental Drugs under Medicare

Enhanced alternative coverage is alternative prescription drug coverage under Medicare Part D with value exceeding that of Medicare Part D's defined standard coverage. Enhanced alternative coverage may include basic prescription coverage and supplemental benefits such as supplemental drugs.

Supplemental drugs are drugs—including drugs for weight loss—that would be covered Part D drugs but for the fact that they are specifically excluded as Part D drugs under Medicare Part D's basic prescription drug coverage. Medicare Part D plans may offer these excluded drugs, such as obesity drugs, as a supplemental drug under enhanced alternative coverage.

A Medicare Part D plan can choose which drugs it covers as a supplemental drug under enhanced alternative coverage—that is, not all plans cover the same supplemental drugs as part of enhanced alternative coverage.

Source: Centers for Medicare & Medicaid Services. | GAO-19-577

Data from CMS on Medicare Part D reimbursement for obesity drugs provide some insight on coverage.[57] For example, our analysis found that in 2017, 27 Medicare Part D plans reimbursed for obesity drugs under enhanced alternative coverage for 209 Medicare beneficiaries.[58] (See table 2 for 2016 and 2017 data.) See appendix VI for more information.

Table 2: Number of Medicare Part D Plans and Beneficiaries Reimbursed for Obesity Drugs, 2016 and 2017

Medicare Part D plan reimbursements for obesity drugs as supplemental drugs under enhanced alternative coverage	2016	2017
Number of Part D plans	32	27
Number of claims	419	555
Number of beneficiaries	196	209

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-19-577

Medicaid. State Medicaid programs or Medicaid managed care plans within states may choose either to cover or exclude obesity drugs from coverage.[59] Our analysis found that in 2017, Medicaid programs or Medicaid managed care plans in 41 states reimbursed pharmacies and other providers for at least one claim for an obesity drug, for a total of

[57]Our analysis was limited to those instances in which a Medicare Part D plan reimbursed for an obesity drug as a supplemental drug under enhanced alternative coverage, and the actual number of Medicare Part D plans that provided coverage for obesity drugs could be higher. For example, some plans may have covered obesity drugs but none of the beneficiaries enrolled in these plans filled a prescription and submitted a claim for an obesity drug.

[58]According to CMS, the amount a plan pays for a supplemental drug under enhanced alternative coverage is not included as part of the Medicare Part D benefit for payment purposes. Additionally, according to the Research Data Assistance Center (a CMS contractor that provides assistance to researchers and others regarding CMS data) the amount the plan pays for supplemental drugs is recouped by the plan through higher premiums for the enhanced benefit.

[59]State Medicaid programs may exclude drugs when used for anorexia, weight loss, or weight gain. See 42 U.S.C. § 1396r–8(d)(2)A).

30,800 prescriptions.[60] (See table 3 for 2016 and 2017 data.) Medicaid managed care organizations may provide coverage of obesity drugs not covered by the state plan, according to CMS. See appendix VII for more information.

Table 3: Numbers of States and Prescriptions with Medicaid Reimbursement for Obesity Drugs, 2016 and 2017

Medicaid reimbursements for obesity drugs	2016	2017
Number of states	42	41
Number of prescriptions	25,312	30,800

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-19-577

[60]States include the 50 states and the District of Columbia. The amount Medicaid reimbursed includes both federal and state reimbursement and includes dispensing fees. There were about 732 million prescriptions reimbursed in Medicaid in fiscal year 2016 and about 757 million prescriptions reimbursed in fiscal year 2017, according to the Medicaid and CHIP Payment and Access Commission. See Medicaid and CHIP Payment and Access Commission, *MACStats: Medicaid and CHIP Data Book* (Washington, D.C.: December 2017) and Medicaid and CHIP Payment and Access Commission, *MACStats: Medicaid and CHIP Data Book* (Washington, D.C.: December 2018).

This analysis was limited to those instances in which Medicaid's data indicated that Medicaid reimbursed for an obesity drug (including instances in which the reimbursement for the drug was included in a monthly capitated rate under a Medicaid managed care plan, and therefore showed up as $0 amounts in the CMS data), and the actual number of states in which Medicaid plans or Medicaid managed care plans provided coverage for obesity drugs could be higher. For example, a state could have provided coverage for obesity drugs, but no beneficiaries in that state filled a prescription for an obesity drug. We did not find comprehensive, reliable data on the number of Medicaid state programs or Medicaid managed care plans within states that provided coverage for obesity drugs.

Employer-sponsored and individually purchased health plans. Coverage of the nine obesity drugs varied in employer-sponsored and individually purchased health plans, according to the insurers and pharmacy benefit managers we interviewed.[61] For example:

- Officials from one large insurer told us that coverage of obesity drugs is included in plans for about 90 percent of their members; only a small percentage of members do not have plans with this coverage.
- Officials from another large insurer surveyed its health plans in different geographic locations and found that, of those that responded, four of the six employer-sponsored and three of the six individually purchased health plans covered the nine obesity drugs. They said that many of the plans that covered obesity drugs in their employer-sponsored markets also covered these drugs in their individual market.
- Officials at a large pharmacy benefit manager said employers that provide employer-sponsored health insurance can choose to customize their formulary and decide whether to include obesity drugs. They said their select and premium prescription drug formularies include obesity drugs, so companies that decide to offer those formularies would cover obesity drugs, but many companies choose to customize their formularies and may not include obesity drugs.

Even if employer-sponsored and individually purchased health plans offer coverage of obesity drugs, these plans often put requirements in place to determine a beneficiary's eligibility for coverage of obesity drugs, according to officials from insurers and pharmacy benefit managers we interviewed. For example, plans may require beneficiaries to obtain prior authorization, require a determination of medical necessity of the drug for the patient, and review the drug's effectiveness prior to making a coverage decision. For example, an official from one large insurer told us

[61]Employer-sponsored health plans may be self-funded (by setting aside funds to pay for employee health care) or fully insured (by purchasing coverage from an issuer). Most small employers purchase fully insured plans, while most large employers self-fund at least some of their employee health benefits. For more information see GAO, P*rivate Health Insurance: Enrollment Remains Concentrated among Few Issuers, including in Exchanges*, GAO-19-306 (Washington, D.C.: Mar. 21, 2019). Individual health insurance plans refer to health insurance that an individual can purchase on their own. Private insurance plans may be subject to state insurance requirements pertaining to drug coverage.

their drug formulary does not include obesity drugs because the clinical evidence indicates that other therapies are more effective for weight loss. However, this official also said that some of its plans would cover obesity drugs as a nonformulary option if a physician or other health care provider indicates that the obesity drug is medically necessary (e.g., after a patient has tried other treatment options, such as behavioral therapy).[62]

Further, if a patient is offered coverage of an obesity drug but fails to receive a clinical benefit within a specified time frame, insurers and pharmacy benefit managers told us the following:

- A patient and his or her physician may decide together whether the patient should continue or discontinue the obesity drug, and plans often defer to physicians to determine whether an obesity drug is medically necessary for a patient.
- Some plans may require additional information from a patient's physician every 6 to 12 months for reapproval of coverage of an obesity drug, such as reporting outcomes (e.g., weight loss) while using the drug.
- Plans could require prior authorization to continue using an obesity drug.
- An individual may be able to try a different obesity drug covered by the formulary.

For the largest employer-sponsored health care program in the United States—FEHBP, managed by the Office of Personnel Management—we found that some FEHBP plans offered by large insurers excluded obesity drugs from coverage.[63] We examined the formularies for 12 plans offered by three large FEHBP insurers and found that the formularies for two plans from one insurer indicated some type of coverage of obesity drugs in 2018. One plan offered coverage for 50 percent of the plan's allowed amount for weight management drugs, and the other plan offered

[62]Nonformulary drugs are not covered unless approved by the health plan as a coverage exception.

[63]Recognizing that many plans exclude such drugs from coverage, the Office of Personnel Management issued guidance clarifying that exclusion of obesity drugs on the basis that obesity is a "lifestyle" condition and not medical, or that obesity treatment is "cosmetic" is not permissible. It also clarified that there is no prohibition on FEHBP plans covering such drugs, provided that appropriate safeguards are implemented. See Office of Personnel Management, *FEHBP Carrier Letter,* No. 2014-04 (March 20, 2014), p. 1.

coverage of two obesity drugs as tier 2 drugs, which have higher copayments than tier 1 drugs.[64]

For individually purchased health plans offered on health care exchanges, nine of the 34 states with federally facilitated exchanges had at least one plan in the silver tier of coverage that included some type of coverage for obesity drugs in 2018, according to a 2018 study.[65] The study found that covered obesity drugs were generally the older drugs and that the newer drugs tended to be covered with higher copayments or more likely to require prior authorizations than other medications.[66]

[64]The two drugs covered as tier 2 drugs were diethylpropion and phentermine. A third formulary for a plan offered by this insurer indicated that the five brand-name drugs and Adipex (a brand name for phentermine) are tier 3 drugs, which means that these drugs are not listed on the drug formulary and are not covered unless approved through an exception process.

[65]This study examined coverage for eight of nine FDA-approved obesity drugs in plans in the silver tier of coverage. See G. Gomez and F.C. Stanford, "US Health Policy and Prescription Drug Coverage of FDA-approved Medications for the Treatment of Obesity," *International Journal of Obesity*, vol. 42 (2018): 495-500.

Federally facilitated exchanges are CMS-operated individual market exchanges. They are categorized into four "metal" tiers of coverage—bronze, silver, gold and platinum—which reflect out-of-pocket costs that may be incurred by an enrollee. For more information see GAO, *Health Insurance Exchanges: HHS Should Enhance Its Management of Open Enrollment Performance*, GAO-18-565 (Washington, D.C.: Jul. 24, 2018). Silver plans, according to 2016 enrollment data, accounted for 71 percent of enrollees using the federally facilitated exchanges at healthcare.gov.

[66]Lower-tiered drugs tend to be generic and are often included in the plan's formulary. Therefore, the copayment is typically lower and often does not require prior authorization. Higher-tiered drugs tend to be brand name, and they are more likely to have higher copayments and often require prior authorization and/or quantity limits. See Gomez and Stanford, "Prescription Drug Coverage of FDA-approved Medications for the Treatment of Obesity," pp. 495-500.

Two-Thirds of Obesity Drug Payments Were Made Out of Pocket; Adults Who Used Obesity Drugs Had Higher Average Estimated Medical Spending

Out-of-pocket payments from the patient or patient's family made up two-thirds of the amounts paid for obesity drugs, according to nationally representative estimates for 2012 through 2016. These amounts could include insurance copayments and deductible amounts, and payments for obesity drugs not covered by insurance. Private health insurance paid about one quarter of the amount paid for obesity drugs, and Medicare and other public health insurance paid the remainder. Average annual medical spending and prescription drug spending were higher for adults who used any of the nine obesity drugs than for those who did not, according to these estimates.[67] However, the differences in these estimates do not establish any causal relationship between using obesity drugs and having higher average annual medical or prescription drug spending.

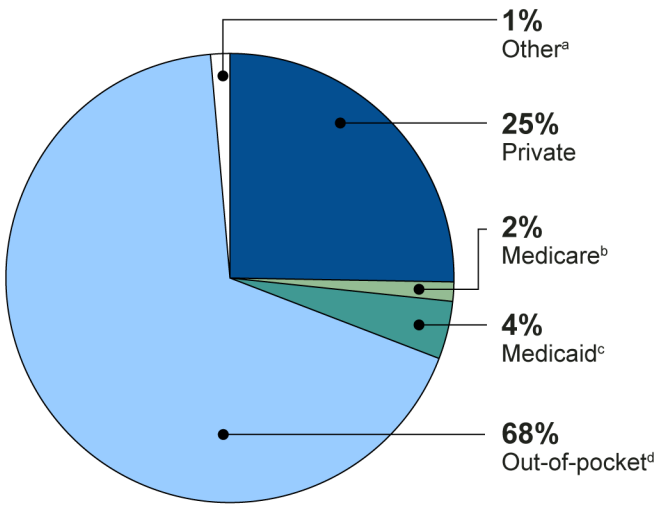
Two-Thirds of Obesity Drug Payments Were Paid Out of Pocket by Patients; Phentermine Was Most Purchased

Out-of-pocket payments made up about two-thirds of total amounts paid for obesity drugs for U.S. adults and private health insurance paid a quarter, according to AHRQ's nationally representative estimates from MEPS data for 2012 through 2016.[68] Medicare, Medicaid, and other public health insurance paid the remainder; however, estimates for each of these sources of payment are imprecise. (See fig. 2.) Similar to studies on the use of obesity drugs, AHRQ's estimates also found that 80 percent of amounts paid for any of the nine obesity drugs was for one obesity drug, phentermine, which is available as a generic drug.

[67]We define use of obesity drugs as having an outpatient prescription fill or refill for any of the nine obesity drugs.

[68]For this analysis, AHRQ estimated the distribution of payments for obesity drugs from MEPS pooled data for years 2012 through 2016 for adults in the U.S. civilian, noninstitutionalized population. For additional information on this analysis, see appendix VIII.

Figure 2: Estimated Average Annual Estimates of Distribution of Payments for Obesity Drugs by Insurance Type, 2012–2016



Source: Agency for Healthcare Research and Quality's estimates from the Medical Expenditure Panel Survey, 2012-2016. | GAO-19-577

[a]Other payments include payments made by TRICARE, the Veterans Administration, or other federal government sources, such as the Indian Health Service and military treatment facilities. The relative standard error is greater than 30 percent for this payment category estimate.

[b]The relative standard error is greater than 30 percent for the Medicare payment estimate.

[c]The relative standard error is greater than 30 percent for the Medicaid payment estimate.

[d]Out-of-pocket payments include payments made by the patient or the patient's family, including insurance copayments and deductible amounts, and payments for obesity drugs not covered by insurance.

We also examined available spending data from CMS on payments for obesity drugs and found the following:

- Medicare Part D prescription drug plans spent $19,714 for obesity drugs in 2016 and $140,296 in 2017, according to our analysis of CMS's Prescription Drug Event data.[69] These amounts include Medicare Part D plan reimbursements for any of the nine obesity drugs under enhanced alternative coverage. CMS's data also showed that total beneficiary spending—that is, the total amount Medicare beneficiaries paid out of pocket as copayments or deductibles—for

[69]In our analysis, Medicare Part D spending reflects plan payments to pharmacies.

any of these prescriptions totaled $4,048 in 2016 and $5,376 in 2017.[70] See appendix VI for more information.

- Total Medicaid state and federal spending—that is, reimbursement amounts for the nine obesity drugs—was at least $5,017,424 in 2016 and $7,453,442 in 2017, according to our analysis of available data from CMS's Medicaid State Drug Utilization data.[71] These amounts do not include all Medicaid spending for obesity drugs under Medicaid managed care. For example, if a Medicaid program pays a managed care organization for drugs as part of their capitated payment for all Medicaid services, they are not reimbursed on a per-drug basis, and obesity drugs covered by Medicaid in that state would show up as a $0 reimbursement amount in CMS's Medicaid State Drug Utilization data.[72] According to CMS data, Medicaid spending for obesity drugs was the greatest in California in 2016 and 2017. See appendix VII for more information.

In addition, when the number of prescriptions dispensed are counted, FDA's estimates from 2017 IQVIA™ data—which are projected nationally from prescriptions dispensed in about 59,900 outpatient retail pharmacies—found that most prescriptions dispensed for obesity drugs

[70]Beneficiary spending refers to how much a beneficiary's responsibility is for a given claim. The amount includes how much a beneficiary pays for a drug that is not reimbursed by a third party, the amount a patient's liability is reduced due to other benefits such as the Veterans Administration and TRICARE, the amount a plan reduced the patient's liability due a beneficiary's low-income cost sharing subsidy amount, and all other qualified third party payments on behalf of the beneficiary, which are referred to as the Other True Out-of-Pocket. The low-income cost sharing subsidy amount and Other True Out-of-Pocket amounts are zero for obesity drugs because they are covered under an enhanced benefit, not as Part D drugs.

In 2015, total Medicare Part D spending for prescription drugs was about $137 billion—this represents payments from all payers including beneficiaries (cost sharing), and excluding rebates and discounts from pharmacies and manufacturers that are not reflected in prices at the pharmacies. See Medicare Payment Advisory Commission, *June 2018 Data Book: Health Care Spending and the Medicare Program* (Washington, D.C.: July 2018), 173.

[71]State and federal reimbursement amounts refer to gross spending or expenditures prior to the application of manufacturer rebates. Total Medicaid state and federal reimbursement for all prescription drugs in fiscal year 2016 was about $60.8 billion and about $64 billion in fiscal year 2017.

[72]We found 776 and 144 prescriptions for obesity drugs in CMS's Medicaid State Drug Utilization data in 2016 and 2017, respectively, that showed $0 reimbursement; according to CMS officials, obesity drugs covered as part of capitated payments under Medicaid managed care plans can be reported with zero dollar amounts in the CMS data.

were paid for by private insurance. FDA's analysis found that almost 64 percent of prescriptions dispensed for any of the nine obesity drugs was paid for by private health insurance, and 35 percent of prescriptions dispensed was paid for by cash (i.e., out-of-pocket) payments paid for by the patient or their family in 2017.[73] The remaining 1 percent of prescriptions dispensed for obesity drugs was paid for by Medicare Part D and Medicaid at an estimated 0.9 percent and 0.1 percent, respectively.

Adults Age 18 to 64 Who Used Obesity Drugs Had Higher Average Medical and Prescription Drug Spending Than Those Who Did Not

For all U.S. adults age 18 to 64, the estimated average annual medical and prescription drug spending per adult was higher for those who used an obesity drug than for those who did not use an obesity drug.[74] Specifically, the estimated average annual medical expenditures were $7,575 per adult who used an obesity drug and $4,302 for those who did not, according to AHRQ's nationally representative estimates from MEPS data for 2012 through 2016. Further, the estimated average annual prescription drug expenditures per adult were $2,198 for those who used an obesity drug and $1,111 for those who did not. However, these data do not necessarily indicate that use of obesity drugs leads to higher average annual medical and prescription drug spending.

For U.S. adults with obesity, there was not a significant difference between the estimated average annual medical and prescription drug expenditures per adult for those who used an obesity drug and those who did not use an obesity drug.[75] This may be due to the small sample size of 279 adults with obesity who used an obesity drug in the MEPS data. Appendix VIII provides more information on AHRQ's estimated expenditures for obesity drugs and other medical and prescription drug spending. We did not identify any studies other than AHRQ's estimates

[73]Cash represents a prescription transaction when a patient pays out of pocket due to reasons such as the drug is not covered by insurance, the patient does not have insurance, or the patient did not present their prescription card; however, the reasons for all cash transactions are not available in the data, according to FDA.

[74]These differences were significant at the 95 percent confidence level. AHRQ's analysis of MEPS data did not report estimates for adults age 65 and older who used obesity drugs due to inadequate precision for estimates resulting from an insufficient sample size.

[75]For these estimates, obesity was defined as a BMI of 30 or higher. BMI is calculated based on individuals' height and weight as reported by household respondents in MEPS. As a result, because some individuals may self report higher than actual height and lower than actual weight, calculations of BMI from MEPS data may be lower than actual BMI.

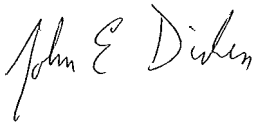
from MEPS data that specifically addressed the medical spending for adults who used obesity drugs compared to those who did not.

Agency Comments

We provided a draft of this report to HHS for review and comment. HHS provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services, appropriate congressional committees, and other interested parties. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs are on the last page of this report. GAO staff who made major contributions to this report are listed in appendix IX.



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Appendix I: Objectives, Scope, and Methodology

The Bipartisan Budget Act of 2018 included a provision for GAO to review the prevalence of obesity and the use of obesity drugs in the Medicare and non-Medicare populations, including spending for and coverage of these drugs.[1] We examined (1) the prevalence of obesity among adults in the United States; (2) what is known about the use of obesity drugs and the individuals who use them; (3) what is known about health insurance coverage of obesity drugs; and (4) what is known about spending on obesity drugs and about medical spending for adults who used obesity drugs compared to those who did not.[2]

To address our reporting objectives, we examined estimates from federal agencies within the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention's (CDC) estimates from the National Health and Nutrition Examination Survey (NHANES), the Agency for Health Care Research and Quality's (AHRQ) estimates from the Medical Expenditure Panel Survey (MEPS), and the Food and Drug Administration's (FDA) estimates from IQVIA and the Sentinel System. We also analyzed Medicare Part D Prescription Drug Event data and Medicaid State Drug Utilization data from the Centers for Medicare & Medicaid Services (CMS). For each data source, we examined the latest available data at the time of our review. In addition, we conducted a literature review; interviewed officials and reviewed documents from stakeholder organizations, federal agencies, insurers, and others; and examined relevant laws and regulations.

National Health and Nutrition Examination Survey

We examined CDC's nationally representative estimates from NHANES of the prevalence of obesity among U.S. adults and use of obesity drugs. NHANES is a cross-sectional survey designed to monitor the health and nutritional status of the civilian, noninstitutionalized U.S. population. The survey consists of interviews conducted in participants' homes and standardized physical examinations, including measured height and weight, conducted in mobile examination centers. CDC analyzed data from two 2-year cycles of NHANES (2013 through 2014 and 2015 through 2016) for the prevalence of obesity [defined as a body mass index (BMI)

[1]Pub. L. No. 115-123, div. E, tit. III, § 50352, 132 Stat. 64, 212.

[2]For our review, we included the following nine FDA-approved prescription drugs for weight loss: benzphetamine, diethylpropion, phendimetrazine, phentermine, bupropion/naltrexone (Contrave), liraglutide (Saxenda), lorcaserin (Belviq), orlistat (Xenical), and phentermine/topiramate (Qsymia). See appendix II for additional information on the obesity drugs included in our review.

of 30 or higher] for all adults by age (18 and older, 18 through 64, and 65 and older), health insurance coverage, and class of obesity.[3] The insurance categories were mutually exclusive: (1) Medicare, which includes all adults who reported having Medicare, regardless of whether they reporting having another type of health insurance (e.g., private health insurance) in addition to Medicare; (2) private health insurance (excluding individuals with Medicare); (3) Medicaid/public health insurance (excluding Medicare); and (4) uninsured.[4] We also examined CDC's estimates from NHANES on the prevalence of overweight (defined as a BMI of 25 to <30) among U.S. adults. In addition, we examined CDC's estimates from NHANES for 2013 through 2016 on adults who took prescription medications for weight loss.[5] NHANES asks participants if they tried to lose weight, and, for those who did, if they took diet pills prescribed by a doctor. CDC's estimates included the lower and upper bounds of the 95 percent confidence intervals (the interval that would contain the actual population value for 95 percent of the samples NHANES could have drawn).

Medical Expenditure Panel Survey

We examined AHRQ's nationally representative estimates from MEPS data on the use of and payment sources for obesity drugs.[6] MEPS collects nationally representative data on health care use, expenditures, sources of payment, and insurance coverage for the U.S. civilian, noninstitutionalized population. For this analysis, AHRQ estimated the distribution of payments for obesity drugs using MEPS pooled data for

[3]These estimates are based on an unweighted sample of 11,375 adults and an estimated population of 240.5 million adults. BMI was calculated from measured weight and measured height (weight in kilograms divided by height in meters squared) from the NHANES physical examination. Pregnant women are excluded from this analysis.

[4]The private health insurance category excluded coverage by a single service plan, such as a dental or a vision plan, or a Medigap (Medicare supplement insurance) plan. The Medicaid/public insurance category excludes Medicare and includes Medicaid, military healthcare, Indian Health Service, state-sponsored health plans, and other government programs. According to CDC's estimates from NHANES data, 46.4 percent of adults with public insurance only had Medicaid. The estimates presented here are internal to CDC's analysis of NHANES data.

[5]These estimates are based on data from 166 NHANES sample members, who reported that they tried to lose weight and took diet pills prescribed by a doctor.

[6]We define use of obesity drugs as having an outpatient prescription filled or refilled for any of the nine obesity drugs.

years 2012 through 2016.[7] We also examined AHRQ's estimates from MEPS of annual expenditures for medical care and all prescription drugs—for those individuals who used obesity drugs and those who did not—and annual expenditures for obesity drugs.[8] AHRQ's estimates included the lower and upper bounds of the 95 percent confidence intervals.

IQVIA

We examined FDA's nationally projected data on the prescriptions dispensed for obesity drugs from outpatient retail pharmacies using 2017 IQVIA™ National Prescription Audit Extended Insights and IQVIA™ Total Patient Tracker.[9] IQVIA™ is proprietary data that includes data for prescriptions dispensed at approximately 59,900 U.S. outpatient retail pharmacies. FDA analyzed IQVIA data and provided aggregated results for the nationally estimated number of prescriptions dispensed for the nine obesity drugs from U.S. outpatient retail pharmacies, by payment method. These patterns may not apply to other settings of care (e.g., mail-order or specialty pharmacies or clinics). In addition, the analysis captures data when a prescription was dispensed; it does not indicate that the patient took the obesity drug, and it does not indicate if the drug was prescribed off label for something other than weight loss.

[7]Because two of the drugs—liraglutide (Saxenda) and bupropion/naltrexone (Contrave)—were approved for the U.S. market in 2014, not all of the obesity drugs were available in all of the years included in this analysis. AHRQ's estimates are based on an unweighted sample of 397 MEPS sample members and an estimated average annual population of approximately 940,000 adults who were reported to have used obesity drugs. This analysis excludes adults age 18 and older with missing BMI data, and women who reported that they were pregnant during the reference period of the interview in which they reported height and weight.

[8]Prescription drug expenditures in 2012 to 2015 were inflated to 2016 dollars using the Consumer Price Index for Prescription Drugs, available from the Bureau of Labor Statistics. Medical expenditures in 2012 to 2015 were inflated to 2016 dollars using the Personal Health Care Expenditure Index available from CMS. Prescription drug expenditure and medical expenditure estimates are based on an unweighted sample of 118,615 adults and an estimated average annual population of 233,060,000 adults. BMIs calculated in MEPS are based on height and weight as reported by household respondents; as a result, fewer individuals are identified as having obesity (with a BMI of 30 or higher) in MEPS data. AHRQ provided the upper and lower bounds of the 95 percent confidence intervals that account for the complex survey design of MEPS.

[9]This analysis included prescriptions dispensed for the obesity drugs; it does not include a link between the prescription and the patient's diagnosis.

Sentinel System

We examined FDA's national estimates of prescriptions for obesity drugs dispensed by outpatient pharmacies for new users of obesity drugs (by number of days supplied and by age and gender of patient) from the agency's Sentinel System.[10] FDA's Sentinel System uses prescription drug dispensing data from populations with federal or commercial insurance to characterize drug utilization of a large U.S. population with private and public health insurance. FDA examined drug dispensing data from January 1, 2008, through December 31, 2017, from 17 of 18 Sentinel data partners, including Medicare, which contributed fee-for-service enrollee data. FDA analyzed dispensings for 267,836 new users of the nine prescription obesity drugs.[11] FDA estimated the duration of the first treatment episode (in days) for patients' prescription dispensings for any of the nine obesity drugs using a 14-day episode gap—that is, if there were more than 14 days between exhausting the previous dispensing's days supplied for that prescription and refilling the prescription, then FDA counted it as a new treatment episode. FDA estimated cumulative treatment duration by summing days' supply of all dispensings of an obesity drug during a patient's presence in the database, without regard to time between dispensings.

Medicare Part D Prescription Drug Event Data

For information on the number of claims for obesity drugs that were reimbursed, the number of plans that provided reimbursement, and the amount reimbursed for obesity drugs under the Medicare prescription drug program known as Medicare Part D, we analyzed Medicare

[10]Dispensing is the act of delivering a prescription drug to a patient or an intermediary who is responsible for administering the drug. A new user was defined as having no use of any obesity drug in the previous 183 days.

[11]FDA's analysis included dispensings of Alli, a lower dose of orlistat that is an over-the-counter weight-loss medication that does not require a prescription.

Because two of the obesity drugs—lorcaserin (Belviq) and phentermine/topiramate (Qsymia) were approved for the U.S market in 2012, and two of the drugs—liraglutide (Saxenda) and bupropion/naltrexone (Contrave) were approved for the U.S. market in 2014, not all of the drugs were available in all of the years included in FDA's analysis of Sentinel System data. Although these data are not medication administration data, this analysis assumes that patients who obtained multiple dispensings took the dispensed doses of their obesity drugs prior to the last refill. Because prescribers are not required to document the indication, it is possible that some drug dispensings were for indications that are not labeled, according to FDA.

Prescription Drug Event data from CMS for 2016 and 2017.[12] We analyzed Medicare Part D plan reimbursements (payments to pharmacies) and beneficiary spending (the total amount Medicare beneficiaries paid out of pocket as copayments or deductibles) for the nine obesity drugs for claims that CMS's data coded as reimbursed as a supplemental drug under enhanced alternative coverage.[13] We excluded 1,787 claims in 2016 and 1,775 claims in 2017 for one obesity drug, orlistat (Xenical), that were listed in CMS's data as covered under Medicare Part D (and were not coded as a supplemental drug under enhanced alternative coverage). According to CMS officials, orlistat has off-label indications including diabetes and hyperlipidemia, and when orlistat is used for these indications the drug would be covered under Medicare Part D, and the Medicare Part D plan is responsible for ensuring it is dispensed appropriately per Medicare Part D policy. We also excluded 25 claims in 2016 and 26 claims in 2017 for prescription obesity drugs listed as over-the-counter in the prescription drug event data because, according to CMS, these appear to be outliers. Because our analysis was limited to those instances in which a Medicare Part D plan reimbursed for an obesity drug as a supplemental drug under enhanced alternative coverage, the number of Medicare Part D plans that provided coverage for obesity drugs could be higher. For example, some plans may have covered obesity drugs, but none of the beneficiaries enrolled in these plans filled a prescription for such a drug.

[12]Medicare Part D provides a voluntary outpatient prescription drug benefit for Medicare beneficiaries. In 2018, there were about 44 million enrollees covered by a Medicare Part D plan. CMS's Prescription Drug Event data contains cost and payment data submitted by plans to CMS for covered Part D drugs to enable CMS to make payments to plans and administer the Part D benefit. Our analysis was limited to those instances in which a Medicare Part D plan reimbursed for an obesity drug as a supplemental drug under enhanced alternative coverage, and the actual number of Medicare Part D plans that provided coverage for obesity drugs could be higher. We did not find comprehensive data on the number of Medicare Part D plans that provided coverage or the number of beneficiaries with coverage for obesity drugs.

[13]Beneficiary spending refers to how much a beneficiary's responsibility is for a given claim. The amount includes how much a beneficiary pays for a drug that is not reimbursed by a third party, the amount a patient's liability is reduced due to other benefits such as the Veterans Administration and TRICARE, the amount a plan reduced the patient's liability due a beneficiary's low-income cost sharing subsidy amount and all other qualified third-party payments on behalf of the beneficiary, which are referred to as the Other True Out-of-Pocket. The low-income cost sharing subsidy amount and Other True Out-of-Pocket amounts are zero for obesity drugs because they are covered under an enhanced benefit, not as Part D drugs.

Medicaid State Drug Utilization Data

For information on obesity drugs reimbursed by state Medicaid programs or Medicaid managed care programs within those states, we analyzed CMS's Medicaid State Drug Utilization data for 2016 and 2017.[14] We analyzed the data to estimate the number of prescriptions reimbursed and total Medicaid state and federal spending—that is, the Medicaid amount reimbursed (state and federal reimbursement, including dispensing fees)—for the nine obesity drugs.[15] These amounts do not include all Medicaid spending for obesity drugs because managed care organizations can be paid for the drugs as part of their capitated payment for all Medicaid services, they are not reimbursed on a per-drug basis, and their payments are not recorded in CMS's Medicaid State Drug Utilization data. Because our analysis was limited to those instances in which Medicaid reimbursed for an obesity drug, the number of states in which state Medicaid programs or Medicaid managed care plans provided coverage for obesity drugs could be higher. For example, a state could have provided coverage for obesity drugs, but no beneficiaries in that state filled a prescription for an obesity drug.

Interviews with Officials in Stakeholder Organizations, Federal Agencies, Insurers, and Others

We obtained information and reviewed studies from officials from eight stakeholder organizations (representing medical associations and advocacy groups for obesity research and treatment) on the use of obesity drugs and guidelines for using obesity drugs and to obtain their perspectives on what physicians and other health care providers take into consideration when prescribing these drugs, among other things.[16] These stakeholders were selected because of their medical or scientific expertise, relevant publications, or familiarity with the treatment of obesity and obesity drugs.

[14]As of March 2019, there were 65.9 million enrollees covered by Medicaid.

[15]The Medicaid State Drug Utilization data does not include information on the indication or indications for which these drugs were prescribed. Therefore, we cannot determine whether these obesity drugs were prescribed off label. A 2018 study compared 2015 Medicaid State Drug Utilization data and publicly available 2016-2017 Medicaid program documents, and found that more states reimbursed for obesity drugs than indicated coverage in the program documents. See N. Jannah, J. Hild, C. Gallagher, and W. Dietz, "Coverage for Obesity Prevention and Treatment Services: Analysis of Medicaid and State Employee Health Insurance Programs," *Obesity*, vol. 26 (2018): 1834-1840.

[16]The stakeholder organizations we contacted were the American Academy of Family Physicians, American Association of Clinical Endocrinologists, American College of Cardiology, American Heart Association, Obesity Action Coalition, Obesity Medicine Association, The Obesity Society, and the Strategies to Overcome and Prevent (STOP) Obesity Alliance.

We also reviewed data and documents and interviewed officials from HHS agencies: CDC, FDA, AHRQ, CMS, and the National Institutes of Health. In addition, we reviewed guidance documents and obtained information from the Office of Personnel Management, which administers the Federal Employees Health Benefits program (FEHBP). FEHBP is the largest employer-sponsored health insurance program in the United States, providing health insurance coverage to about 8 million federal employees, retirees, and their dependents in 2016 through contracts with private health insurance plans.

We obtained information about the health insurance coverage of obesity drugs from officials from the three largest pharmacy benefit managers, four large insurers, and two organizations knowledgeable about prescription drug benefits for employer-sponsored health plans.[17] We also reviewed drug formularies for selected private health insurance plans, including FEHBP plans, to determine if any of the nine obesity drugs were included.[18]

Literature Review

We conducted a literature review of relevant peer-reviewed studies published from January 2012 through January 2019. We identified studies through a search of bibliographic databases, including ProQuest, Scopus, MEDLINE, and International Pharmaceutical Abstracts, using terms such as “obesity,” “weight loss,” and “prescriptions.” Of the 765 citations we identified, we reviewed 220 full studies, which we examined for information related to the use of obesity drugs and individuals who use

[17]Pharmacy benefit managers administer prescription drug programs for health plans, including commercial health plans and Medicare Part D plans. The pharmacy benefit managers that we contacted were Express Scripts, Optum RX, and CVS Caremark, all of which comprise about 70 percent of the pharmacy benefit manager market. We selected the four large insurers—Blue Cross Blue Shield, United Healthcare, Kaiser Permanente, and Aetna—based on the criteria of the insurers covering more than 1 million lives and operating in multiple states. The other two organizations we contacted were Willis Towers Watson, an employer benefit consultant, and the National Business Group on Health, an organization that represents over 430 large employers.

[18]A formulary is a list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits. A plan may cover drugs that are not included on the formulary if, for example, a patient has previously used other prescription drugs or therapies and the health care provider determines the prescription drug not included in the formulary is medically necessary for the patient. We reviewed formularies from the three largest FEHBP plans, including the Blue Cross Blue Shield’s Basic and Standard formularies, Kaiser Permanente’s eight regional formularies, and Government Employees Health Association preferred and specialty drug lists. See GAO-18-52 for more information on FEHBP plans.

them, coverage of obesity drugs, and spending for obesity drugs for individuals who used them compared to those who did not. We determined 19 studies were relevant to the use of obesity drugs and 1 study was relevant to coverage of obesity drugs. Our literature review focused on studies with a U.S.-based, adult population (age 18 and older); we excluded studies related to childhood obesity and studies on animals. We also examined available information on the clinical trials conducted prior to FDA approval of the prescription obesity drugs for the U.S. market, including 64 studies from our literature review that summarized one or more of the clinical trials. We also identified 17 additional studies in our literature review that provided relevant background information.

Additionally, we reviewed five studies provided by stakeholder organizations (in addition to the studies we had identified in our literature review) that we determined were relevant to our research objectives, as well as guidelines for the use of obesity drugs in obesity treatment.[19]

To determine the reliability of the data we used for all four objectives—CDC's estimates from NHANES, AHRQ's estimates from MEPS, FDA's data from IQVIA and the Sentinel System, and CMS's Medicare Part D Prescription Drug Event data and Medicaid State Drug Utilization data—we reviewed documentation on data collection processes and discussed limitations of the data with the relevant federal agency officials. In addition, we conducted data reliability checks on the data, when appropriate. We determined the data used in this report were sufficiently reliable for our purposes.

We conducted this performance audit from April 2018 to August 2019 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our

[19]These guidelines include: (1) American College of Cardiology and American Heart Association Task Force on Practice Guidelines and The Obesity Society, "A Guideline for the Management of Overweight and Obesity in Adults," (2013); (2) C.M. Apovian et al., "Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline," *Journal of Clinical Endocrinology and Metabolism*, vol. 100, no. 2, (2015): 342-362; (3) W.T. Garvey et al., "American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity," *Endocrine Practice,* vol. 22, supp. 3, (2016): 1-203; and (4) Obesity Medicine Association, *Obesity Algorithm 2017-2018*, (Denver, CO: June 2018).

findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: List of FDA-Approved Prescription Obesity Drugs

Table 4 provides additional information on the nine prescription drugs approved by the Food and Drug Administration (FDA) to treat obesity that we included in our review.

Table 4: FDA-Approved Prescription Obesity Drugs, as of June 2019

Generic name	Brand name(s)	Year approved	Approved use	Approved for adults/children
Phentermine	Adipex-P and Lomaira	1959[a]	Short-term[b]	Age 16 and older
Diethylpropion	n/a[c]	1959	Short-term	Age 16 and older
Benzphetamine	n/a[c]	1960	Short-term	Age 12 and older
Phendimetrazine	n/a[c]	1961	Short-term	Age 17 and older
Orlistat	Xenical	1999	Long-term	Age 12 and older
Lorcaserin	Belviq	2012	Long-term	Adults (18 and older)
Phentermine + Topiramate	Qsymia	2012	Long-term	Adults (18 and older)
Liraglutide	Saxenda	2014	Long-term	Adults (18 and older)
Bupropion + Naltrexone	Contrave	2014	Long-term	Adults (18 and older)

Source: Food and Drug Administration (FDA). | GAO-19-577

Notes: Two additional prescription drugs approved by FDA for weight loss—methamphetamine and amphetamine—were not recommended for use by any medical society guidelines for the treatment of obesity. Methamphetamine is a controlled substance with high abuse potential and is thus rarely used for obesity treatment, according to an official from the National Institutes of Health's Office of Obesity Research. In addition, amphetamines are not used in the treatment of obesity, according to officials from a scientific membership organization focused on obesity issues and officials from medical associations with clinician members who treat obesity. We therefore excluded methamphetamine and amphetamine from the list of prescription obesity drugs. Additionally, we excluded Victoza, which has the same active ingredient as Saxenda (liraglutide), because it is indicated for diabetes. We also excluded Alli, a lower dose of orlistat, because it is an over-the-counter drug that does not require a prescription.

[a]Phentermine was initially approved by FDA in 1959; however, it has since been approved and marketed under different brand names in different dosage levels.

[b]Short-term use is generally considered to be use of the drug for about 12 weeks or less.

[c]According to FDA, these drugs are not marketed under a brand name, they are only available as a generic drug—that is, a drug that is created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

Appendix III: Prevalence of Obesity and Overweight among U.S. Adults

This appendix presents national estimates of the prevalence of obesity among U.S. adults age 18 and older, based on the Centers for Disease Control and Prevention's (CDC) estimates from the National Health and Nutrition Examination Survey (NHANES) for 2013 through 2016.[1] It presents the estimates and the ranges for the 95 percent confidence intervals for prevalence of obesity by age and class of obesity (see table 5), and by insurance coverage and class of obesity (see table 6).[2] It also presents national estimates of the prevalence of overweight (defined as a body mass index of 25 to <30) among U.S. adults, by age and insurance coverage (see table 7).

[1]Data from two 2-year cycles of NHANES (2013 through 2014 and 2015 through 2016) were used for this analysis. NHANES is a cross-sectional survey designed to monitor the health and nutritional status of the civilian, noninstitutionalized U.S. population. The survey consists of interviews conducted in participants' homes and standardized physical examinations, including measured height and weight, in mobile examination centers.

[2]The 95 percent confidence interval is the interval that would contain the actual population value for 95 percent of the samples NHANES could have drawn. As a result, we are 95 percent confident that each of the confidence intervals based on NHANES includes the true values in the population.

Table 5: Prevalence of Obesity among U.S. Adults, 2013–2016, by Age and Class of Obesity

(percentage)

	Estimate	95 percent confidence interval	
		Lower bound	Upper bound
All U.S. adults	**38.4**	**36.5**	**40.2**
Class 1 (BMI of 30 to <35)[a]	21.0	19.8	22.2
Class 2 (BMI of 35 to <40)	9.8	9.0	10.6
Class 3 (BMI ≥40)	7.6	6.7	8.5
Age 18–64	38.5	36.3	40.8
Class 1 (BMI of 30 to <35)	20.4	18.9	21.9
Class 2 (BMI of 35 to <40)	9.7	8.8	10.7
Class 3 (BMI ≥40)	8.4	7.4	9.6
Age 65 and older	37.6	34.7	40.5
Class 1 (BMI of 30 to <35)	23.6	21.2	26.1
Class 2 (BMI of 35 to <40)	10.0	8.3	11.9
Class 3 (BMI ≥40)	4.0	2.8	5.6

Source: Centers for Disease Control and Prevention's estimates from the National Health and Nutrition Examination Survey (NHANES), 2013–2016. | GAO-19-577

Notes: Adults are defined as age 18 and older. Pregnant women are excluded from this analysis.

These estimates are based on an unweighted sample of 11,375 adults and an estimated population of 240.5 million adults.

[a]Body mass index (BMI) is calculated from measured weight and measured height (weight in kilograms divided by height in meters squared) from the NHANES physical examination.

Table 6: Prevalence of Obesity among U.S. Adults, 2013–2016, by Insurance Coverage and Class of Obesity

(percentage)

	Estimate	95 percent confidence interval	
		Lower bound	Upper bound
Medicare coverage[a]	39.5	36.5	42.5
Class 1 (BMI of 30 to <35)[b]	23.9	21.3	26.6
Class 2 (BMI of 35 to <40)	9.7	8.2	11.4
Class 3 (BMI ≥40)	5.8	4.4	7.6
Private insurance[c]	37.0	34.5	39.7
Class 1 (BMI of 30 to <35)	20.3	18.3	22.5
Class 2 (BMI of 35 to <40)	9.4	8.2	10.7
Class 3 (BMI ≥40)	7.3	6.4	8.3
Medicaid and other public health insurance (excluding Medicare)[d]	42.1	36.8	45.7

	Estimate	95 percent confidence interval	
		Lower bound	Upper bound
Class 1 (BMI of 30 to <35)	20.5	17.8	23.5
Class 2 (BMI of 35 to <40)	10.8	9.1	12.7
Class 3 (BMI ≥40)	10.8	8.5	13.4
Uninsured	38.0	34.5	41.7
Class 1 (BMI of 30 to <35)	19.3	16.9	21.9
Class 2 (BMI of 35 to <40)	10.3	8.6	12.1
Class 3 (BMI ≥40)	8.4	6.6	10.6

Source: Centers for Disease Control and Prevention's (CDC) estimates from the National Health and Nutrition Examination Survey (NHANES), 2013–2016. | GAO-19-577

Notes: All of the health insurance coverage categories are mutually exclusive. Adults are defined as age 18 and older. Pregnant women are excluded from this analysis.

These estimates are based on an unweighted sample of 11,375 adults and an estimated population of 240.5 million adults.

[a]Medicare estimates include all adults who reported having Medicare, including adults who also reported having private health insurance or other public health insurance; if they reported having Medicare, they were counted in the Medicare category and not in the private insurance or other public insurance category. An estimated 87 percent of adults covered by Medicare were 65 and older, while an estimated 13 percent were age 18 through 64.

[b]Body mass index (BMI) is calculated from measured weight and measured height (weight in kilograms divided by height in meters squared) from the NHANES physical examination.

[c]Adults who reported having private health insurance and another type of insurance, such as Medicaid, were counted in the private insurance category except if they had Medicare—in which case they were counted in the Medicare category. This excluded coverage by a single service plan, such as a dental or a vision plan, or a Medigap (Medicare supplement insurance) plan.

[d]Medicaid accounted for about 46.4 percent of adults in the Medicaid/other public insurance category in the NHANES analysis, according to CDC. The category also includes military healthcare, Indian Health Service, state-sponsored health plans, and other government programs. This excludes Medicare coverage.

Table 7: Prevalence of Overweight among U.S. Adults, 2013–2016, by Age and Insurance Coverage

(percentage)

	Estimate	95 percent confidence interval	
		Lower bound	Upper bound
All U.S. adults	**32.0**	**31.0**	**33.0**
Age 18–64	30.8	29.4	32.2
Age 65 and older	36.9	34.6	39.4
Medicare coverage[a]	35.8	33.6	38.0
Private insurance[b]	31.5	29.8	33.1
Medicaid and other public health insurance (excluding Medicare)[c]	26.7	24.4	29.1
Uninsured	32.9	29.4	36.6

Source: Centers for Disease Control and Prevention's (CDC) estimates from the National Health and Nutrition Examination Survey (NHANES), 2013–2016. | GAO-19-577

Notes: Overweight is defined as a body mass index (BMI) of 25 to <30. BMI is calculated from measured weight and measured height (weight in kilograms divided by height in meters squared) from the NHANES physical examination.

All of the health insurance coverage categories are mutually exclusive.

Adults are defined as age 18 and older. Pregnant women are excluded from this analysis.

These estimates are based on an unweighted sample of 11,375 adults and an estimated population of 240.5 million adults.

[a]Medicare estimates include all adults who reported having Medicare, including adults who also reported having private health insurance or other public health insurance; if they reported having Medicare, they were counted in the Medicare category and not in the private insurance or other public insurance category. An estimated 87 percent of adults covered by Medicare were 65 and older, while an estimated 13 percent were age 18 through 64.

[b]Adults who reported having private health insurance and another type of insurance, such as Medicaid, were counted in the private insurance category except if they had Medicare—in which case they were counted in the Medicare category. This excluded coverage by a single service plan, such as a dental or a vision plan, or a Medigap (Medicare supplement insurance) plan.

[c]Medicaid accounted for about 46.4 percent of adults in the Medicaid/other public insurance category in the NHANES analysis, according to CDC. The category also includes military healthcare, Indian Health Service, state-sponsored health plans, and other government programs. This excludes Medicare coverage.

Appendix IV: List of Selected Studies Reviewed

Table 8 is a list of selected studies, categorized by specific topic area, that we reviewed that pertain to our research objectives, including information related to the use of obesity drugs and individuals who use them, physician considerations in prescribing obesity drugs, and health insurance coverage of obesity drugs. We identified these studies either through our literature review of peer-reviewed studies published from January 2012 through January 2019 or from one of the stakeholder organizations we contacted.

Table 8: List of Selected Studies Pertaining to Our Research Objectives, by Topic Area

Topic area	Study citation
Use of obesity drugs among U.S. adults	A.C. Del Re, S.M. Frayne, and A.H.S Harris, "Antiobesity Medication Use Across the Veterans Health Administration: Patient-Level Predictors of Receipt," *Obesity*, vol. 22 (2014): 1968-1972.
	C. Hampp, E.M. Kang, and V. Borders-Hemphill, "Use of Prescription Antiobesity Drugs in the U.S.," *Pharmacotherapy*, vol. 33 (2013): 1299-1307.[a]
	T.P. Semla, C. Ruser, C.B. Good, S.Z. Yanovski, D. Ames, L.A. Copeland, C. Billington, U.I. Ferguson, L.J. Aronne, T.A. Wadden, W.T. Garvey, C.M. Apovian, and D. Atkins, "Pharmacotherapy for Weight Management in the VHA," *Journal of General Internal Medicine*, vol. 32 (2017): 70-73.
	C.E. Thomas, E.A. Mauer, A.P. Shukla, S. Rathi, L.J. Aronne. "Low Adoption of Weight Loss Medications: A Comparison of Prescribing Patterns of Anti-Obesity Pharmacotherapy and SGLT2s." *Obesity*, vol. 24 (2016): 1955-1961.
	D.D. Thomas, M.E. Waring, O. Ameli, J.I. Reisman, and V.G. Vimalananda, "Patient Characteristics Associated with Receipt of Prescription Weight-Management Medications Among Veterans Participating in MOVE!" *Obesity*, vol. 27, no. 7 (2019): 1168-1176.
	S. Zhang, S. Manne, J. Lin, and J. Yang, "Characteristics of Patients Potentially Eligible for Pharmacotherapy for Weight Loss in Primary Care Practice in the United States," *Obesity Science & Practice*, vol. 2, no. 2 (2016): 104-144.
Physician considerations and attitudes in prescribing obesity drugs	T.A. Glauser, N. Roepke, B. Stevenin, A.M. Dubois, and S.M. Ahn, "Physician Knowledge About and Perceptions of Obesity Management," *Obesity Research & Clinical Practice*, vol. 9 (2015): 573-583.
	B. Granara and J. Laurent, "Provider Attitudes and Practice Patterns of Obesity Management with Pharmacotherapy," *Journal of the American Association of Nurse Practitioners*, (2017): 543-550.
	S. Iwamoto, D. Saxon, A. Tsai, E. Leister, R. Speer, H. Heyn, E. Kealey, E. Juarez-Colunga, K. Gudzune, S. Bleich, J. Clark, and D. Bessesen, "Effects of Education and Experience on Primary Care Providers' Perspectives of Obesity Treatments during a Pragmatic Trial," *Obesity*, vol. 26 (2018): 1532-1538.
	L.M. Kaplan, A. Golden, K. Jinnett, R.L. Kolotkin, T.K. Kyle, M. Look, J. Nadglowski, P.M. O'Neil, T. Parry, K.J. Tomaszewski, B. Stevenin, S.K. Lilleøre, and N.V. Dhurandhar, "Perceptions of Barriers to Effective Obesity Care: Results from the National ACTION Study," *Obesity*, vol. 26, no. 1 (2018): 61-69.
	C. Petrin, S. Kahan, M. Turner, C. Gallagher, and W.H. Dietz, "Current Practices of Obesity Pharmacotherapy, Bariatric Surgery Referral and Coding for Counselling by Healthcare Professionals," *Obesity Science & Practice*, vol. 2, no. 3 (2016).
	R. Simon and S.W. Lahiri, "Provider Practice Habits and Barriers to Care in Obesity Management in a Large Multicenter Health System," *Endocrine Practice*, vol. 24, no. 4 (2018): 321-328.
	M. Turner, N. Jannah, S. Kahan, C. Gallagher, and W. Dietz, "Current Knowledge of Obesity Treatment Guidelines by Health Care Professionals," *Obesity*, vol. 26, no. 4 (2018): 665-671.

Topic area	Study citation
Use of obesity drugs in conjunction with other items or services (e.g., behavioral counseling)	A.G. Tsai, E. Raube, J. Conrad, D.H. Bessesen, and J.M. Rozwadowski, "A Pilot Randomized Trial Comparing a Commercial Weight Loss Program with a Clinic-Based Intervention for Weight Loss," *Journal of Primary Care & Community Health*, vol. 3, no. 4 (2012): 251–255. T.A. Wadden, O.A. Walsh, R.I. Berkowitz, A.M. Chao, N. Alamuddin, K. Gruber, S. Leonard, K. Mugler, Z. Bakizada, and J. Shaw Tronieri, "Intensive Behavioral Therapy for Obesity Combined with Liraglutide 3.0 mg: A Randomized Controlled Trial," *Obesity*, vol. 27 (2019): 75-86.
Adherence to using the prescribed obesity drug	R. Ganguly, Y. Tian, S.X. Kong, M. Hersloev, T. Hobbs, B.G. Smolarz, A. Ramasamy, C.L. Haase, and W. Weng, "Persistence of Newer Anti-Obesity Medications in a Real-World Setting," *Diabetes Research and Clinical Practice*, vol. 143 (2018): 348-356. T. R. Grabarczyk, "Observational Comparative Effectiveness of Pharmaceutical Treatments for Obesity within the Veterans Health Administration," *Pharmacotherapy*, vol. 38, no. 1 (2018): 19-28. C. Hampp, E.M. Kang, and V. Borders-Hemphill, "Use of Prescription Antiobesity Drugs in the U.S.," *Pharmacotherapy*, vol. 33 (2013): 1299-1307.
Maintaining weight loss over time by individuals who have used obesity drugs	E.A. Bohula, S.D. Wiviott, D.K. McGuire, S.E. Inzucchi, J. Kuder, K.A. Im, C.L. Fanola, A. Qamar, C. Brown, A. Budaj, A. Garcia‐Castillo, M. Gupta, L.A. Leiter, N.J. Weissman, H.D. White, T. Patel, B. Francis, W. Miao, C. Perdomo, S. Dhadda, M.P. Bonaca, C.T. Ruff, A.C. Keech, S.R. Smith, M.S. Sabatine, and B.M. Scirica, "Cardiovascular Safety of Lorcaserin in Overweight or Obese Patients," *The New England Journal of Medicine*, vol. 379, no. 12 (2018): 1107-1117.[b] K. Fujioka, P.M. O'Neil, M. Davies, F. Greenway, D.C.W. Lau, B. Claudius, T.V. Skjøth, C.B. Jensen, and J.P.H. Wilding, "Early Weight Loss with Liraglutide 3.0 mg Predicts 1-Year Weight Loss and is Associated with Improvements in Clinical Markers," *Obesity*, vol. 24, no. 11 (2016): 2278-2288. K. Fujioka, R. Plodkowski, P.M. O'Neil, K. Gilder, B. Walsh, and F.L. Greenway, "The Relationship between Early Weight Loss and Weight Loss at 1 Year with Naltrexone ER/Bupropion ER Combination Therapy," *International Journal of Obesity*, vol. 40 (2016): 1369-1375. E.S. LeBlanc, C.D. Patnode, E.M. Webber, N. Redmond, M. Rushkin, and E.A. O'Connor, "Behavioral and Pharmacotherapy Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults: Updated Evidence Report and Systematic Review for the U.S. Preventive Services Task Force," *JAMA*, vol. 320, no. 11 (2018): 1172-1191. K.H. Lewis, H. Fischer, J. Ard, L. Barton, D.H. Bessesen, M.F. Daley, J. Desai, S. Fitzpatrick, M. Horberg, C. Koebnick, C. Oshiro, A. Yamamoto, D.R. Young, and D.E. Arterburn, "Safety and Effectiveness of Longer-Term Phentermine Use: Clinical Outcomes from an Electronic Health Record Cohort," *Obesity*, vol. 27, no. 4 (2019): 591-602. S.R. Smith, P.M. O'Neil, A. Astrup, N. Finer, M. Sanchez-Kam, K. Fraher, R. Fain, and W.R. Shanahan, "Early Weight Loss While on Lorcaserin, Diet and Exercise as a Predictor of Week 52 Weight-Loss Outcomes," *Obesity*, vol. 22, no. 10 (2014): 2137–2146. J.S. Tronieri, T.A. Wadden, R.I. Berkowitz, A.M. Chao, R.L. Pearl, N. Alamuddin, S.M. Leonard, R. Carvajal, Z.M. Bakizada, E. Pinkasavage, K.A. Gruber, O.A. Walsh, and N. Alfaris, "A Randomized Trial of Lorcaserin and Lifestyle Counseling for Maintaining Weight Loss Achieved with a Low-Calorie Diet," *Obesity*, vol. 26 (2018): 299-309.
Health insurance coverage of obesity drugs	G. Gomez and F.C. Stanford, "US Health Policy and Prescription Drug Coverage of FDA-approved Medications for the Treatment of Obesity," *International Journal of Obesity*, vol. 42 (2018): 495-500.

Source: GAO. | GAO-19-577

[a]This study is also listed in the adherence to using the prescribed obesity drug section because it also examines duration of use for select obesity drugs, in addition to the use of obesity drugs.

[b]While this study was conducted in eight countries and is not an entirely U.S.-based study, we included it because of the large number of participants (12,000 patients with obesity or who were overweight), the length of the study (median follow-up period of 3.3 years), and because it was a recent study (2018). Further, although the primary outcome of this study was to assess the

cardiovascular safety of lorcaserin, the study also assessed the effect of lorcaserin on weight through 40 months of follow up, which we determined was relevant to maintaining weight loss over time.

Appendix V: Estimates of New Adult Users of Obesity Drugs, 2008-2017

This appendix presents estimates of prescriptions dispensed for new adult users of obesity drugs by duration of use and by age and gender, using data from the Food and Drug Administration's (FDA) Sentinel System from 2008 through 2017.[1] Of the 267,836 new users of obesity drugs included in this analysis, the first treatment episode did not exceed 30 days in about 54 percent of patients and exceeded 90 days in about 22 percent of patients. Cumulatively, about 42 percent of patients who used any of the obesity drugs did so for more than 90 days across treatment episodes. (See table 9.) Overall, most new users of obesity drugs were female (82.2 percent) and under age 65 (91.7 percent). (See table 10.) Phentermine and bupropion/naltrexone (Contrave) were the most commonly used obesity drugs in FDA's Sentinel System analysis.

[1]Dispensing is the act of delivering a prescription drug to a patient or an intermediary who is responsible for administering the drug. FDA's Sentinel System uses prescription drug dispensing data to characterize drug utilization on a large U.S. population with private and public health insurance. A new user was defined as having no use of any obesity drug in the previous 183 days. FDA examined drug dispensing data for new users of obesity drugs from January 1, 2008, through December 31, 2017, from 17 of 18 Sentinel data partners, including Medicare, which contributed fee-for-service enrollee data. FDA analyzed dispensings of the nine prescription obesity drugs: benzphetamine, diethylpropion, phendimetrazine, phentermine, bupropion/naltrexone (Contrave), liraglutide (Saxenda), lorcaserin (Belviq), orlistat (Xenical), and phentermine/topiramate (Qsymia). In addition, FDA's analysis included dispensings of Alli, a lower dose of orlistat that is an over-the-counter weight-loss medication that does not require a prescription. Because two of the drugs—lorcaserin (Belviq) and phentermine/topiramate (Qsymia) were approved for the U.S market in 2012, and two of the drugs—liraglutide (Saxenda) and bupropion/naltrexone (Contrave)—were approved for the U.S. market in 2014, not all of the drugs were available in all of the years included in FDA's analysis. The Sentinel System only contains data from populations with federal or commercial insurance.

Table 9: Duration of Use for New Adult Users of Obesity Drugs, 2008-2017

Duration of use	Number of new adult users (percent)				Total number of new users (percent)	Median duration (days)	Average duration (days)
	1-30 days	31-60 days	61-90 days	91 or more days			
First treatment episode duration[a]	144,563 (53.9)	26,939 (10.1)	38,551 (14.4)	57,783 (21.6)	267,836 (100.0)	30.0	69.1
Cumulative treatment duration[b]	83,994 (31.4)	37,772 (14.1)	32,706 (12.2)	113,364 (42.3)	267,836 (100.0)	72.0	135.1

Source: Food and Drug Administration's (FDA) estimates from FDA's Sentinel System, 2008-2017. | GAO-19-577

Notes: A new user was defined as having no use of any obesity drug in the previous 183 days. In addition to new users of the nine prescription obesity drugs, FDA's analysis included 125 new users of Alli, a lower dose of orlistat that is an over-the-counter weight-loss medication that does not require a prescription. Because four of the drugs—lorcaserin (Belviq), phentermine/topiramate (Qsymia), liraglutide (Saxenda), and bupropion/naltrexone (Contrave)—were approved for the U.S. market in 2012 or later, not all of the drugs were available in all of the years included in this analysis.

[a]FDA estimated the duration of the first treatment episode (in days) for patients' prescription dispensings for any of the nine obesity drugs using a 14-day episode gap—that is, if there were more than 14 days between exhausting the previous dispensing's days supplied for that prescription and refilling the prescription, then FDA counted it as a new treatment episode.

[b]FDA estimated cumulative treatment duration by summing days' supply of all dispensings of an obesity drug within each patient's presence in the database, without regard to time between dispensings. This measure combined drug exposure from multiple treatment episodes, if present.

Table 10: New Adult Users of Obesity Drugs by Age and Gender, 2008-2017

	Number of new adult users (percent)
Age	
18-44	132,317 (49.4)
45-64	113,325 (42.3)
65 and older	22,194 (8.3)
All Ages	**267,836 (100)**
Gender	
Female	220,273 (82.2)
Male	47,557 (17.8)

Source: Food and Drug Administration's (FDA) estimates from FDA's Sentinel System, 2008-2017. | GAO-19-577

Notes: A new user was defined as having no use of any obesity drug in the previous 183 days. In addition to new users of the nine prescription obesity drugs, FDA's analysis included 125 new users of Alli, a lower dose of orlistat that is an over-the-counter weight-loss medication that does not require a prescription. Because four of the drugs—lorcaserin (Belviq), phentermine/topiramate (Qsymia), liraglutide (Saxenda), and bupropion/naltrexone (Contrave)—were approved for the U.S. market in 2012 or later, not all of the drugs were available in all of the years included in this analysis.

Appendix VI: Reimbursement for Obesity Drugs in Medicare Part D Enhanced Alternative Coverage, 2016 and 2017

This appendix presents information on Medicare Part D plan reimbursement for obesity drugs under enhanced alternative coverage from our analysis of Centers for Medicare & Medicaid Services' (CMS) Prescription Drug Event data.[1] Medicare Part D plans can choose whether or not to offer enhanced alternative coverage, and not all Medicare Part D plans that provide enhanced alternative coverage cover obesity drugs as supplemental drugs.[2] As of February 2017, 1,949 Medicare Part D plans provided enhanced alternative coverage to 18.9 million Medicare beneficiaries, according to the Medicare Payment Advisory Commission. Additionally, in 2015, total Medicare Part D spending for prescription drugs was about $137 billion—this represents payments from all payers including beneficiaries (cost sharing), and excluding rebates and discounts from pharmacies and manufacturers that are not reflected in prices at the pharmacies.[3]

Tables 11 and 12 show the number of claims reimbursed, the number of plans that provided reimbursement, and the amount reimbursed for

[1]Enhanced alternative coverage is alternative prescription drug coverage under Medicare Part D with value exceeding that of Medicare Part D's defined standard coverage. Enhanced alternative coverage may include basic prescription coverage and supplemental benefits such as supplemental drugs. Medicare beneficiaries who select a Part D plan that offers supplemental benefits, which may include coverage of obesity drugs, must pay the full premium cost for those additional benefits (i.e., Medicare does not subsidize them). For example, in 2017, average monthly premiums for beneficiaries in standalone Medicare Part D plans with enhanced benefits were $54 per month compared with an average premium of $31 for basic coverage. See Medicare Payment Advisory Commission, *June 2018 Data Book: Health Care Spending and the Medicare Program*, Section 10 (Washington, D.C.: July 2018) and Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, Chapter 14 (Washington, D.C.: March 2018).

[2]Medicare Payment Advisory Commission, *June 2018 Data Book: Health Care Spending and the Medicare Program*, Section 10 (Washington, D.C.: July 2018), and Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, Chapter 14 (Washington, D.C.: March 2019).

[3]Medicare Payment Advisory Commission, *June 2018 Data Book: Health Care Spending and the Medicare Program* (Washington, D.C.: July 2018), 173.

obesity drugs under Medicare Part D enhanced alternative coverage for 2016 and 2017, respectively.[4]

Table 11: Medicare Part D Number of Claims, Unique Plans, Unique Beneficiaries, Plan Spending, and Beneficiary Liability for the Nine Obesity Drugs, 2016

Obesity drug	Number of claims	Number of plans	Number of beneficiaries	Plan spending (dollars)	Beneficiary liability (dollars)
Phentermine	344	24	170	714	2,648
Any obesity drug (covered as a supplemental drug)[a]	419	32	196	19,714	4,048

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-577

Notes: We excluded 1,787 claims for one obesity drug (orlistat) that were listed in CMS's data as covered under Medicare Part D. According to CMS officials, orlistat has off-label indications, including diabetes and hyperlipidemia, and it is covered under Medicare Part D when it is prescribed for these indications. We also excluded 25 claims for obesity drugs listed as over-the-counter drugs in CMS's data.

[a]Any obesity drug includes aggregated data for all nine obesity drugs.

[4]We analyzed CMS's Prescription Drug Event data for 2016 and 2017 for nine prescription obesity drugs: benzphetamine, diethylpropion, phendimetrazine, phentermine, bupropion/naltrexone (Contrave), liraglutide (Saxenda), lorcaserin (Belviq), orlistat (Xenical), and phentermine/topiramate (Qsymia). We limited our analysis to claims coded as supplemental drugs covered under enhanced alternative coverage and excluded claims for one obesity drug (orlistat) that were listed in CMS's data as covered (and not enhanced) drugs under Medicare Part D. According to CMS officials, orlistat has off-label indications, including for diabetes and hyperlipidemia, and it is covered under Medicare Part D when it is prescribed for these indications. We also excluded claims for obesity drugs listed as over-the-counter drugs in CMS's data.

Table 12: Medicare Part D Number of Claims, Unique Plans, Unique Beneficiaries, Plan Spending, and Beneficiary Liability for the Nine Obesity Drugs, 2017

Obesity drug	Number of claims	Number of plans	Number of beneficiaries	Plan spending (dollars)	Beneficiary liability (dollars)
Bupropion + Naltrexone	282	≤10	110	76,209	2,919
Lorcaserin	157	≤10	60	45,865	2,114
Phentermine	84	11	32	676	135
Any obesity drug (covered as a supplemental drug)[a]	555	27	209	140,296	5,376

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-577

Notes: We excluded 1,775 claims for one obesity drug (orlistat) that were listed in CMS's data as covered under Medicare Part D. According to CMS officials, orlistat has off-label indications including for diabetes and hyperlipidemia, and it is covered under Medicare Part D when it is prescribed for these indications. We also excluded 26 claims for obesity drugs listed as over-the-counter drugs in CMS's data.

[a]Any obesity drug includes aggregated data for all nine obesity drugs.

Appendix VII: Reimbursement for Obesity Drugs in Medicaid, 2016 and 2017

This appendix presents information on Medicaid reimbursements for obesity drugs under state Medicaid programs or Medicaid managed care programs within those states from our analysis of Centers for Medicare & Medicaid Services' (CMS) Medicaid State Drug Utilization data. State Medicaid programs or Medicaid managed care programs reimbursed for at least one obesity drug prescription in 42 states in 2016 and 41 states in 2017.[1] The amount that Medicaid reimbursed and the total number of prescriptions for obesity drugs reimbursed by Medicaid in 2016 and 2017 are shown by state (tables 13 and 14), and by obesity drug (tables 15 and 16).[2] Over half of the prescriptions for obesity drugs reimbursed under Medicaid in 2016 and 2017 were for the generic obesity drug, phentermine.

Table 13: Medicaid Amount Reimbursed and Number of Prescriptions for Obesity Drugs in Each State, 2016

State	Medicaid amount reimbursed (dollars)	Number of prescriptions
Alabama	509	≤10
Arizona	92,012	383
California	1,438,603	8,346
Colorado	1,084	≤10
Connecticut	214,849	426
District of Columbia	21,658	190
Delaware	7,396	25
Florida	13,630	120
Georgia	9,114	15
Hawaii	377,311	370
Iowa	34,524	149
Idaho	10,707	21
Illinois	4,505	26

[1]The Medicaid State Drug Utilization data do not include information on the indication or indications for which these drugs were prescribed. Therefore, we cannot determine whether these obesity drugs were prescribed off label for an indication other than obesity.

[2]The Medicaid amount reimbursed includes state and federal reimbursement and dispensing fees. These amounts do not include all Medicaid spending for obesity drugs under Medicaid managed care—because managed care organizations can be paid for the drugs as part of their capitated payment for all Medicaid services, they are not reimbursed on a per-drug basis and their payment amounts are not recorded in CMS's Medicaid State Drug Utilization data.

State	Medicaid amount reimbursed (dollars)	Number of prescriptions
Indiana	2,207	≤10
Kansas	544,255	1,092
Kentucky	342,704	742
Louisiana	82,352	146
Massachusetts	77,312	3,198
Maryland	79,232	154
Michigan	144,506	844
Minnesota	42,427	93
Missouri	15,539	84
Mississippi	130	≤10
Montana	1,095	≤10
North Carolina	19	≤10
North Dakota	2,432	35
New Hampshire	10,945	65
New Jersey	4,374	18
New Mexico	1,098	≤10
Nevada	7,787	79
New York	29,359	1,351
Ohio	2,158	13
Oregon	6,406	24
Pennsylvania	26,117	121
Rhode Island	7,417	117
South Carolina	22,036	168
Tennessee	16,236	32
Texas	152,087	296
Virginia	115,677	704
Washington	9,226	51
Wisconsin	1,040,564	5,789
West Virginia	5,826	11

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-577

Notes: The table shows the obesity drugs for which the state Medicaid Program or Medicaid managed care program paid a portion or all of a claim. The Medicaid amount reimbursed includes state and federal reimbursement and dispensing fees. These amounts do not include all Medicaid spending for obesity drugs under Medicaid managed care—because managed care organizations can be paid for the drugs as part of their capitated payment for all Medicaid services, they are not reimbursed on a per-drug basis, and their payment amounts are not recorded as amounts reimbursed in CMS's Medicaid State Drug Utilization data. The number of prescriptions reimbursed includes 776 prescriptions for obesity drugs that showed zero dollar amounts for Medicaid reimbursement in CMS's Medicaid State Drug Utilization data.

Table 14: Medicaid Amount Reimbursed and Total Number of Prescriptions for Obesity Drugs in Each State, 2017

State	Medicaid amount reimbursed (dollars)	Number of prescriptions
Alabama	6,080	25
Arizona	96,919	379
California	2,846,888	11,437
Colorado	815	≤10
Connecticut	260,890	484
District of Columbia	33,728	154
Delaware	12	90
Florida	3,489	78
Georgia	1,623	31
Hawaii	27,099	492
Idaho	9,245	16
Illinois	2,625	14
Indiana	1,056	15
Kansas	1,200,333	2,086
Kentucky	751,439	1,233
Louisiana	71,627	122
Massachusetts	94,737	3,961
Maryland	49,391	99
Michigan	93,505	496
Minnesota	12,307	28
Missouri	2,444	56
Mississippi	3,346	≤10
North Carolina	2,004	≤10
North Dakota	2,248	82
Nebraska	546	≤10
New Hampshire	15,270	75
New Jersey	116	≤10
New Mexico	2,462	20
Nevada	8,570	78
New York	2,752	22
Ohio	5,796	14
Oregon	25,140	39
Pennsylvania	33,359	88
Rhode Island	24,196	1,388

State	Medicaid amount reimbursed (dollars)	Number of prescriptions
South Carolina	24,461	180
Tennessee	21,012	29
Texas	149,520	281
Virginia	70,657	473
Washington	8,715	69
Wisconsin	1,484,032	6,633
West Virginia	2,984	≤10

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-577

Notes: The table shows the obesity drugs for which the state Medicaid Program or Medicaid managed care program paid a portion or all of a claim. The Medicaid amount reimbursed includes state and federal reimbursement and dispensing fees. These amounts do not include all Medicaid spending for obesity drugs under Medicaid managed care—because managed care organizations can be paid for the drugs as part of their capitated payment for all Medicaid services, they are not reimbursed on a per-drug basis, and their payment amounts are not recorded as amounts reimbursed in CMS's Medicaid State Drug Utilization data. The number of prescriptions reimbursed includes 144 prescriptions for obesity drugs that showed zero dollar amounts for Medicaid reimbursement in CMS's Medicaid State Drug Utilization data.

Table 15: Medicaid Amount Reimbursed and Total Number of Prescriptions for Each of the Nine Obesity Drugs, 2016

Obesity drug	Medicaid amount reimbursed (dollars)	Number of prescriptions
Phentermine	421,084	13,274
Diethylpropion	31,735	203
Benzphetamine	907	53
Phendimetrazine	8,861	238
Orlistat	1,240,859	2,403
Lorcaserin	623,974	2,942
Phentermine + Topiramate	342,891	1,910
Liraglutide	1,941,148	2,052
Bupropion + Naltrexone	406,144	2,237
All obesity drugs	**5,017,424**	**25,312**

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-577

Notes: The table shows the obesity drugs for which the state Medicaid Program or Medicaid managed care program paid a portion or all of a claim. The Medicaid amount reimbursed includes state and federal reimbursement and dispensing fees. These amounts do not include all Medicaid spending for obesity drugs under Medicaid managed care—because managed care organizations can be paid for the drugs as part of their capitated payment for all Medicaid services, they are not reimbursed on a per-drug basis, and their payment amounts are not recorded as amounts reimbursed in CMS's Medicaid State Drug Utilization data. The number of prescriptions reimbursed includes 776 prescriptions for obesity drugs that showed zero dollar amounts for Medicaid reimbursement in CMS's Medicaid State Drug Utilization data.

Table 16: Medicaid Amount Reimbursed and Total Number of Prescriptions for Each of the Nine Obesity Drugs, 2017

Obesity drug	Medicaid amount reimbursed (dollars)	Number of prescriptions
Phentermine	130,329	15,526
Diethylpropion	5,919	260
Benzphetamine	1,612	44
Phendimetrazine	2,095	125
Orlistat	1,195,505	2,214
Lorcaserin	629,405	2,695
Phentermine + Topiramate	382,877	2,147
Liraglutide	4,534,941	4,858
Bupropion + Naltrexone	570,759	2,931
All obesity drugs	**7,453,442**	**30,800**

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-577

Notes: The table shows the obesity drugs for which the state Medicaid Program or Medicaid managed care program paid a portion or all of a claim. The Medicaid amount reimbursed includes state and federal reimbursement and dispensing fees. These amounts do not include all Medicaid spending for obesity drugs under Medicaid managed care—because managed care organizations can be paid for the drugs as part of their capitated payment for all Medicaid services, they are not reimbursed on a per-drug basis, and their payment amounts are not recorded as amounts reimbursed in CMS's Medicaid State Drug Utilization data. The number of prescriptions reimbursed includes 144 prescriptions for obesity drugs that showed zero dollar amounts for Medicaid reimbursement in CMS's Medicaid State Drug Utilization data.

Appendix VIII: Estimates of Medical and Prescription Drug Expenditures for Adults Who Used and Did Not Use Obesity Drugs

This appendix presents nationally representative estimates of U.S. adults' average annual expenditures (spending) for medical care, all prescription drugs, and for obesity drugs from the Agency for Healthcare Research and Quality (AHRQ) based on data from the Medical Expenditure Panel Survey (MEPS) for 2012 through 2016. Table 17 shows the estimated average annual expenditures for all prescription drugs and table 18 shows the estimated average annual medical expenditures, including prescription drugs, per adult who used and per adult who did not use any obesity drugs.[1] For adults age 18 to 64, the differences in the estimated average annual expenditures for all medical care and for all prescriptions drugs per adult who used and who did not use any of the nine obesity drugs in our review were statistically significant.[2] However, the differences in these estimates do not indicate that there was a causal relationship between using obesity drugs and having higher average annual medical or prescription drug expenditures. Table 19 shows the estimated average annual expenditures per adult for obesity drugs.

[1]MEPS collects nationally representative data on health care use, expenditures, sources of payment, and insurance coverage for the U.S. civilian, noninstitutionalized population. For this analysis, AHRQ pooled MEPS data from 2012 through 2016 for individuals, including individuals who used any of nine obesity drugs: benzphetamine, diethylpropion, phendimetrazine, phentermine, bupropion/naltrexone (Contrave), liraglutide (Saxenda), lorcaserin (Belviq), orlistat (Xenical), and phentermine/topiramate (Qsymia). Because two of the drugs—Saxenda and Contrave—were approved for the U.S. market in 2014, not all of the drugs were available in all of the years included in this analysis. We define use of obesity drugs as having an outpatient prescription fill or refill for any of the nine obesity drugs.

[2]We compared the 95 percent confidence intervals of these estimates to determine whether any differences we found are statistically significant. This is the interval that would contain the actual population value for 95 percent of the samples MEPS could have drawn. Statistical significance indicates that the difference between the estimates is unlikely due to chance alone. Confidence intervals account for the complex survey design of the MEPS.

Table 17: Estimates of Average Annual Expenditures per Adult for All Prescription Drugs, 2012–2016

(dollars)

	Estimate	95 percent confidence interval	
		Lower bound	Upper bound
All U.S. adults	**1,419**	**1,358**	**1,481**
BMI ≥ 30	1,999	1,849	2,149
BMI < 30	1,163	1,109	1,217
Age 18–64	1,117	1,047	1,186
Age 65 and older	2,665	2,533	2,797
Used any obesity drug[a]	2,305	1,519	3,091
BMI ≥ 30	2,357	1,415	3,300
BMI < 30	2,179	992	3,366
Age 18–64	2,198	1,390	3,006
Age 65 and older	n/a[b]	n/a[b]	n/a[b]
Did not use any obesity drug	1,416	1,355	1,477
BMI ≥ 30	1,995	1,846	2,144
BMI < 30	1,161	1,107	1,215
Age 18–64	1,111	1,043	1,180
Age 65 and older	2,663	2,531	2,795

Source: Agency for Health Care Research and Quality's (AHRQ) estimates from the Medical Expenditure Panel Survey (MEPS), 2012–2016. | GAO-19-577

Notes: Body mass index (BMI) is calculated from individuals' height and weight as reported by household respondents in MEPS. As a result, because some individuals may self report higher than actual height and lower than actual weight, calculations of BMI from MEPS data may be lower than actual BMI. These estimates are from MEPS pooled data for years 2012 through 2016 and exclude adults age 18 and older with missing BMI data and women who reported that they were pregnant during the reference period of the interview in which they reported height and weight.

Prescription drug expenditures in 2012 to 2015 were inflated to 2016 dollars using the Consumer Price Index for Prescription Drugs, available from the Bureau of Labor Statistics. Confidence intervals account for the complex survey design of the MEPS. Estimates are based on an unweighted sample of 118,615 adults and an estimated average annual population of 233,060,000 adults.

[a]Estimates are based on 397 MEPS sample members who were reported to have used any of the nine obesity drugs in the 2012 through 2016 MEPS. AHRQ estimates that there are an average of 940,000 adults per year who reported using obesity drugs.

[b]Estimates for individuals age 65 and older who used obesity drugs are not reported due to inadequate precision for estimates resulting from an insufficient sample size.

Table 18: Estimates of Average Annual Medical Expenditures per Adult, 2012 – 2016

(dollars)

	Estimate	95 percent confidence interval	
		Lower bound	Upper bound
All U.S. adults	5,493	5,338	5,647
BMI ≥ 30	6,666	6,370	6,962
BMI < 30	4,973	4,814	5,131
Age 18–64	4,317	4,161	4,473
Age 65 and older	10,326	9,951	10,701
Used any obesity drug[a]	7,932	5,603	10,261
BMI ≥ 30	8,386	5,234	11,539
BMI < 30	6,837	4,897	8,778
Age 18–64	7,575	5,139	10,010
Age 65 and older	n/a[b]	n/a[b]	n/a[b]
Did not use any obesity drug	5,483	5,330	5,636
BMI ≥ 30	6,650	6,358	6,941
BMI < 30	4,969	4,811	5,128
Age 18–64	4,302	4,147	4,456
Age 65 and older	10,322	9,947	10,696

Source: Agency for Health Care Research and Quality's (AHRQ) estimates from the Medical Expenditure Panel Survey (MEPS), 2012–2016. | GAO-19-577

Notes: Estimates include expenditures for prescription drugs. Body mass index (BMI) is calculated from individuals' height and weight as reported by household respondents in MEPS. As a result, because some individuals may self report higher than actual height and lower than actual weight, calculations of BMI from MEPS data may be lower than actual BMI. These estimates are from MEPS pooled data for years 2012 through 2016 and exclude adults age 18 and older with missing BMI data and women who reported that they were pregnant during the reference period of the interview in which they reported height and weight.

Medical expenditures in 2012 to 2015 were inflated to 2016 dollars using the Personal Health Care Expenditure Index available from the Centers for Medicare & Medicaid Services. Confidence intervals account for the complex survey design of the MEPS. Estimates are based on an unweighted sample of 118,615 adults and an estimated average annual population of 233,060,000 adults.

[a]Estimates are based on 397 MEPS sample members who were reported to have used any of the nine obesity drugs in the 2012 through 2016 MEPS. AHRQ estimates that there are an average of about 940,000 adults per year who reported using obesity drugs.

[b]Estimates for individuals age 65 years and older who used obesity drugs are not reported due to inadequate precision for estimates resulting from an insufficient sample size.

Table 19: Estimates of Average Annual and Median Expenditures per Adult for All Obesity Drugs Purchased, 2012–2016

(dollars)

	Estimated average (mean)	95 percent confidence interval		Estimated median	95 percent confidence interval	
		Lower bound	Upper bound		Lower bound	Upper bound
All U.S. adults	**174**	**141**	**207**	**87**	**74**	**103**
BMI ≥ 30	193	149	237	94	71	118
BMI < 30	129	93	165	81	59	98
Age 18–64	169	137	202	87	72	103
Age 65 and older	n/a[a]	n/a[a]	n/a[a]	n/a[a]	n/a[a]	n/a[a]

Source: Agency for Health Care Research and Quality's (AHRQ) estimates from the Medical Expenditure Panel Survey (MEPS), 2012–2016. | GAO-19-577

Notes: Estimates are based on 397 MEPS sample members who were reported to have used any of the nine obesity drugs in the 2012 through 2016 MEPS. AHRQ estimates that there are an average of about 940,000 adults per year who reported using obesity drugs. Body mass index (BMI) is calculated from individuals' height and weight as reported by household respondents in MEPS. As a result, because some individuals may self report higher than actual height and lower than actual weight, calculations of BMI from MEPS data may be lower than actual BMI. These estimates are from MEPS pooled data for years 2012 through 2016 and exclude adults age 18 and older with missing BMI data and women who reported that they were pregnant during the reference period of the interview in which they reported height and weight.

Expenditures in 2012 to 2015 were inflated to 2016 dollars using the Consumer Price Index for Prescription Drugs from the Bureau of Labor Statistics. Confidence intervals account for the complex survey design of the MEPS.

[a]Estimates for individuals age 65 years and older who used obesity drugs are not reported due to inadequate precision for estimates resulting from an insufficient sample size.

Appendix IX: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

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