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IN FOCUS

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Medicare Coverage of GLP-1 Drugs

Glucagon-like peptide-1 (GLP-1) receptor agonists, marketed under brand names such as Wegovy and Ozempic, are a class of medications used primarily in the treatment of type 2 diabetes mellitus (T2DM). Recently, GLP-1 drugs have gained attention for their effectiveness in obesity treatment. Given the increasing prevalence of obesity amongst Medicare beneficiaries, the demand for GLP-1 drugs also has increased, leading to discussions about their coverage under Medicare's outpatient prescription drug benefit (Part D), the associated spending implications, and policy considerations for Congress. This In Focus provides a brief overview of GLP-1 drugs, their current coverage status under Medicare Part D, and related policy considerations.

Overview of GLP-1 Drugs

Beginning in the 1980s, scientists realized that certain hormones played vital roles in the human body's regulation of insulin production. One of the key hormones is GLP-1, a gastrointestinal hormone released after eating. GLP-1 drugs mimic the effects of this hormone and therefore help regulate insulin production, which is a vital function for patients with T2DM.

The first GLP-1 drug, exenatide (brand name Byetta), was approved by the Food and Drug Administration (FDA) for the treatment of T2DM in 2005. As more GLP-1 drugs came on the market, researchers discovered additional benefits beyond managing T2DM. Clinical trials provided evidence that GLP-1 drugs were capable of slowing digestion, affecting areas of the brain that process hunger, and thus reducing a patient's weight. In 2014, Saxendra (Liraglutide) was the first GLP-1 drug approved by the FDA for weight loss. In 2021, the FDA approved Novo Nordisk's application to market a GLP-1 drug for weight loss under the brand name Wegovy. In 2023, the FDA approved another GLP-1 drug for weight loss, tirzepatide, under the brand name Zepbound.

Not all GLP-1 drugs are FDA approved for weight loss. Despite its popularity as a weight loss treatment, Ozempic, another GLP-1 drug manufactured by Novo Nordisk, is only FDA approved for the treatment of T2DM. The delivery mechanism also differs within this class of drugs. Both Wegovy and Ozempic are injectable, but some GLP-1 drugs such as Rybelsus can be taken orally. There are indications that GLP-1 drugs could be used for conditions other than T2DM and weight loss. In March 2024, the FDA approved the use of Wegovy to reduce the risk of heart attack and stroke in adults with cardiovascular disease (CVD) who were either obese or overweight.

Overview of Medicare Part D Benefit

Medicare Part D is a voluntary outpatient prescription drug benefit administered by private health payers (plan sponsors) through stand-alone Prescription Drug Plans (PDPs) or Medicare Advantage (MA) plans with a Part D benefit (MA-PD). Each year, the Centers for Medicare & Medicaid Services (CMS) issues guidance that defines a standard Part D benefit. The defined standard benefit sets limits on out-of-pocket (OOP) spending, deductibles, and cost sharing. CMS requires every Part D sponsor to offer at least one basic plan in a given service area that is either the standard benefit or actuarially equivalent to the standard benefit.

This basic coverage applies to all Part D-covered drugs. Part D-covered drugs are generally defined as FDA-approved drugs and vaccines that are on the formulary of a Part D plan and are not covered under Medicare Parts A or B. Part D plans must offer a formulary that covers substantially all drugs available in the six protected drug classes: immune-suppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic (cancer). Outside of the six protected classes, Part D drug plans are required to operate formularies that cover at least two drugs in each drug class and category but have flexibility over which drugs to offer.

Coverage Under the Standard Benefit

Certain types of drugs are prohibited from being considered covered Part D drugs under the standard plan. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173), which created Part D, excluded drugs used for anorexia, weight loss, or weight gain. The restrictions were based on the existing definition of drugs or classes of drugs that may be excluded from Medicaid coverage under Social Security Act Section 1927(d)(2). Therefore GLP-1 drugs, even if they have received FDA approval for weight loss, are not covered under Part D drugs when used for that purpose.

Currently, Medicare allows coverage through Part D plans for GLP-1 drugs that the FDA has approved for T2DM and CVD. As of August 2024, Ozempic, Mounjaro, Rybelsus, and Wegovy are considered covered Part D drugs for the treatment of those conditions. **Table 1** displays Medicare expenditures in 2022 for a subset of these covered GLP-1 drugs. Eligibility for Part D coverage does not ensure all Part D plans will include those GLP-1 drugs in their formulary. As described above, Part D plans are required to cover at least two drugs each for the treatment of T2DM and/or CVD, but it is not required that either drug be a GLP-1 drug.

Table 1. 2022 Medicare Spend on Selected GLP-1 Drugs

Brand Name	Ozempic	Rybelsus	Mounjaro
Generic Name	Semaglutide	Semaglutide	Tirzepatide
Manufacturer	Novo Nordisk	Novo Nordisk	Eli Lilly & Co.
FDA Approval for	T2DM	T2DM	T2DM
Total Medicare Spending in 2022	$4.6 billion	$974 million	$144 million
Average Spend per Claim in 2022	$1,356.90	$1,420.41	$ 1,189.44

Sources: CRS Analysis of Centers for Medicare & Medicaid Services Medicare Part D Spending by Drug 2022; FDA.
Note: This table represents a subset of GLP-1 drugs available under Medicare Part D to provide a snapshot of Part D utilization. This table shows the most recent publicly available data.

Coverage Under Enhanced Alternative Plans

Part D sponsors also may offer enhanced alternative (EA) Part D plans in addition to their basic plans. CMS defines an EA plan as coverage that includes the standard prescription coverage as well as supplemental benefits. Approximately 75% of Medicare Part D beneficiaries are enrolled in EA plans. Some EA plans offer a lower deductible and/or reduced enrollee cost sharing. Another example of a qualifying supplemental benefit is coverage of drugs that are excluded from the definition of a Part D drug, such as a GLP-1 drugs approved by the FDA for weight loss but not for T2DM or CVD. An EA plan also could potentially allow a beneficiary to access a GLP-1 drug that is currently covered by Part D for off-label use, such as weight loss. There is no requirement that EA plans offer GLP-1 drugs, and beneficiaries who choose an EA plan may be required to pay a higher monthly premium in order to access its broader formulary.

Barriers to Access

If a Part D plan covers a GLP-1 drug, either under the standard benefit for T2DM and/or CVD or under an enhanced plan for weight loss, enrollees still may experience varying levels of cost sharing or formulary restrictions. Plans can place drugs on different tiers within their formularies, with higher tiers associated with greater enrollee cost sharing. If beneficiaries are facing difficulties accessing a GLP-1 drug, they can apply for exceptions to gain access to a drug not on their plan's formulary or lower their cost sharing if the drug is on a high tier.

Plans also can use drug utilization management strategies, such as step therapy and prior authorization, that would require patients to go through additional processes before being prescribed a GLP-1 drug. Both Blue Cross Blue Shield and UnitedHealthCare now require prior authorization for GLP-1 drug coverage under their MA products, to ensure only individuals with a diagnosis of T2DM are using these drugs. Despite these restrictions, there are still widespread shortages for many GLP-1 medications, with even individuals who have T2DM struggling to access them.

Congressional Policy Considerations

As the use of GLP-1 drugs expands beyond diabetes management to cardiovascular and obesity treatment, the associated costs and coverage policies likely will continue to be a focal point facing policymakers. Congressional actions in the coming years could significantly shape the future landscape of Medicare coverage for GLP-1 drugs, with potential implications for both the future cost of the program and the health outcomes of beneficiaries.

Under the current design of the Medicare Part D benefit, many beneficiaries do not have access to GLP-1 drugs for the treatment of obesity, unless they have another qualifying condition such as T2DM or CVD. In the 118th Congress, some have expressed interest in expanding the permitted utilization of these drugs under Medicare Part D. H.R. 4818, the Treat and Reduce Obesity Act of 2023, would expand Medicare Part D coverage to include prescription drugs for the treatment of obesity. Under this bill, individuals who are not obese but are overweight and have certain comorbidities also would qualify for coverage of GLP-1 drugs. An amended H.R. 4818 was voted out of committee in June 2024. S. 2407, a companion bill, was introduced in the Senate in July 2023.

In addition to interest in expanding access to these drugs, there has been scrutiny on their cost. As shown in **Table 1**, Medicare expenditures on Ozempic alone exceeded $4 billion in 2022. Although these drugs are new, current studies suggest that patients have to continue using the drugs to sustain their weight loss. Goldman Sachs has forecast a $100 billion worldwide market for obesity drugs by 2030. The Inflation Reduction Act of 2022 (P.L. 117-169) authorized the Secretary of the Department of Health and Human Services to negotiate prices for certain high-cost drugs. Although no GLP-1 drugs were selected in the first round of negotiations, these drugs' high costs and the prevalence of diabetes among Medicare beneficiaries make them possible candidates for future negotiations.

The financial impact of legislation related to GLP-1 drugs is difficult to predict. In October 2023, the Congressional Budget Office (CBO) issued a request for new research in the area of obesity. According to CBO, the budgetary effect of such legislation would depend on prices as well as any effect of usage on other health care spending: "In CBO's assessment, Medicare's coverage of anti-obesity medications at their current prices (accounting for rebates and discounts) would increase overall federal spending." CBO added that there is little information on longer-term effects of the drugs.

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