Department of Health and Human Services

Office of Inspector General



Office of Audit Services

DATA BRIEF

December 2024 | A-05-24-00016

Medicaid Gross Spending on 10 Selected Diabetes and 2 Selected Weight Loss Drugs Totaled More Than \$9 Billion in 2023, an Increase of 540 Percent From 2019

HHS OIG Data Brief • A-05-24-00016

Medicaid Gross Spending on 10 Selected Diabetes and 2 Selected Weight Loss Drugs Totaled More Than \$9 Billion in 2023, an Increase of 540 Percent From 2019

Key Takeaways:

Medicaid gross spending on 10 selected diabetes and 2 selected weight loss drugs substantially increased from \$1.5 billion in 2019 to \$9.4 billion in 2023 (a 540-percent increase).

- ✓ From 2019 to 2023, Medicaid gross spending increased by 506 percent for 10 selected diabetes drugs and by 4,938 percent for 2 selected weight loss drugs.
- ✓ We estimated that Medicaid gross spending on the 12 selected drugs accounted for approximately 9 percent of Medicaid spending on covered outpatient prescription drugs in 2023.

This substantial increase could have a financial impact on the Medicaid program. Information in this data brief may be beneficial to CMS and State Medicaid agencies when developing future program guidance related to these drugs.

Purpose of This Data Brief

Certain diabetes drugs initially approved by the Food and Drug Administration (FDA) to help control blood sugar levels for individuals with type 2 diabetes are known to be highly effective weight loss agents. Similar drugs were later approved by FDA specifically for weight loss. Most State Medicaid agencies cover the diabetes drugs to treat diabetes in Medicaid enrollees, but most States do not cover the weight loss drugs or the diabetes drugs if prescribed for weight loss.¹

We are providing this data brief to the Centers for Medicare & Medicaid Services (CMS) to show the substantial increase in Medicaid gross spending and utilization from January 1, 2019, through December 31, 2023 (audit period) on 10 selected diabetes and 2 selected weight loss drugs.²

Our objective was to identify national Medicaid gross spending on and utilization of selected diabetes and weight loss drugs that occurred during our audit period.³

¹ As of Aug. 2, 2024, 18 States offered Medicaid coverage for the 2 weight loss drugs (Wegovy and Saxenda) that we included in our analysis.

² Throughout this data brief we use the term "gross spending" to represent the expenditure amounts before any rebates were collected by the States or the managed care organizations.

³ We did not review any potential health benefits or long-term cost savings associated with these selected drugs.

The Medicaid Program

The Medicaid program provides medical assistance to certain low-income individuals and individuals with disabilities (Title XIX of the Social Security Act (the Act)). The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, CMS administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although each State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

States may offer Medicaid benefits on a fee-for-service (FFS) basis, through managed care plans, or both. Under the FFS model, the State pays providers directly for each covered service received by a Medicaid enrollee. Under managed care, the State pays a fee to a managed care plan for each person enrolled in the plan. Managed care organizations (MCOs) submit encounter data to the State agency. Encounter data is a collection of individual encounters that includes information about the specific services provided to each enrollee, including the first and last date of service provided to an enrollee and how much the MCO paid for the services.

Diabetes

More than 38 million Americans have diabetes, and 1 in 5 people with diabetes do not know they have diabetes (Figure 1 below). In the last 20 years, the number of adults with diabetes has more than doubled.⁴

About 38 million
people have
diabetes

About 1 in every 10 people
have diabetes

About 1 in every 5 people
with diabetes do not know
that they have diabetes

Figure 1: Americans With Diabetes

Type 2 diabetes accounts for up to 95 percent of all diagnosed cases of diabetes. Type 2 diabetes is a disease that occurs when blood glucose, also called blood sugar, is too high.

⁴ "Diabetes Information." Accessed July 29, 2024.

Type 2 diabetes most often develops in people 45 or older, but more and more children, teens, and young adults are also developing it.

Certain diabetes drugs known as glucagon-like peptide 1 receptor agonists (GLP-1 drugs) were initially approved to help control blood sugar levels for individuals with type 2 diabetes. However, these drugs are known to be highly effective weight loss agents. GLP-1 drugs work by mimicking a hormone in the intestines to stimulate the release of insulin and reduce blood sugar after eating a meal. These drugs slow down food traveling through the digestive tract, which can help make someone feel full longer. GLP-1 receptor agonists are also present in parts of the brain that regulate appetite. Besides GLP-1 drugs, there is a second class of diabetic drugs, sodium glucose cotransporter 2 inhibitors (SGLT-2 drugs), that may lead to weight loss and improved blood sugar control. SGLT-2 drugs lower blood sugar by causing the kidneys to remove sugar from the body through the urine.

A drug called metformin has long been considered the first-line medication for type 2 diabetes. Health care professionals generally recommend metformin combined with diet and exercise as the best early approach to diabetes care given its low cost, tolerability, and effectiveness. Metformin is used alone or in combination with other drugs used to treat diabetes. Although metformin is generally recommended for most people living with type 2 diabetes, alternate medications such as GLP-1 and SGLT-2 drugs can be prescribed to achieve optimal blood sugar levels. State Medicaid programs can require a trial of metformin before initial authorization of GLP-1 and SGLT-2 drugs for individuals with type 2 diabetes.

Medicaid Coverage of Outpatient Drugs

Section 1927 of the Act authorizes States to exclude from coverage or otherwise restrict drugs or classes of drugs when used for weight loss. As a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, a State may require prior authorization before a drug is dispensed for any medically accepted indication. The term "medically accepted indication" means any use for a covered outpatient drug that is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in certain specified compendia.⁵ States maintain a list of preferred outpatient drugs that should be prescribed over others. These preferred drugs are drugs that the State has identified as the most cost-effective within each therapeutically equivalent or therapeutically similar class, or all drugs within such a class if the State does not differentiate between preferred and non-preferred drugs (42 CFR § 447.51).

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⁵ In this context, compendium refers to a comprehensive listing of FDA-approved drugs and biologicals. Section 1927 of the Act requires that the State outpatient drug program assess data on drug use against predetermined standards consistent with peer-reviewed medical literature and a compendium that includes the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System.

Most State Medicaid agencies cover GLP-1 drugs and SGLT-2 drugs to treat type 2 diabetes, and some cover GLP-1 drugs as treatment for weight loss.

Medicaid Drug Rebate Program

The Omnibus Budget Reconciliation Act of 1990 created the Medicaid Drug Rebate Program to help offset Federal and State costs for most prescription drugs dispensed to Medicaid enrollees. For Federal financial participation (Federal share) to be available for covered outpatient drugs provided under Medicaid, manufacturers must enter into rebate agreements with the Secretary of Health and Human Services and pay quarterly rebates to State Medicaid agencies. These rebates decrease the cost of Medicaid prescription drugs and as a result decrease the amount of the Federal share. Section 1927(a)(1) of the Act states: "In order for payment to be available under section 1903(a) . . . for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement." Section 1903(a) of the Act provides for Federal financial participation in State expenditures for these drugs. Additionally, State agencies may negotiate their own supplemental drug rebate agreements with drug manufacturers, either directly or through their contractors, for drugs dispensed to people enrolled in Medicaid.

In Federal fiscal year 2023, Medicaid spent approximately \$104.9 billion on covered outpatient prescription drugs and collected \$53.7 billion in rebates, bringing net drug spending to \$51.2 billon.⁶

Data Used To Develop This Data Brief

We selected 12 drugs for our audit and identified the unique National Drug Codes associated with nine selected GLP-1 drugs and three selected SGLT-2 drugs that were approved by FDA.⁷ We then obtained Medicaid FFS and encounter claim data covering the period January 1, 2019, through December 31, 2023, for the 10 selected diabetes and 2 selected weight loss drugs in 49 States, D.C., Puerto Rico, and the U.S. Virgin Islands.⁸ During our 5-year audit period, Medicaid gross spending was \$22.4 billion associated with 29.2 million claims for the 12 selected diabetes

⁶ "Medicaid Outpatient Prescription Drug Expenditures and Rebates." Accessed on Nov. 27, 2024. CMS's technical comments noted that there was a miscalculation and that Medicaid collected \$44.1 billion in rebates and net spending was \$60.8 billion in Federal fiscal year 2023.

⁷ The 12 drugs were selected based on having highly effective weight loss agents. Of the nine GLP-1 drugs, seven were approved to treat type 2 diabetes, and two were approved for weight loss. All three SGLT-2 drugs were approved to treat type 2 diabetes. We did not use medical review to determine whether these drugs were prescribed to Medicaid enrollees according to the drugs' medically accepted indication.

⁸ At the time of our request, Montana did not have complete Transformed Medicaid Statistical Information System (T-MSIS) paid claim data for the 12 selected diabetes and weight loss drugs.

and weight loss drugs. We obtained this data from CMS's Transformed Medicaid Statistical Information System (T-MSIS).⁹

We conducted this performance audit 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.

The Appendix describes our audit scope and methodology.

RESULTS OF ANALYSIS

Medicaid gross spending on and utilization of 12 selected diabetes and weight loss drugs substantially increased from 2019 to 2023. This substantial increase could have a financial impact on the Medicaid program. Information in this data brief may be beneficial to CMS and State Medicaid agencies when developing future program guidance related to these drugs.

Medicaid Gross Spending on and Utilization of Selected Diabetes and Weight Loss Drugs From 2019 Through 2023

During our 5-year audit period, Medicaid gross spending was \$21.7 billion associated with 28.6 million claims for the 10 selected diabetes drugs (Table 1 on the next page).

⁹ T-MSIS contains enhanced information about beneficiary eligibility, beneficiary and provider enrollment data, service utilization data, claim and managed care data, and expenditure data. States submit their T-MSIS data to CMS monthly.

¹⁰ During the COVID-19 public health emergency, Medicaid enrollment increased by over 35 percent from February 2020 to March 2023. <u>"Medicaid Enrollment."</u> Accessed on Aug. 23, 2024.

Table 1: Nationwide Medicaid Paid Claims for 10 Selected Diabetes Drugs From January 1, 2019, Through December 31, 2023

Drug Brand Name	Therapeutic Class	Drug Class	FDA Original Approval Date	Total Claims	Gross Spending
Trulicity	Diabetic Therapy	GLP-1	9/18/2014	8,083,989	\$6,850,380,771
Ozempic	Diabetic Therapy	GLP-1	12/5/2017	4,591,375	3,926,940,425
Victoza	Diabetic Therapy	GLP-1	1/25/2010	3,303,261	2,759,959,092
Bydureon	Diabetic Therapy	GLP-1	1/27/2012	790,198	555,209,526
Rybelsus	Diabetic Therapy	GLP-1	9/20/2019	542,683	524,434,015
Mounjaro	Diabetic Therapy	GLP-1	5/13/2022	490,133	441,503,339
Byetta	Diabetic Therapy	GLP-1	4/28/2005	97,896	72,299,079
Jardiance	Diabetic Therapy	SGLT-2	8/1/2014	7,093,270	4,436,424,975
Farxiga	Diabetic Therapy	SGLT-2	1/8/2014	2,703,148	1,590,278,882
Invokana	Diabetic Therapy	SGLT-2	3/29/2013	890,963	540,833,906
Totals				28,586,916	\$21,698,264,010

During our 5-year audit period, Medicaid gross spending was \$734.3 million associated with 589,647 claims for the two selected weight loss drugs (Table 2 below).

Table 2: Nationwide Medicaid Paid Claims for Two Selected Weight Loss Drugs From January 1, 2019, Through December 31, 2023

Drug Brand Name	Therapeutic Class	Drug Class	FDA Original Approval Date	Total Claims	Gross Spending
Wegovy	Anti-Obesity Agents	GLP-1	6/4/2021	380,807	\$486,899,766
Saxenda	Anti-Obesity Agents	GLP-1	12/23/2014	208,840	247,400,188
Totals				589,647	\$734,299,954

Gross Spending on Selected Diabetes and Weight Loss Drugs Increased Substantially

Medicaid gross spending on the 12 selected diabetes and weight loss drugs increased from \$1.5 billion in 2019 to \$9.4 billion in 2023 (a 540-percent increase) (Figure 2 below).

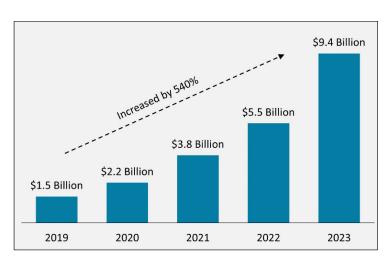
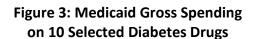


Figure 2: Medicaid Gross Spending on 12 Selected Diabetes and Weight Loss Drugs

Medicaid gross spending on the 10 selected diabetes drugs increased from \$1.5 billion in 2019 to \$8.9 billion in 2023 (a 506-percent increase) (Figure 3 below). Medicaid gross spending on the two weight loss drugs increased from \$11.2 million in 2019 to \$562.5 million in 2023 (a 4,938-percent increase) (Figure 4 below).



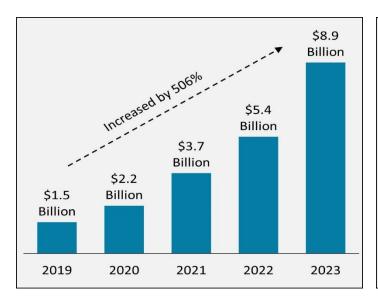
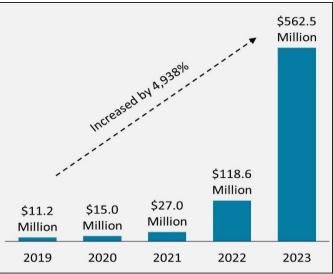
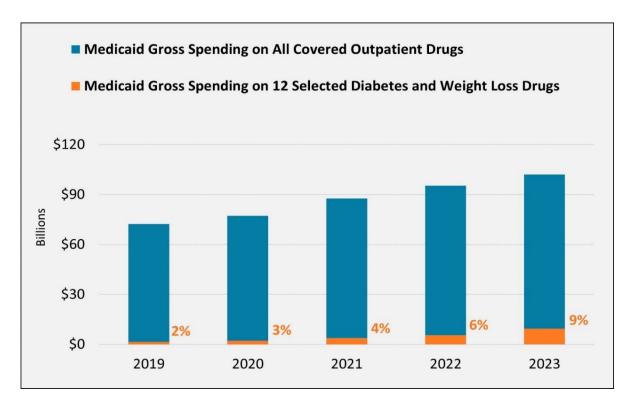


Figure 4: Medicaid Gross Spending on Two Selected Weight Loss Drugs



Medicaid gross spending on the 12 selected drugs accounted for approximately 6 percent of Medicaid spending on covered outpatient prescription drugs in 2022. This was an increase from 2 percent in 2019. We did not have complete data for the total Medicaid gross spending on all covered outpatient prescription drugs in 2023. The smallest year-over-year increase in total Medicaid gross spending on all covered outpatient drugs observed in our audit period was 7 percent. Therefore, we conservatively estimated 2023 total gross spending on all covered outpatient drugs at \$102 billion, which is a 7-percent increase on 2022 total gross spending. We then estimated that the 12 selected drugs accounted for approximately 9 percent of Medicaid spending on covered outpatient prescription drugs in 2023 (Figure 5 below).

Figure 5: Medicaid Gross Spending on 12 Selected Diabetes and Weight Loss Drugs Compared to Medicaid Gross Spending on All Covered Outpatient Prescription Drugs¹²



Annual gross spending on these diabetes and weight loss drugs has increased substantially. For example, Medicaid gross spending on Ozempic generally doubled each year from 2019 through 2023. Specifically, Medicaid gross spending on Ozempic (a type 2 diabetes drug) increased from

¹¹ "Medicaid Gross Spending on Outpatient Prescription Drugs, 2019-2022." Accessed on June 18, 2024.

¹² We estimated 2023 total gross spending on all covered outpatient drugs (\$102 billion) by multiplying the total 2022 actual gross spending on all covered outpatient drugs (\$95.4 billion) by 107 percent. We then estimated that the 12 selected drugs accounted for approximately 9 percent of Medicaid spending on covered outpatient prescription drugs in 2023 by dividing the 2023 actual gross spending on the 12 selected drugs (\$9.4 billion) by the estimated 2023 total gross spending (\$102 billion).

\$113.9 million in 2019 to \$2.1 billion in 2023 (a 1,775-percent increase) (Figure 6 below). Also, Medicaid gross spending on Wegovy (a weight loss drug) increased from \$3.4 million in 2021 to \$446.2 million in 2023 (a 12,871-percent increase) (Figure 7 below).¹³

Figure 6: Medicaid Gross Spending on Ozempic

\$2.1 Billion

\$2.1
Billion

\$896.6
Million

\$113.9
Million

2019

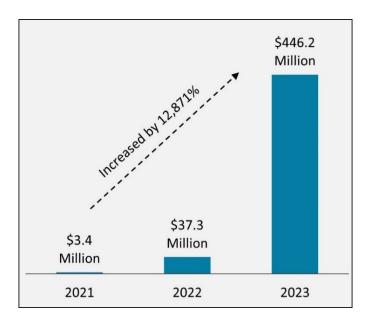
2020

2021

2022

2023

Figure 7: Medicaid Gross Spending on Wegovy

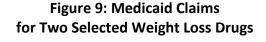


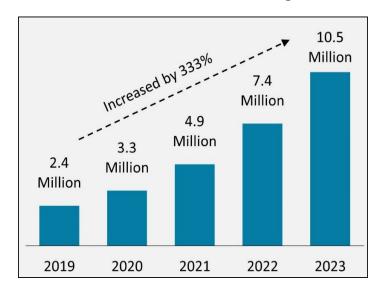
Utilization of Selected Diabetes and Weight Loss Drugs Increased Substantially

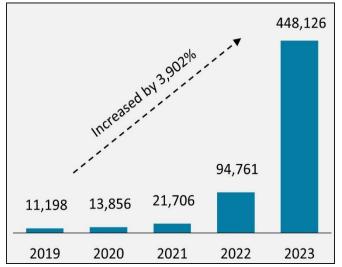
The number of Medicaid claims for 10 selected diabetes drugs increased from 2.4 million in 2019 to 10.5 million in 2023 (a 333-percent increase) (Figure 8 on the next page). The number of Medicaid claims for 2 selected weight loss drugs increased from 11,198 in 2019 to 448,126 in 2023 (a 3,902-percent increase) (Figure 9 on the next page).

¹³ Wegovy was approved by FDA on June 4, 2021.

Figure 8: Medicaid Claims for 10 Selected Diabetes Drugs







We observed that the increase in Medicaid gross spending and the number of claims was similar for the nine GLP-1 and three SGLT-2 drugs during our audit period (Figure 10 below).

Figure 10: Increase in Medicaid Gross Spending and Claims for Selected Diabetes and Weight Loss Drugs From 2019–2023

		GLP-1	SGLT-2
•0•	Gross	549%	518%
	Spending	Increase	Increase
	Number	358%	335%
	of Claims	Increase	Increase

Medicaid Gross Spending on and Utilization of Metformin Remained Relatively Stable

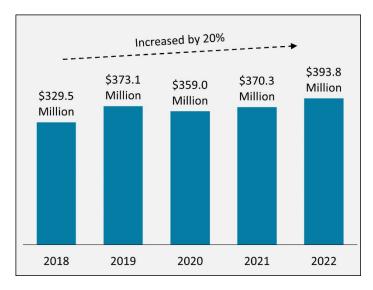
As previously mentioned, metformin has long been considered the first-line medication for type 2 diabetes. Medicaid gross spending on metformin has not incurred the substantial increases noted with the 12 selected diabetes and weight loss drugs. Specifically, gross spending on metformin increased from \$329.5 million in 2018 to \$393.8 million in 2022 (a 20-percent increase) (Figure 11 on the next page). Additionally, the number of Medicaid claims for

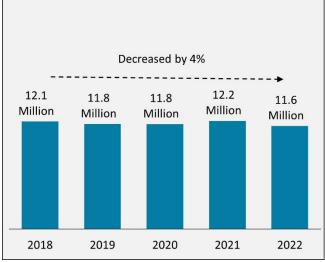
¹⁴ We consider a 20-percent increase over a 5-year period to be a relatively stable change when compared to the 5-year increase in gross spending on the other 12 selected drugs.

metformin remained relatively stable over the 5-year period (a 4-percent decrease) (Figure 12 below). 15

Figure 11: Medicaid Gross Spending on Metformin

Figure 12: Medicaid Claims for Metformin





Annual Medicaid claims for the 10 selected diabetes drugs (10.5 million claims in 2023) are approaching the number of Medicaid claims for metformin (11.6 million claims in 2022). Despite the substantial increase in utilization of these 10 drugs, the utilization of metformin has remained relatively stable.

Projected Gross Spending on Selected Diabetes and Weight Loss Drugs

Medicaid gross spending on the 12 selected diabetes and weight loss drugs increased from \$1.5 billion in 2019 to \$9.4 billion in 2023 (a 540-percent increase). The smallest annual percentage increase in gross spending during this 5-year period was 47 percent. If Medicaid gross spending continues at a similar rate, we estimate that Medicaid gross spending on these 12 drugs could potentially amount to over \$29 billion in 2026 (Figure 13 on the next page). Our estimate was based on the actual gross spending trends that we observed during our audit period.

¹⁵ Metformin gross spending and utilization data was obtained from a CMS public database and not T-MSIS. The latest available data on Medicaid gross spending and utilization was for the year ending 2022. "Metformin Data." Accessed June 18, 2024.

¹⁶ We estimated 2024 total gross spending on the 12 selected drugs (\$13,852,318,892) by multiplying the total 2023 actual gross spending (\$9,423,346,185) by 147 percent. We made similar calculations for 2025 and 2026.

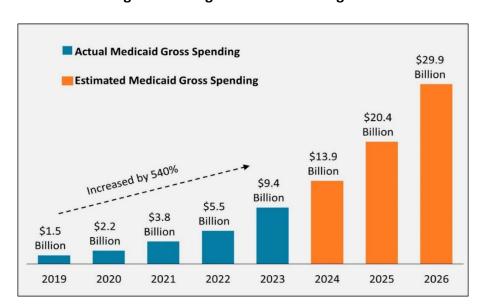


Figure 13: Medicaid Gross Spending on 12 Selected Diabetes and Weight Loss Drugs From 2019 Through 2026

CONCLUSION

There has been a substantial increase in the use of certain diabetes and weight loss drugs in recent years. For this data brief, we have identified that Medicaid gross spending on these 12 drugs increased by 540 percent from 2019 to 2023, totaling \$9.4 billion in 2023. During this same time period, utilization of the 12 drugs increased by 350 percent, totaling 11 million claims in 2023.

We estimated that Medicaid gross spending on these 12 drugs accounted for approximately 9 percent of all Medicaid spending on covered outpatient prescription drugs in 2023. If the annual percentage increase in gross spending on the 12 selected drugs continued at a rate of 47 percent, the smallest annual rate of increase that we observed during our audit period, it could potentially amount to over \$29 billion in Medicaid spending on these drugs in 2026.

OIG plans to conduct additional audits related to Medicaid gross spending on and utilization of selected diabetes and weight loss drugs to determine whether States ensured that these diabetes and weight loss drugs were prescribed in accordance with Federal and State requirements.

This data brief presents information about trends in national Medicaid gross spending on and utilization of selected diabetes and weight loss drugs that may be beneficial to CMS and State Medicaid agencies when developing future program guidance related to these drugs. This data brief does not contain any recommendations.

We issued a draft of this data brief to CMS. addressed as appropriate.	CMS furnished technical comments, which we

APPENDIX: AUDIT SCOPE AND METHODOLOGY

Our audit covered Medicaid FFS and encounter paid claim data for 12 selected diabetes and weight loss drugs from January 1, 2019, through December 31, 2023. We obtained this data from CMS's T-MSIS for 49 States, D.C., Puerto Rico, and the U.S. Virgin Islands. We used this data to identify Medicaid gross spending and utilization trends for the selected diabetes and weight loss drugs. We did not independently verify the accuracy of the T-MSIS data. In addition, we did not use medical review to determine whether these selected drugs were prescribed to Medicaid enrollees according to the drugs' medically accepted indication or review any potential health benefits or long-term cost savings associated with these drugs.

Our objective did not require an overall assessment of CMS's internal control structure. Rather, we interviewed CMS officials about the oversight of State Medicaid agencies' coverage of the selected diabetes and weight loss drugs and reviewed CMS requirements and guidance related to these drugs.

We conducted our audit from April to November 2024, which included discussing the results of the audit with CMS officials.

We issued a draft of this data brief to CMS. CMS furnished technical comments, which we addressed as appropriate.

We conducted this performance audit 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.

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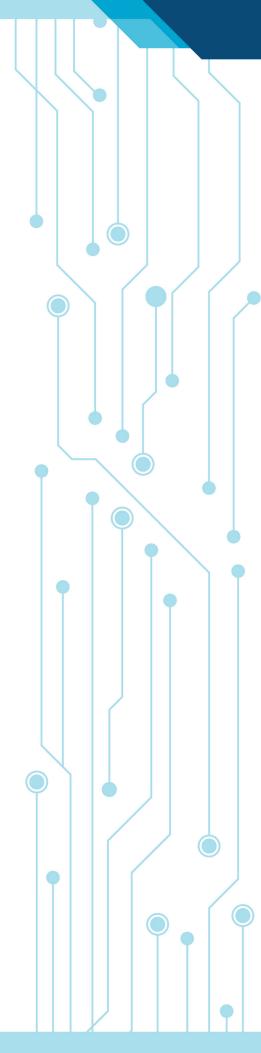
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