MILLIMAN WHITE PAPER

GLP-1 agonists in Medicaid: Utilization, growth, and management

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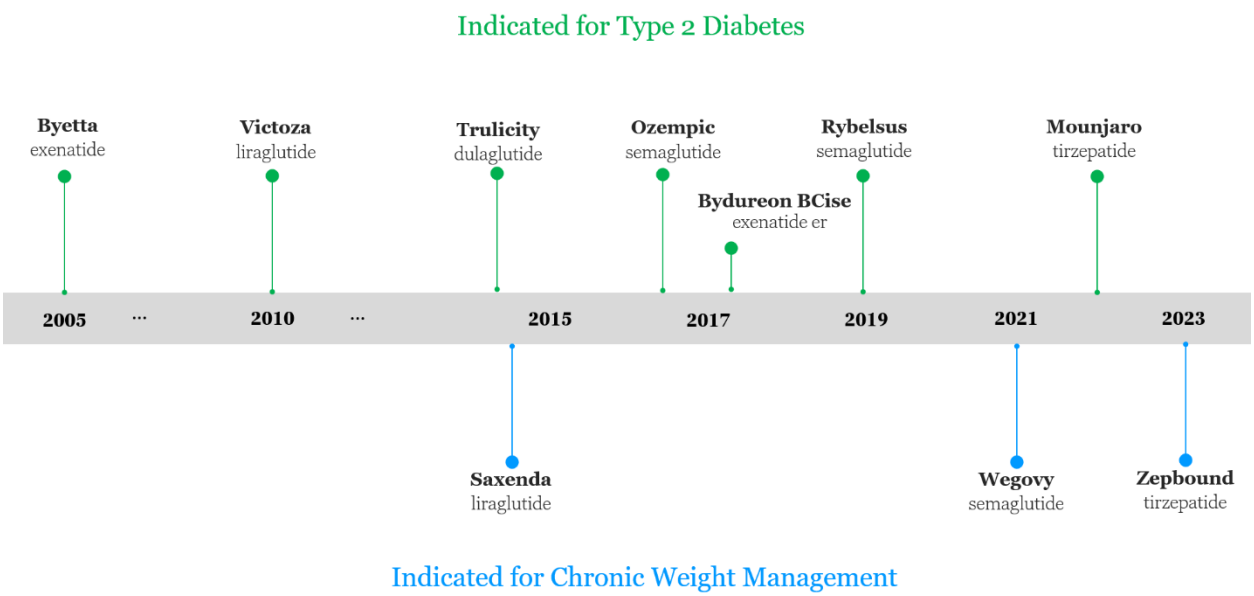
Executive Summary

Although glucagon-like peptide-1 (GLP-1) agonists are not a new therapeutic class, there is growing attention to them due to increased demand and heightened media coverage. Both Medicaid fee-for-service (FFS) and managed Medicaid have observed an increase in utilization and spend associated with GLP-1 agonists in recent years. While drugs indicated for chronic weight management are not covered in all states, there is limited but growing coverage of these products. Comparatively, GLP-1 agonists indicated for type 2 diabetes have widespread Medicaid coverage, although states have varying degrees of prior authorization requirements. This paper explores the recent growth in GLP-1 agonist utilization and spend in Medicaid, methods that states are currently using to manage utilization, and provides a framework for state Medicaid programs when making benefit design decisions.

BACKGROUND ON GLP-1S

GLP-1 agonists and glucose-dependent insulinotropic polypeptide (GIP) agonists mimic naturally occurring incretin hormones to slow gastric emptying, increase the feeling of fullness, promote insulin secretion, and inhibit the inappropriate release of glucagon.[i] GLP-1 agonists were initially approved for treating type 2 diabetes, with subsequent approvals for chronic weight management and reduction of the risk of major cardiovascular events in patients with established cardiovascular disease and type 2 diabetes. More recently, two dual-acting GLP-1/GIP agonists[1] have been approved, Mounjaro® (tirzepatide) for type 2 diabetes and Zepbound® (tirzepatide) for chronic weight management. A timeline of GLP-1 agonist approvals by indication is provided in Figure 1, with a more detailed summary in Appendix A.

FIGURE 1: TIMELINE OF GLP-1 AGONIST APPROVALS BY TYPE 2 DIABETES AND CHRONIC WEIGHT MANAGEMENT INDICATION[2]



[1] This paper includes GLP-1 and GIP agonists when referring to GLP-1 agonists.
[2] Timeline of approvals excludes discontinued GLP-1 agonists (i.e., Bydureon and Adlyxin).

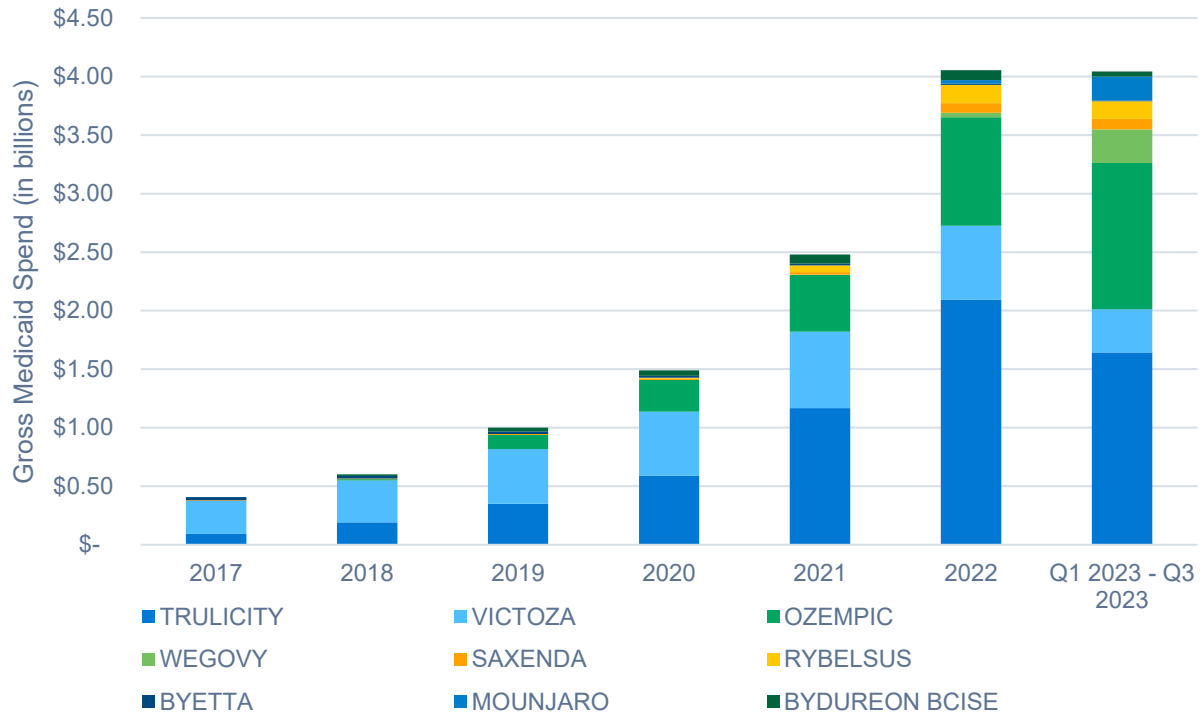
The active ingredients in some GLP-1 agonists indicated for type 2 diabetes are the same active ingredient approved for chronic weight management, although dosing may differ between products. For example, Wegovy® (semaglutide), approved for chronic weight management, shares the same active ingredient as Ozempic® (semaglutide) and Rybelsus® (semaglutide), which are approved for the treatment of type 2 diabetes.

RECENT GROWTH AND MARKET DEMAND

While the first approval of GLP-1 agonists dates back to 2005, there has been a significant increase in utilization and demand for drugs in the GLP-1 therapeutic class in the last few years. Novo Nordisk®, the manufacturer of Ozempic and Wegovy, projects 2023 full-year sales of these products to grow between 32% and 38% year-over-year, despite availability issues during the year.[ii] This recent growth can be attributed to published outcomes of this drug class, success stories, growing popularity on social media, and the explosion of telehealth and digital health companies offering prescriptions for GLP-1s as part of a comprehensive weight loss program.[iii]

Based on our analysis of State Drug Utilization Data,[3] Medicaid has observed growth in GLP-1 agonist utilization and spend. Figure 2 illustrates the year-over-year Medicaid spend on GLP-1 agonists by drug. GLP-1 agonists represented nearly $4.1 billion (4.6%) in gross Medicaid spend in 2022 and reached $4.0 billion (6.7%) through the third quarter of 2023.

FIGURE 2: GROSS MEDICAID SPEND BY YEAR FOR GLP-1 AGONISTS* (IN BILLIONS) [iv]

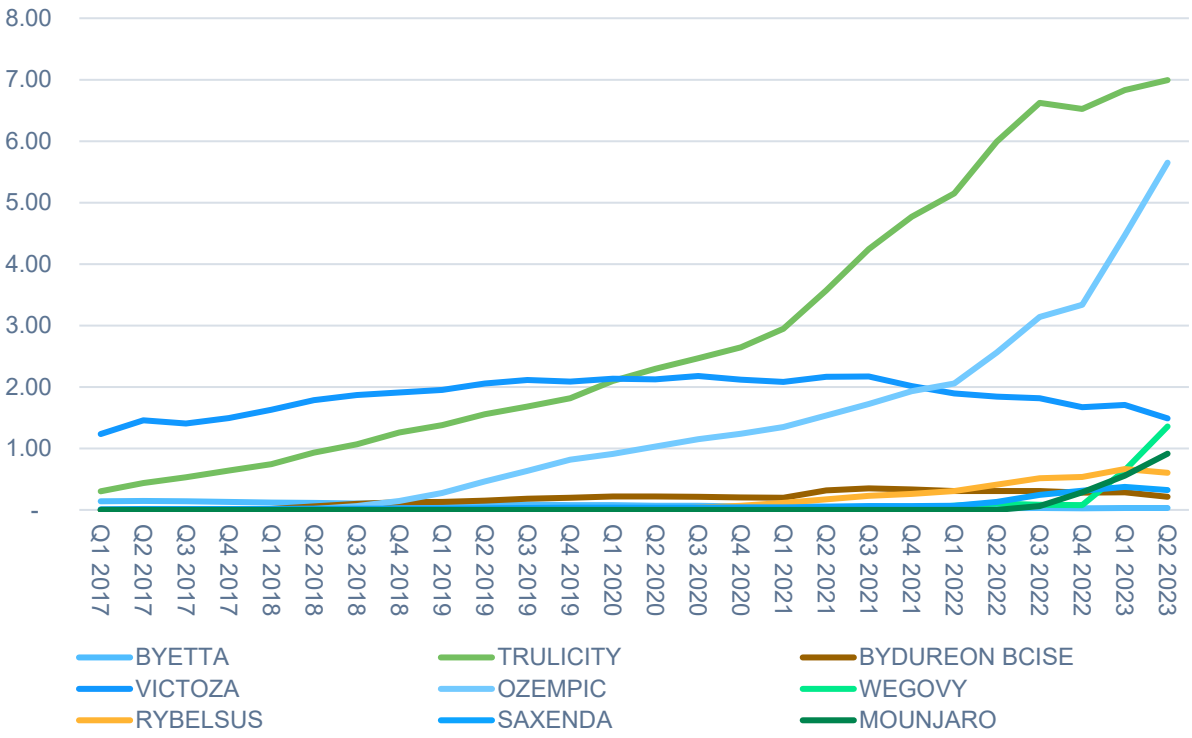


* Data from 2023 includes data through Q3 and likely does not have complete runout. Zepbound is not included because it was not available during the time period studied.

Notably, between 2019 and 2022, Trulicity (dulaglutide) and Ozempic, indicated for the treatment of type 2 diabetes, observed a 278% and 405% increase in prescription volume per 1,000 Medicaid enrollees, respectively. Saxenda® (liraglutide), indicated for chronic weight management, observed a 543% increase in prescription volume per 1,000 during the same time period, which may be partially driven by states expanding coverage of weight loss products and changes in clinical practice guidelines.[v,vi] A summary of Medicaid script volume per 1,000 enrollees for select GLP-1 agonists can be found in Figure 3.

[3] Includes data from all state Medicaid programs for covered outpatient drugs.

FIGURE 3: MEDICAID GLP-1 AGONIST PRESCRIPTION VOLUME PER 1,000 ENROLLEES BY QUARTER*



* State Drug Utilization Data and Medicaid enrollment data from the first month of each quarter were used to calculate scripts per 1,000 members. Enrollment data was sourced from Kaiser Family Foundation.[vii] Zepbound is not included because it was not available during the time period studied.

DRIVERS OF GLP-1 AGONIST UTILIZATION GROWTH

Medicaid has experienced continued growth in GLP-1 agonist utilization, driven by robust demand for drugs to treat type 2 diabetes and obesity and overweight diagnoses, the expansion of coverage for GLP-1 agonists for chronic weight management, expanded uses, new product approvals, and potential off-label utilization.

Off-label Utilization

As public interest in GLP-1 agonists grows, off-label utilization has become a concern for state Medicaid agencies and managed care organizations. States lacking utilization management for drugs in the GLP-1 agonist therapeutic class may encounter increased challenges with off-label utilization. For example, formulations indicated specifically for type 2 diabetes (i.e., Ozempic) may be prescribed off-label for chronic weight management. Although not specific to Medicaid, an analysis examining the proportion of Ozempic utilizers with a diagnosis of type 2 diabetes from 2018 to 2021 found that those with a diabetes or prediabetes diagnosis decreased from 92% to 77% over the same time period. Additionally, the percentage of new Ozempic utilizers with an obesity diagnosis, but no evidence of a diabetes or prediabetes diagnosis, increased from 4% to 13% over the same time period.[viii] Payers have indicated that they are monitoring off-label utilization to manage this trend. For instance, Anthem Blue Cross Blue Shield's Special Investigations Unit proactively addressed instances where prescribers across multiple states were prescribing Ozempic to patients without sufficient evidence of diabetes by sending educational letters.[ix]

Pipeline

GLP-1 agonist Medicaid utilization may continue to grow as new GLP-1 agonists are approved and currently available therapies are approved for expanded indications. For example:

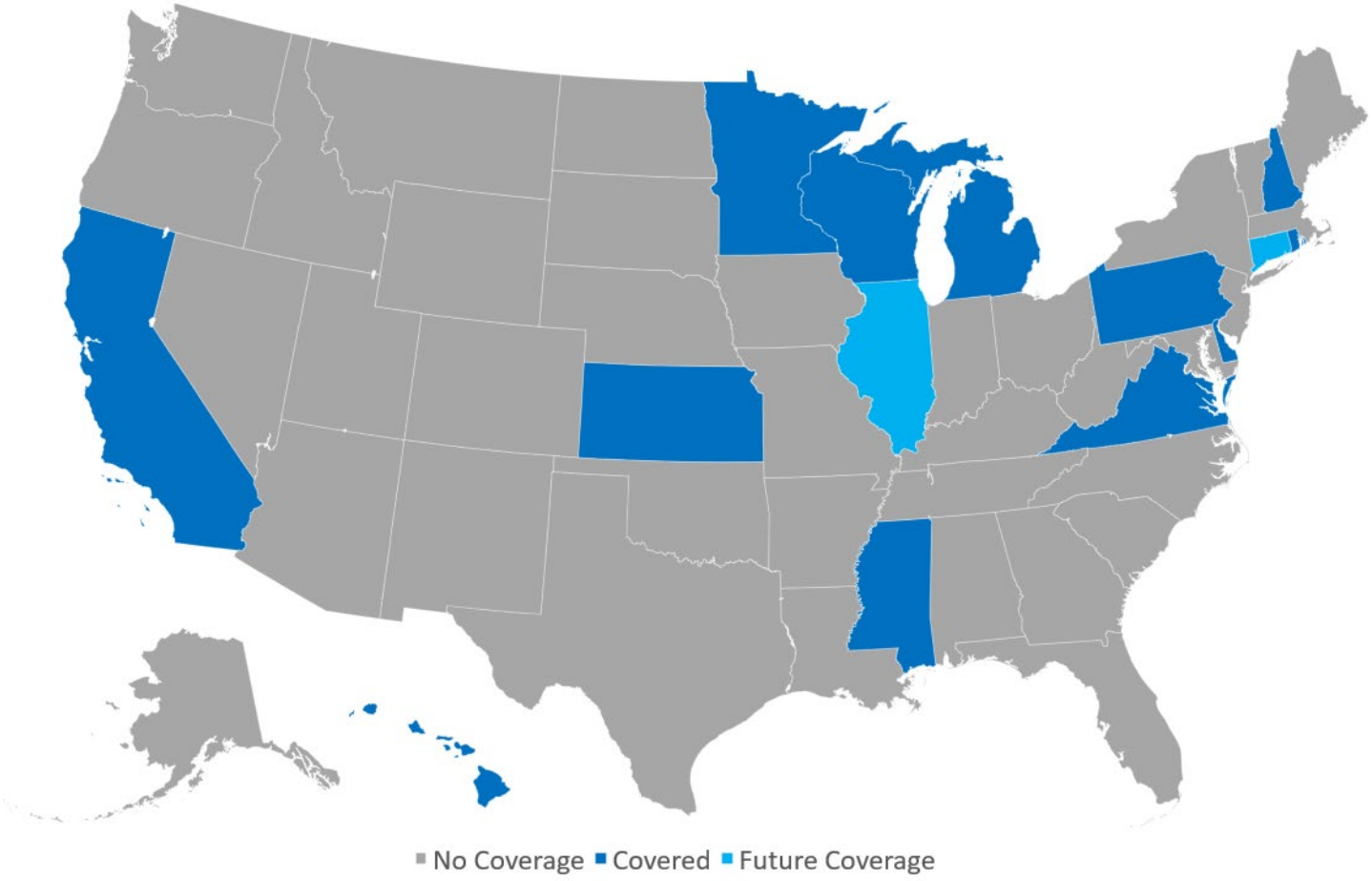
- Studies are underway for new GLP-1 agonists, such as subcutaneously administered retatrutide and orally administered orforglipron with some Phase III clinical trials anticipated to be completed in early 2024.[x]

- GLP-1 agonists approved by the U.S. Food and Drug Administration (FDA) are also being studied for a wide range of expanded indications, such as Alzheimer's disease, heart failure, chronic kidney disease, and nonalcoholic steatohepatitis. GLP-1 agonists indicated for chronic weight management are being studied to determine whether they reduce the risk of major adverse cardiovascular events in overweight or obese adults.[xi]
- While most GLP-1 agonists are administered subcutaneously, studies are being conducted on oral formulations.
- GLP-1 agonists are also being studied in combination with new active ingredients.[xii, xiii]

MEDICAID COVERAGE OF GLP-1 AGONISTS FOR CHRONIC WEIGHT MANAGEMENT

The Federal Medicaid Drug Rebate Program requires state Medicaid programs to provide coverage for all of a participating manufacturer's FDA-approved drugs; however, states may exclude certain categories of medications, such as drugs for chronic weight management. As such, Medicaid coverage of GLP-1 agonists indicated for chronic weight management remains limited and varies by state. A summary of state Medicaid coverage of drugs indicated for chronic weight management can be found in Figure 4, based on research from a Bloomberg survey and supplemented by internal Milliman research.[xiv]

FIGURE 4: COVERAGE OF GLP-1 AGONISTS FOR CHRONIC WEIGHT MANAGEMENT BY STATE MEDICAID PROGRAM (2023)*



*Illinois plans to review the class for drug placement based on a recent recommendation from the Drugs and Therapeutic Advisory Board.[xv] Connecticut's coverage is pending recently passed legislation.[xvi]

HOW ARE STATE MEDICAID PROGRAMS MANAGING UTILIZATION OF GLP-1 AGONISTS INDICATED FOR CHRONIC WEIGHT MANAGEMENT?

For states that provide coverage of GLP-1 agonists indicated for chronic weight management, coverage criteria vary by state. Examples of coverage criteria are outlined in Figure 5.

FIGURE 5: EXAMPLES OF STATE MEDICAID COVERAGE CRITERIA FOR GLP-1 AGONISTS INDICATED FOR CHRONIC WEIGHT MANAGEMENT*

STATE	AUTHORIZATION CRITERIA	LENGTH OF APPROVAL
Mississippi[xvii]	Three phases of authorization: Initial authorization: Patient must qualify for treatment based on body mass index (BMI) and/or BMI and comorbid conditions, and a treatment plan is developed. Reauthorization: Patient is reevaluated to ensure progress toward overcoming obesity and/or weight-related comorbidities is being made. Maintenance authorization: To ensure the patient stays within 15% of their goal BMI.	Each authorization phase is valid for six months for Saxenda and Wegovy.
Virginia[xviii]	Authorization criteria include patient plan for weight loss via comprehensive lifestyle interventions, provider attestation that patient's obesity is disabling and life-threatening, patient trial and failure of a non-GLP-1 agonist weight loss drug in the previous six months, and patient BMI requirements. Reauthorization criteria requires achievement of a percentage of weight loss, although weight loss response is not required for patients with two or more weight-related risk factors.	The length of initial approval varies by drug and ranges from four to six months. The length of renewal is six months.
Michigan[xix]	Prior authorization on all covered GLP-1 agonists indicated for chronic weight management. Initial authorization: BMI requirements, age restrictions, prescriber attestation that metabolic or other reasons for obesity or symptoms have been ruled out or diagnosed and treated, and provider attestation that the drug is part of a comprehensive treatment plan, including diet and exercise or activity appropriate for patient's ability. Renewal authorization: Clinical documentation that patient has maintained a weight loss of at least 5% from baseline weight, or has maintained or improved a BMI percentile for patients under 18.	The initial approval and renewal authorizations are effective for six months.

* Table reflects information as of December 2023.

MEDICAID COVERAGE OF GLP-1 AGONISTS FOR TYPE 2 DIABETES

While drugs indicated for weight loss are not uniformly covered by all state Medicaid programs, GLP-1 agonists indicated for type 2 diabetes have widespread Medicaid coverage, although states may require prior authorization or other clinical criteria.

How are state Medicaid programs managing utilization of GLP-1 agonists indicated for type 2 diabetes?

States have taken different approaches to managing utilization of GLP-1 agonists indicated for the treatment of type 2 diabetes. Examples of state strategies are outlined in Figure 6. While some states do not require a prior authorization for preferred GLP-1 agonists, other states have varying degrees of prior authorization criteria. Examples of common prior authorization criteria for preferred GLP-1 agonists include a documented diagnosis of type 2 diabetes, step therapy, and/or documented comorbid conditions.

FIGURE 6: EXAMPLES OF PRIOR AUTHORIZATION CRITERIA FOR GLP-1 AGONISTS INDICATED FOR THE TREATMENT OF TYPE 2 DIABETES*

STATE	PREFERRED AGENTS	PRIOR AUTHORIZATION CRITERIA FOR PREFERRED AGENTS
Michigan[xx]	Byetta, Trulicity, Victoza	No prior authorization required.
Pennsylvania[xxi]	Ozempic, Trulicity, Victoza	Preferred GLP-1 agonists require a prior authorization when the quantity limit is exceeded or if there is therapeutic duplication with another GLP-1 agonist or dipeptidyl peptidase 4 (DPP-4) inhibitor.
Delaware[xxii]	Ozempic, Trulicity, Victoza	Preferred GLP-1 agonists require a prior authorization with a documented diagnosis of type 2 diabetes and use of metformin within the last 90 days, and when not within the dose and frequency range approved by the FDA.
Kentucky[xxiii]	Byetta, Ozempic, Victoza	Preferred GLP-1 agonists require a prior authorization with a diagnosis of type 2 diabetes and additional criteria, such as trial and failure, intolerance, or contraindication to metformin and/or additional diagnoses for comorbid conditions.

* Table reflects information as of December 2023. Effective January 1, 2024, Michigan plans to implement prior authorization criteria.

In addition to prior authorizations, other utilization management strategies used by state Medicaid programs include system edits, such as: maximum doses, minimum age limits, and prohibiting duplication of therapy (GLP-1 agonist + GLP-1 agonist or GLP-1 agonist + dipeptidyl peptidase 4 [DPP-4] inhibitor).

FRAMEWORK FOR ENSURING APPROPRIATE UTILIZATION IN MEDICAID

Due to growing utilization and spend on GLP-1 agonists, state Medicaid programs may apply utilization management criteria to reduce waste associated with low adherence[4] and persistence,[5] to ensure the right patients have access to therapy, and to mitigate against the potential for off-label utilization. GLP-1 agonist shortages also highlight the importance of ensuring the right patients have access to treatment. Increased demand and supply shortages for these medications resulted in a drug shortage that began in 2022 and decreased supply for patients.[xxiv] As of December 2023, semaglutide injection, liraglutide injection, dulaglutide injection, and tirzepatide injection were all in shortage according to the FDA drug shortage list.[xxv]

UTILIZATION MANAGEMENT STRATEGIES

Comprehensive coverage policies for GLP-1 agonists are at the forefront of Medicaid programs due to the increase in utilization, the need for lifestyle modification patient support to supplement pharmacological treatments, and the number of products potentially coming to market. For example, Mississippi's Drug Utilization Review Board recommended promotion of preferred products to combat the increase in non-preferred prescribing and advocated implementation of an electronic prior authorization to encourage utilization with appropriate diagnoses.[xxvi] These recommendations can be adopted by other states to manage appropriate utilization of preferred products and provide consistency across programs.

Diagnosis verification

States that do not cover GLP-1 agonists indicated for chronic weight management may experience increased demand for GLP-1 agonists indicated for type 2 diabetes, driven by patients seeking access to a medication that is not covered for obesity or weight management. Because GLP-1 agonist products currently have different indications, label names, and National Drug Codes (NDCs), payers can manage these therapies for covered uses. However, this could change with future expanded indications, in that a single NDC indicated for both a covered indication and a non-covered indication[xxvii] could pose a challenge for states that do not cover weight loss medications to manage covered uses.[6] Without a system edit or utilization management program to verify diagnosis, medications can be prescribed for a non-covered or off-label use, including utilization for patients who do not meet the FDA label, i.e., below the body mass index (BMI) threshold, lack of comorbidities, used for acute weight loss.

[4] Typically, patients with at least an 80% proportion of days covered (PDC) are considered adherent.
[5] The length of time from initiation of treatment to discontinuation.
[6] Wegovy is pursuing an additional indication for reduction in major cardiovascular events in overweight or obese patients with established cardiovascular disease, based on results from the SELECT trial.

Prior authorization to ensure appropriate utilization

Prior authorizations are a core utilization management tool used to limit non-covered use of medications, reduce unnecessary spending of state resources, and ensure the patient is receiving coverage for the right medication. To limit off-label use of GLP-1 agonists indicated for type 2 diabetes, states may implement prior authorization requirements to ensure the patient has an appropriate diagnosis prior to initiating treatment. Similarly, states may implement prior authorization for a GLP-1 agonist indicated for chronic weight management to ensure the patient meets the BMI and comorbidity thresholds and participates in lifestyle modifications.

Reauthorization, or prior authorization to continue therapy, may benefit the patient and provider by monitoring and managing side effects, ensuring the patient is adherent to treatment, and receiving measurable benefit. While prior authorization approvals differ in length and requirements, states' prior authorization criteria may include those shown in Figure 7.

FIGURE 7: PRIOR AUTHORIZATION CRITERIA

Vermont Medicaid is an example of a state that implemented prior authorization criteria, following a significant increase in GLP-1 agonist utilization. Vermont Medicaid observed a 49% increase in gross spend and a 41% increase in claim volume for GLP-1 agonists indicated for type 2 diabetes from state fiscal year (SFY) 2022 to SFY 2023. Following this observation, Vermont Medicaid implemented a requirement for diagnosis of type 2 diabetes for GLP-1 agonists in January 2023.[xxviii] A report to the Vermont legislature acknowledges that this increase in claims and an increase in the prior authorization denial rate could possibly be due to off-label utilization and prescribing.

PATIENT SUPPORT FOR LIFESTYLE MODIFICATIONS AND NON-PHARMACOLOGICAL APPROACHES

With the increasing popularity of pharmacotherapy use for chronic weight management, payers are looking to comprehensively engage patients to participate in a multimodal approach that includes lifestyle modifications. Comprehensive lifestyle interventions include a reduced-calorie diet, increased physical activity, and behavior therapy that may result in long-term benefits for patients.[xxix] However, accessible resources and programs may be needed for patients to utilize specific evidence-based diet and exercise programs endorsed by the medical community and industry for these medications.

In the Wegovy and Zepbound clinical trials, patients received instruction for a reduced calorie diet and increased physical activity counseling throughout the trial and, in one Wegovy trial, received an initial eight-week low-calorie diet. Specifics for lifestyle management programs in the clinical trials for GLP-1 agonists indicated for type 2 diabetes are less elucidated. In the clinical trial, participants received 34 phone visits and 17 lifestyle counseling sessions over 68 weeks. However, clinical trial engagement is known to exceed real-world levels, and replicating it may demand significant resources.

For lifestyle management programs, states may consider establishing an optimal or minimal cadence of patient engagement. Patient engagement may be offered in person, via telehealth, or via an app.

Monitoring GLP-1 agonist utilization and associated costs

States may also consider monitoring potential waste and total healthcare costs for patients on GLP-1 agonists, including increased costs associated with side effects, as well as potential savings associated with improved long-term health outcomes.

Adherence and persistence

While there is limited data available specific to the Medicaid program, payers have expressed concern with GLP-1 agonist adherence and persistence. According to an analysis of adults in the United States with type 2 diabetes who utilized GLP-1 agonists, just over half were adherent to the medication after 12 months, with 47.7% having discontinued therapy after 12 months.[xxx] Another study conducted by two pharmacy benefit managers (PBMs) on commercially insured individuals with obesity or prediabetes who had newly initiated treatment with a GLP-1 agonist, 32% of members were persistent at one year and 27% were adherent to therapy in the year following.[xxxi]

Patients who are non-adherent or discontinue treatment may not experience the health benefits associated with these therapies, thus generating wasted spend for the state Medicaid program. A previous Milliman white paper on GLP-1 agonists indicated for chronic weight management illustrates a potential 26% of wasted spend when patients do not sustain therapy for at least 12 months. State Medicaid programs may consider monitoring patients on GLP-1 agonists for adherence and persistency, to identify, monitor, and address potential waste.

Associated costs

While clinical trials for GLP-1 agonists approved for chronic weight management showed reduction in patient body weight, it remains to be seen whether health benefits associated with the use of these therapies can lead to a reduction in healthcare costs and, if so, in what timeframe. States may consider monitoring potential waste and total healthcare costs for patients on GLP-1 agonists, including increased costs associated with adverse events due to treatment as well as potential savings associated with improved long-term health outcomes.

- Cost associated with side effects: Medicaid payers may also experience increased healthcare costs associated with the adverse gastrointestinal events in patients taking GLP-1 agonists, which have been linked to increased risks of biliary disease, pancreatitis, bowel obstruction, and gastroparesis in diabetic patients.
- Impact to overall healthcare costs: In 2019, the Centers for Disease Control and Prevention (CDC) estimated annual medical costs for obese adults were $1,861 higher than medical costs for people with healthy weight.[xxxii] It is possible that patients utilizing GLP-1 agonists who achieve health benefits, such as improvements in cardiovascular risk factors, would have a reduction in healthcare costs over time. However, further research is needed to understand the long-term impacts of GLP-1 agonists on insulin use, healthcare utilization, and therapeutic improvements related to comorbid conditions.

OPPORTUNITIES FOR VALUE-BASED CONTRACTING

State Medicaid programs may consider contracting with manufacturers through supplemental or value-based agreements to help reduce the cost of the medications and to lead states toward receiving more value for their limited resources. Value-based contracting also can serve as a tool for states to monitor and demonstrate positive patient outcomes, such as:

- Alleviation of the primary health condition (reduction in HbA1C, weight, or BMI) or other comorbidities (hypertension, hypercholesterolemia, sleep apnea, etc.)
- Reduction in healthcare resource utilization (hospitalizations, urgent care, or emergency department visits)

Two other outcomes that may be included in value-based contracts are adherence and weight. Adherence, a measurement that can be calculated from claims data, has been used as a performance measure in value-based contracting arrangements between manufacturers and state Medicaid programs and may be a well-positioned outcome measurement for GLP-1 agonists. Additionally, measuring weight change over time does not involve a blood test, extensive workups, or high-technology machines. This could be considered a less risky measure because clinical trial data can be relied upon.

CONCLUSION

There has been an increase in utilization and spend associated with GLP-1 agonists across Medicaid. Drugs indicated for chronic weight management are not required to be covered by state Medicaid programs. As such, there is limited but growing coverage of GLP-1 agonists indicated for chronic weight management. On the other hand, GLP-1 agonists indicated for type 2 diabetes have widespread Medicaid coverage, although states have varying degrees of prior authorization requirements. State Medicaid programs may consider implementing appropriate utilization management criteria to address the growing utilization and spend on GLP-1 agonists, potential off-label utilization, patient access issues, and potential waste associated with non-adherence or discontinuation. When making benefit design decisions, state Medicaid programs may consider which patients should qualify for these therapies and how patients should be managed while receiving GLP-1 agonist treatment. As spend on these therapies continues to grow, state Medicaid programs may benefit from monitoring and addressing GLP-1 agonist adherence, persistence, potential waste, adverse events, longitudinal medical outcomes, and impacts on healthcare utilization in their populations. This research is particularly important as there is a lack of real-world evidence in the Medicaid population and because clinical trial results may differ from real-world results. Monitoring and analysis of results may provide insights for resource prioritization and policy decisions, with the aim of improving patient outcomes in the short and long term.

CAVEATS AND LIMITATIONS

The material in this paper represents the opinion of the authors and is not representative of the view of Milliman. As such, Milliman is not advocating for, or endorsing, any specific views contained in this paper related to GLP-1 medications.

The information in this paper is designed to provide an overview of GLP-1 agonist utilization, coverage, and management in Medicaid. This information may not be appropriate, and should not be used, for other purposes. We do not intend this information to benefit any third party that receives this work product. Any third-party recipient of this paper that desires professional guidance should not rely upon Milliman's work product, but should engage qualified professionals for advice appropriate to its specific needs.

APPENDIX A: SUMMARY OF GLP-1S BY APPROVAL DATE AND INDICATION

TYPE 2 DIABETES		
Byetta® (exenatide)	April 28, 2005	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Victoza® (liraglutide)	January 25, 2010	As an adjunct to diet and exercise to improve glycemic control in adults and patients aged 10 years and older with type 2 diabetes mellitus. To reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke) in patients with type 2 diabetes mellitus and established cardiovascular disease.
Trulicity® (dulaglutide)	September 18, 2014	As an adjunct to diet and exercise to improve glycemic control in type 2 diabetes mellitus in adults and patients aged 10 years and older. To reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke) in patients with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors.
Bydureon Bcise® (exenatide ER)*	October 20, 2017	As an adjunct to diet and exercise to improve glycemic control in type 2 diabetes mellitus in adults and patients aged 10 years and older.
Ozempic® (semaglutide)	December 5, 2017	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. To reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.
Rybelsus® (semaglutide)	September 20, 2019	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Mounjaro™ (tirzepatide)**	May 13, 2022	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Chronic Weight Management		
Saxenda® (liraglutide)	December 23, 2014	As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in: Adult patients with an initial body mass index (BMI) of: 30 kg/m2 or greater (obese) 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) Pediatric patients aged 12 years and older with: Body weight above 60 kg An initial BMI corresponding to 30 kg/m2 or greater for adults (obese) by international cutoffs (Cole Criteria)
Wegovy® (semaglutide)	June 4, 2021	As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in: Adult patients with an initial body mass index (BMI) of: 30 kg/m2 or greater (obesity) 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia). Pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater for age and sex (obesity). Chronic weight management in adults with obesity or overweight diagnoses with at least one weight-related condition (such as high blood pressure, type 2 diabetes mellitus, or high cholesterol).
Zepbound™ (tirzepatide)**	November 8, 2023	As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in: Adult patients with an initial body mass index (BMI) of: 30 kg/m2 or greater (obesity) 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).

* Bydureon Suspension® and Bydureon Pen have been discontinued.

** Tirzepatide is a dual glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist.

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ENDNOTES

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