

# Payer strategies for GLP-1 medications for weight loss

Helping payers understand the landscape, develop a coverage strategy, and minimize waste

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Approximately 42% of the U.S. population has obesity<sup>1</sup> and, with more than 200 diseases associated with this condition, the demand for weight loss solutions has never been higher. The glucagon-like peptide-1 (GLP-1) receptor agonist drug class, which has been clinically proven to effectively manage type 2 diabetes,<sup>2</sup> is also proving to be highly effective for the treatment of obesity.<sup>3</sup> Many believe it has the potential to meet this growing need.

While GLP-1 medications are costly, they have the potential to decrease medical cost if treated patients achieve sustained weight control<sup>4</sup> in combination with diet and exercise. Furthermore, these medications have now been shown to reduce the risk of major adverse cardiovascular events.<sup>5</sup> They also have potential gastrointestinal (GI) side effects, which may contribute to low medication adherence and early discontinuation of therapy. In a recent study, more than 68% of patients did not maintain GLP-1 therapy for 12 months.<sup>6</sup> Based on these published results, Milliman estimates that a payer with similar discontinuation rates may experience 26% waste in drug spend.

To properly manage these opportunities and challenges, there are key actions payers should take related to coverage of GLP-1s for weight loss, including: evaluating coverage of obesity medications, ensuring appropriate utilization to address adherence and persistency issues, developing a patient engagement strategy to ensure optimal value, and evaluating pharmacy supply chain contracts to ensure optimal pricing. Ultimately, a comprehensive weight loss and therapy management approach is needed to increase treatment success and improve patient wellness.

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<sup>1</sup> Centers for Disease Control and Prevention. FastStats: Obesity and Overweight. Retrieved August 17, 2023, from <https://www.cdc.gov/nchs/fastats/obesity-overweight.htm>.

<sup>2</sup> Nauck, M.A. et al. (October 14, 2020). GLP-1 Receptor Agonists in the Treatment of Type 2 Diabetes – State-of-the-Art. *Mol Metab*. Retrieved August 17, 2023, from <https://pubmed.ncbi.nlm.nih.gov/33068776/>.

<sup>3</sup> Jensterle, M. et al. (May 3, 2022). Efficacy of GLP-1 RA Approved for Weight Management in Patients With or Without Diabetes: A Narrative Review. *Adv Ther*. Retrieved August 17, 2023, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9063254>.

<sup>4</sup> Cawley, J. et al. (July 2015). Savings in Medical Expenditures Associated With Reductions in Body Mass Index Among U.S. Adults With Obesity, by Diabetes Status. *Pharmacoeconomics*. Retrieved August 17, 2023, from <https://pubmed.ncbi.nlm.nih.gov/25381647/>.

<sup>5</sup> Novo Nordisk (August 8, 2023). Semaglutide 2.4 mg Reduces the Risk of Major Adverse Cardiovascular Events by 20% in Adults With Overweight or Obesity in the SELECT Trial. News release. Retrieved August 17, 2023, from <https://www.novonordisk.com/content/nncorp/global/en/news-and-media/news-and-ir-materials/news-details.html?id=166301>.

<sup>6</sup> Leach, J. et al. (July 11, 2023). Real-World Analysis of Glucagon-Like Peptide-1 Agonist (GLP-1a) Obesity Treatment One Year Cost-Effectiveness and Therapy Adherence. Prime Therapeutics and MagellanRx. Retrieved August 17, 2023, from <https://www.primetherapeutics.com/wp-content/uploads/2023/07/GLP-1a-obesity-treatment-1st-year-cost-effectiveness-study-abstract-FINAL-7-11.pdf>.

Over the past year, there has been a dramatic increase in utilization of the GLP-1 receptor agonist drug class. This class of drugs includes recently approved injectables that have demonstrated a much greater efficacy in weight loss, with a fast onset, and low incidence of serious side effects (requiring warnings and precautions in labeling). Figure 1 summarizes the select GLP-1 receptor agonist medications with weight loss indication and their reported effect on body weight.

## Current medications

FIGURE 1: SUMMARY OF GLP-1 MEDICATIONS FOR WEIGHT LOSS

MEDICATION	FDA APPROVAL DATE FOR CHRONIC WEIGHT MANAGEMENT	AVERAGE % CHANGE IN BODY WEIGHT (RANGE)	ADDITIONAL NOTES
Saxenda (liraglutide)	12/23/2014	6.7% to 9.2% <sup>7</sup>	Liraglutide was approved for the treatment of type 2 diabetes in 2010 under the brand name Victoza. Saxenda is available in higher doses than Victoza.
Wegovy (semaglutide)	6/4/2021	9.6% to 16% <sup>8</sup>	Semaglutide was approved for the treatment of type 2 diabetes in 2017 under the brand name Ozempic. Wegovy is available in higher doses than Ozempic.
Mounjaro (tirzepatide)	PDUFA date in Q4 2023	15.7% to 22.5% <sup>9,10</sup>	Approved for the treatment of type 2 diabetes in 2022.

Note: Average percentage change in body weight based on maximum dose. The Prescription Drug User Fee Act (PDUFA) date is at the end of the review period after a drug is filed with the FDA for approval.

Additional medications in this class (Adlyxin, Bydureon, Byetta, Rybelsus, and Trulicity) were not included in this review due to limited use for and effect on weight loss.<sup>11</sup>

The estimated average annual wholesale acquisition cost (WAC) for GLP-1 drug class products that are utilized for weight loss ranges from \$12,200 to \$17,600.<sup>12</sup> Three other medications (Qsymia, Contrave, and Xenical) are currently approved for chronic weight management, with the WAC ranging from \$2,300 to \$9,200 annually.

## Clinical distinction

GLP-1 drugs mimic the action of naturally occurring GLP-1 hormone in the intestinal tract. One of GLP-1's mechanisms of action is increasing the sense of satiety, the feeling of being sated or full, by slowing down the rate at which food leaves the stomach. GLP-1s also impact the brain's perception of fullness, leading people to reduce food intake.<sup>13</sup>

The first GLP-1 drugs were originally studied and approved to treat type 2 diabetes, showing effectiveness at lowering blood sugar levels and A1C (a blood test showing average blood sugar over the prior two to three months). It became evident during drug trials that some of the GLP-1 drugs were also causing significant weight loss in a large portion of the study population, which led to specific drug trials for that indication. GLP-1 drugs approved for weight loss are all injectable products, dosed either daily or weekly. Once daily Rybelsus (semaglutide) is the sole oral

<sup>7</sup> Novo Nordisk (April 2023). Saxenda prescribing information. Retrieved August 17, 2023, from <https://www.novo-pi.com/saxenda.pdf>.

<sup>8</sup> Novo Nordisk (August 2022). Wegovy prescribing information. Retrieved August 17, 2023, from <https://www.novo-pi.com/wegovy.pdf>.

<sup>9</sup> Eli Lilly and Company (June 24, 2023). Lilly's SURMOUNT-2 Results Published in The Lancet Show Tirzepatide Achieved a Mean Weight Reduction of 15.7% at the Highest Dose (15 mg) in Adults With Obesity or Overweight and Type 2 Diabetes. News release. Retrieved August 17, 2023, from <https://investor.lilly.com/news-releases/news-release-details/lillys-surmount-2-results-published-lancet-show-tirzepatide>.

<sup>10</sup> Eli Lilly and Company (April 28, 2022). Lilly's Tirzepatide Delivered Up to 22.5% Weight Loss in Adults With Obesity or Overweight in SURMOUNT-1. News release. Retrieved August 17, 2023, from <https://investor.lilly.com/node/47141/pdf>.

<sup>11</sup> Trujillo, J.M. et al. (March 9, 2021). GLP-1 Receptor Agonists: An Updated Review of Head-to-Head Clinical Studies. *Ther Adv Endocrinol Metab*. Retrieved August 17, 2023, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7953228/>.

<sup>12</sup> Based on 2023 WAC prices accessed from the Texas Health and Human Services prescription drug price disclosure program. Retrieved August 17, 2023, from <https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/data-overview>. Includes Wegovy, Saxenda, Ozempic, Victoza, and Mounjaro. Additional medications in this class (Adlyxin, Bydureon, Byetta, Rybelsus, and Trulicity) were not included in this review due to limited use for and effect on weight loss. Annual cost based on WAC does not factor in any manufacturer rebates or discounts. Annual is defined as 365 days of therapy.

<sup>13</sup> Ard, J. et al. (May 11, 2021). Weight Loss and Maintenance Related to the Mechanism of Action of Glucagon-Like Peptide 1 Receptor Agonists. *Adv Ther*. Retrieved August 17, 2023, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8189979/>.

GLP-1 product currently on the market. It is only indicated for the treatment of type 2 diabetes, but it is being studied for weight loss at significantly higher doses than those indicated for treatment of diabetes. Initial results were recently released and show weight loss comparable to the injectable versions of the drug.<sup>14</sup>

The most common side effects of this drug class involve the digestive system. Incidence rates are dependent on the medication and dose, but the most frequent adverse reactions are nausea (31%-44%), diarrhea (21%-32%), vomiting (12%-25%), and constipation (12%-23%).<sup>15,16,17,18</sup> To minimize the initial side effects of these products, they require an initial dose escalation period (stepwise escalation in dosage to achieve therapeutic levels). For example, to reach the full maintenance dose, Saxenda and Victoza have the shortest dose escalation period (four escalations over 28 days), while Ozempic and Wegovy have four escalations over a 16-week period, and Mounjaro has five escalations over a 20-week period. Some potentially serious but much rarer side effects include acute pancreatitis, thyroid tumors, acute kidney injury, heart rate increases, and acute gallbladder disease.<sup>15,16,17,18</sup>

Noticeable weight loss can often be seen in a few weeks after starting the drugs, with peak weight loss typically seen after approximately 12 to 18 months on therapy. Weight loss is typically maintained until therapy is discontinued, meaning that sustained weight loss may require long-term therapy. One drug manufacturer's study showed that patients regained two-thirds of their weight back after being off the drug for a year.<sup>19</sup> These medications have been shown to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes,<sup>20</sup> but the potential long-term effects (positive or negative) of taking these medications for weight loss for an extended period of time remains unclear. There are multiple ongoing studies being conducted to measure these impacts, with the first trial results expected later this year.<sup>21</sup>

## Media attention and market demand

In 2021 alone, Americans spent an estimated \$72.6 billion on weight loss (diet programs, surgeries, drugs, supplements, apps, etc.).<sup>22</sup> Numerous diets, drugs, food plans, and other programs for weight loss have shown promise in the past but have not been able to materially slow the rising rate of obesity. GLP-1 medications are the latest entry in this search for an effective and lasting weight loss method, generating significant buzz, especially across social media. Adding to the published outcomes of the effects of this drug class are celebrity testimonials, a dramatic spike in social media activity (the hashtag #mounjaro has over 600 million views on TikTok), and numerous national media stories that share information about the quick and dramatic weight loss reported by some users of these products. Advertising and promotion by pharmaceutical manufacturers and intense marketing by weight loss and telehealth companies offering the products as part of their weight loss services has also increased significantly in the past year.<sup>23</sup>

<sup>14</sup> Novo Nordisk (May 22, 2023). Oral Semaglutide 50 mg Achieved 15.1% Weight Loss (17.4% if all people adhered to treatment) in Adults With Obesity or Overweight in the OASIS 1 Trial. News release. Retrieved August 17, 2023, from <https://www.novonordisk.com/news-and-media/news-and-ir-materials/news-details.html?id=166110>.

<sup>15</sup> Liu, L. et al. (December 7, 2022). Association Between Different GLP-1 Receptor Agonists and Gastrointestinal Adverse Reactions: A Real-World Disproportionality Study Based on FDA Adverse Event Reporting System Database. *Front. Endocrinol.* Retrieved August 17, 2023, from <https://www.frontiersin.org/articles/10.3389/fendo.2022.1043789/full>.

<sup>16</sup> Jastreboff, A. M. et al. (July 21, 2022). Tirzepatide Once Weekly for the Treatment of Obesity. *N Engl J Med.* Retrieved August 17, 2023, from <https://www.nejm.org/doi/full/10.1056/NEJMoa2206038>.

<sup>17</sup> Wegovy prescribing information, op cit.

<sup>18</sup> Saxenda prescribing information, op cit.

<sup>19</sup> Wilding, J.P.H. et al. (April 19, 2022). Weight Regain and Cardiometabolic Effects After Withdrawal of Semaglutide: The STEP 1 Trial Extension. *Diabetes, Obesity and Metabolism.* Retrieved August 17, 2023, from <https://dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.14725>.

<sup>20</sup> Sattar, N. et al. (August 20, 2021). Cardiovascular, Mortality, and Kidney Outcomes With GLP-1 Receptor Agonists in Patients With Type 2 Diabetes: A Systematic Review and Meta-Analysis of Randomized Trials. *The Lancet.* Retrieved August 17, 2023, from [https://www.thelancet.com/journals/landia/article/PIIS2213-8587\(21\)00203-5/fulltext](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(21)00203-5/fulltext).

<sup>21</sup> Novo Nordisk, loc. cit.

<sup>22</sup> Marketdata LLC. The U.S. Weight Loss Market: 2022 Status Report & Forecast (March 2022). Retrieved August 23, 2023, from <https://www.researchandmarkets.com/reports/5556414/the-u-s-weight-loss-market-2022-status-report>.

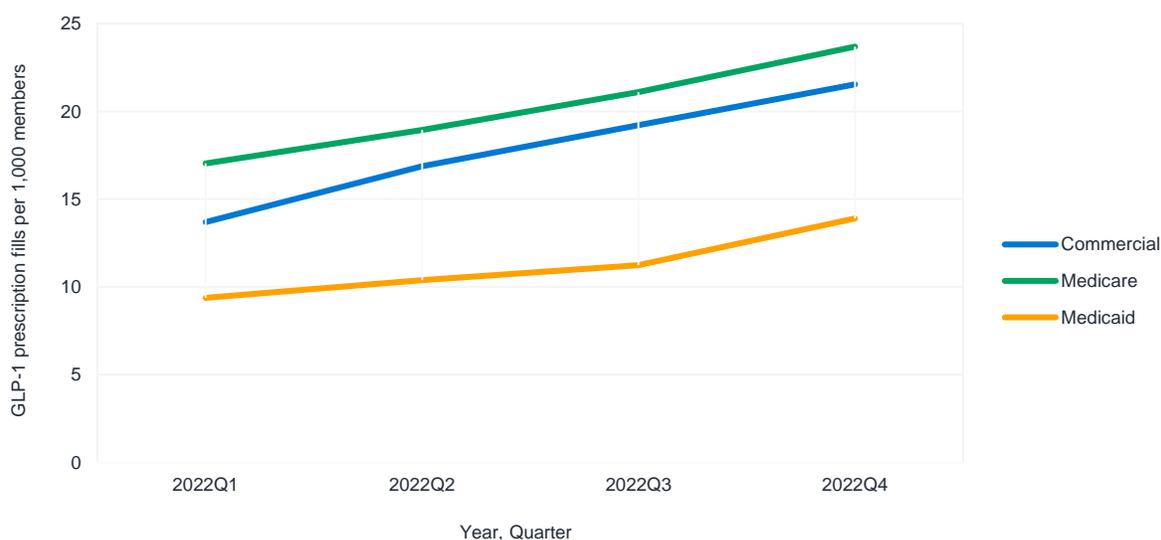
<sup>23</sup> Landi, H. (May 9, 2023). Digital Health Companies Making a Long-Term Play to Tackle Metabolic Health Amid Hype Over \$100B Weight Loss Drug Market. *Fierce Healthcare.* Retrieved August 17, 2023, from <https://www.fiercehealthcare.com/health-tech/telehealth-companies-target-100b-weight-loss-drug-market-patients-grapple-access-costs>.

All these factors have combined to create significant demand for these products. The result has been a shortage of products for patients with diabetes, as well as for those seeking to lose weight. Compounding pharmacies have even started mixing the injectable product to fill the gap and offer a lower-cost prescription (reported to be as low as \$300 per patient per month).<sup>24</sup> At least four states<sup>25</sup> have taken action to curb the compounding of semaglutide over safety concerns, and the manufacturer of Ozempic and Wegovy recently brought suit to challenge this practice with considerations for patent protection and compounding regulations.

Patients have also been attempting to source these products from other countries, such as Canada, where there is reportedly a significant outflow of thousands of doses of Ozempic each month, so much so that the Canadian Health Minister is exploring ways to prevent “mass exportation” of these products.<sup>26</sup>

Figure 2 shows quarterly utilization for GLP-1s for the most recent 12-month period. From Q1 to Q4 2022, there was an increase in GLP-1 utilization across core sources of health benefits coverage—57% for the commercial market, 39% for Medicare (includes Medicare prescription drug plans [PDPs] and Medicare Advantage), and 48% for Medicaid.

**FIGURE 2: GLP-1 PRESCRIPTION FILLS PER 1,000 CONTINUOUSLY ENROLLED MEMBERS AGED 12 YEARS AND OLDER FOR MOST RECENT 12-MONTH PERIOD BY QUARTER**



Source: Analysis of utilization for liraglutide, semaglutide, and tirzepatide using Milliman MedInsight® Emerging Experience research data. Note: Medicare results are only for a diabetes indication as Medicare does not cover medications for obesity and weight loss indications.

<sup>24</sup> Landsverk, G. (February 2, 2023). Shortages of a “Game Changer” Weight-Loss Drug Are Driving People to Buy Potentially Risky Knockoff Versions. Insider. Retrieved August 17, 2023, from <https://www.insider.com/buy-compounded-semaglutide-online-risks-wegovy-ozempic-2023-1>.

<sup>25</sup> Ibid.

<sup>26</sup> The Canadian Press (April 12, 2023). Canada’s Health Minister Calls Mass Exports of Ozempic to U.S. an “Outrageous” Abuse. Toronto Star. Retrieved August 17, 2023, from <https://www.thestar.com/politics/2023/04/12/canadas-health-minister-calls-mass-exports-of-ozempic-to-us-an-outrageous-abuse.html>.

## Current coverage status by U.S. market segments

In 2013 the American Medical Association (AMA) officially recognized obesity as a complex chronic disease.<sup>27</sup> However, there is stigma around obesity and many still see it as strictly a behavioral problem rather than a disease with behavioral components that can be medically managed and prevented.<sup>28</sup> In addition, older anti-obesity medications have either shown limited effectiveness or significant side effects. That combination of factors has led many government payers and some commercial payers to exclude weight loss medications from coverage.

### COMMERCIAL INSURERS INCLUDING EMPLOYER-SPONSORED PLANS

Most fully insured commercial payers cover GLP-1 medications for weight loss but typically with coverage restrictions (patient qualification) and step therapy. Of the 17 largest insurers in the United States, 11 have a public coverage policy detailing coverage for GLP-1 medications for weight management, with nine of the 11 having restrictions beyond the U.S. Food and Drug Administration (FDA) label.<sup>29</sup> Employer-sponsored (self-funded) coverage of weight loss drugs has ranged from 33% to 63% of employer groups, based on recent data from pharmacy benefit managers (PBMs), with up to 80% of those groups covering the GLP-1s for weight loss applying prior authorization to control utilization.<sup>30</sup>

### HEALTH EXCHANGE PLANS

The Patient Protection and Affordable Care Act (ACA) does not consider weight loss medications “essential benefits” and therefore does not require plan sponsors to cover GLP-1 drugs for weight loss or obesity. There are requirements for plans to offer diet counseling and obesity screening and counseling as part of preventive care benefits without cost sharing to the beneficiary, but those service categories do not include these new medications or older treatments for weight loss and obesity.

The U.S. Preventive Services Task Force (USPSTF) currently has a draft research plan out for public comment regarding “Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Interventions.” If GLP-1s are graded as an A or B recommendation from the USPSTF as a result of this study, then coverage for these products would be mandatory as a preventive service, with plans required to provide them at no cost sharing for patients.<sup>31</sup>

### TRADITIONAL MEDICARE, MEDICARE ADVANTAGE AND PART D (MA-PD), AND PDPS

Obesity and weight loss medications are excluded from coverage in Medicare Part B and Part D by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. However, the versions of these medications that are indicated for diabetes (e.g., Ozempic, Victoza, and Mounjaro), are required to be covered at a class level for treatment of diabetes under Medicare Part D.

As shown in Figure 2 above, Medicare Part D plans have also recently seen a dramatic increase in the prescriptions for these medications, despite the fact that they are only covered for treatment in diabetes. Much of this increase can be attributed to an increase in the overall use of GLP-1s as first line therapy in diabetes, driven by label expansions to help prevent cardiovascular complications from diabetes and the potential for weight loss in diabetics, along with updated guidelines from the American Diabetes Association related to treating diabetics with cardiovascular disease.<sup>32</sup>

<sup>27</sup> Kyle, T.K., Dhurandhar, E.J., & Allison, D.B. (September 2016). Regarding Obesity as a Disease: Evolving Policies and Their Implications. *Endocrinol Metab Clin North Am*. Retrieved August 17, 2023, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4988332/>.

<sup>28</sup> Puhl, R.M. & Heuer, C.A. (September 6, 2012). The Stigma of Obesity: A Review and Update. *Obesity*. Retrieved August 17, 2023, from <https://onlinelibrary.wiley.com/doi/full/10.1038/oby.2008.636>.

<sup>29</sup> Tepper, N. (May 16, 2023). Insurers, PBMs Restrict Access to Weight Loss Drugs as Demand Soars. *Modern Healthcare*. Retrieved August 17, 2023, from <https://www.modernhealthcare.com/insurance/pbms-insurers-ozempic-wegovy-weight-loss-drug-access-cigna-centene> (subscription required).

<sup>30</sup> Welliver, S., Susie, C., & Binkely, D. (March 16, 2023). #Ozempic: TikTok Fad or Weight Management Disruptor?. *Mercer*. Retrieved August 17, 2023, from <https://www.mercer.com/en-us/insights/us-health-news/ozempic-tiktok-fad-or-weight-management-disruptor/>.

<sup>31</sup> U.S. Preventive Services Task Force (May 18, 2023). Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Interventions. Retrieved August 17, 2023, from <https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-research-plan/weight-loss-prevent-obesity-related-morbidity-mortality>.

<sup>32</sup> American Diabetes Association Professional Practice Committee (December 16, 2021). 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2022. *Diabetes Care* 2022. Retrieved August 17, 2023, from [https://diabetesjournals.org/care/article/45/Supplement\\_1/S125/138908/9-Pharmacologic-Approaches-to-Glycemic-Treatment](https://diabetesjournals.org/care/article/45/Supplement_1/S125/138908/9-Pharmacologic-Approaches-to-Glycemic-Treatment).

With this increase, utilization management strategies that are within the bounds of Centers for Medicare and Medicaid Services (CMS) rules, such as prior authorization to validate diagnosis, are being considered by plan sponsors to limit the utilization to those indications covered by Medicare. Some plan sponsors are concerned about the potential future cost of these medications if they are covered for weight management. According to one study, it would cost taxpayers more than \$26 billion annually if just 10% of eligible patients got these new drugs.<sup>33</sup> More studies are needed to better assess the potential impact and benefit of covering obesity and weight loss medications using real-world data.

Recently, several advocacy groups have been asking Congress and the Biden administration to allow coverage of weight loss medications.<sup>34</sup> Three potential routes to coverage would be Congressional action,<sup>35</sup> an innovation program proposed by the presidential administration, or having CMS redefine these medications for treatment of a chronic disease (obesity) instead of “agents when used for weight loss.”<sup>36</sup>

## MEDICAID

Medicaid coverage of GLP-1 products varies by state, with multiple states not providing coverage for the products indicated for weight loss. Most GLP-1 coverage under Medicaid is for GLP-1 products with the diabetes indications only, and it is common for these products to require a prior authorization to apply clinical criteria under Medicaid.

## Importance of medication adherence and persistency

Research shows that semaglutide and liraglutide must be taken consistently and long-term to achieve and maintain weight loss benefits.<sup>37</sup> Patients who discontinue use after a few initial doses or are inconsistent with their dosing will likely not see any material health benefits and could incur waste in prescription benefit dollars.

A recent real-world analysis of GLP-1 agonist obesity treatment conducted by two pharmacy benefit managers (PBMs) found that 32% of members on treatment were persistent at one year, and 27% of those remaining on therapy were adherent during the following year.<sup>38</sup> Adherence is measured using proportion of days covered (PDC); the number of days’ supply a drug is dispensed divided by the number of days the prescription is in the patient’s possession.<sup>39</sup> Optimal adherence is defined as a PDC of 80% or higher.<sup>40</sup> Persistence, a leading indicator of adherence, represents the time (e.g., days, months, and years) over which a patient continues the treatment.

While not detailed in the aforementioned PBM study, there are several factors that may be contributing to early discontinuation of treatment, including clinical side effects, cost barriers, and inefficient or inconvenient prior authorization processes. Due to the significant rate of therapy drop-offs indicated by the study, payers may want to develop a comprehensive plan to encourage adherence. Wegovy and Saxenda are currently indicated for patients with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obese) or 27 kg/m<sup>2</sup> or greater (overweight), in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia), where the greatest impact to overall health improvement can be realized.

<sup>33</sup> Lapid, N. (March 11, 2023). Economists Warn of Costs if Medicare Covers New Obesity Drugs. Reuters. Retrieved August 17, 2023, from <https://www.reuters.com/world/us/economists-warn-costs-if-us-medicare-covers-new-obesity-drugs-2023-03-11>.

<sup>34</sup> Whyte, L.E. (April 24, 2023). Weight-Loss Drugmakers Lobby for Medicare Coverage. Wall Street Journal. Retrieved August 17, 2023, from <https://www.wsj.com/articles/weight-loss-drugmakers-lobby-for-medicare-coverage-69188697>.

<sup>35</sup> Congress.gov (2021-2022). S.596 – Treat and Reduce Obesity Act of 2021. Retrieved August 17, 2023, from <https://www.congress.gov/bill/117th-congress/senate-bill/596>.

<sup>36</sup> Neuman, T. & Cubanski, J. (May 18, 2023). What Could New Anti-Obesity Drugs Mean for Medicare? Kaiser Family Foundation Policy Watch. Retrieved August 17, 2023, from <https://www.kff.org/policy-watch/what-could-new-anti-obesity-drugs-mean-for-medicare/>.

<sup>37</sup> Wilding, J.P.H. et al., op cit.

<sup>38</sup> Leach, J. et al., op cit.

## Potential for prescription benefit spend waste

Due to the high cost of GLP-1s and the challenges in maintaining optimal medication adherence, it is important to acknowledge the potential for added waste in the system and ultimately for payers. Figure 3 illustrates the potential for significant financial waste if patients do not sustain therapy for at least 12 months.

**FIGURE 3: ILLUSTRATION OF MEDICATION WASTE FOR 100,000 ENROLLEES**

CALCULATION COMPONENT		VALUE	SOURCE
Number of enrollees for a commercial payer	A	100,000	Assumption
% with obesity	B	40.9%	See notes
Enrollees with obesity	C	40,900	= A x B
Average annual net cost to payer for Wegovy, Saxenda	D	\$10,100	See notes
% of enrollees with obesity that start therapy	E	10%	Modeling assumption
Number of enrollees with obesity that start therapy	F	4,090	= C x E
% patients who drop off therapy after 12 months*	G	68%	See notes
Number of patients who drop off therapy	H	2,781	= F x G
Cost of wasted drugs for 2 months**	I	\$1,683	= D x (2/12)
Total wasted medication cost	J	\$4,681,687	= H x I
Total cost for non-drop-off patients***	K	\$13,218,880	= D x F x (1 - G)
Total medication cost	L	\$17,900,567	= J + K
<b>% wasted spend</b>		<b>26%</b>	<b>= J / L</b>

Notes: Assumes a typical commercial payer with 100,000 enrollees (A), and that 40.9% of insured adults have obesity (B).<sup>41</sup>

Assumes formulary coverage and estimated based on wholesale acquisition cost (WAC) price minus average rebate and 80% patient compliance factor (D). WAC prices as of 2023.<sup>42</sup> Average rebate calculated from the ICER Medications for Obesity Management report.<sup>43</sup> ICER\_Obesity\_Final\_Evidence\_Report\_and\_Meeting\_Summary\_102022.pdf

\* See Prime Therapeutics and MagellanRx July 2023 study.<sup>44</sup>

\*\* Assumed average length of therapy for patients who drop off within 12 months.

\*\*\* Assumes non-drop-off patients with obesity are adherent, with PDC scores of 80%.

## Utilization and care management impact

A recent study showed that people who stopped taking semaglutide after regular use gained back an average of two-thirds of their prior weight loss.<sup>45</sup> For those patients using a GLP-1 for weight management, long-term GLP-1 adherence, along with lifestyle modification, is critical to achieving and maintaining healthy weight, but patients may not want to continue taking a medication for the rest of their lives. Including education and care management practices, before, during, and after a patient plans to utilize a GLP-1, will provide a higher likelihood of long-term maintained healthy weight.

<sup>41</sup> Dieguez, G., Pyenson, B., Tomicki, S. et al. (March 2021). Obesity in a Claims-Based Analysis of the Commercially Insured Population: Prevalence, Cost, and the Influence of Obesity Services and Anti-Obesity Medication Coverage on Health Expenditures. Milliman Report. Retrieved August 17, 2023, from <https://www.novonordiskworks.com/content/dam/nnw/resource-library/pdf/milliman-white-paper.pdf>.

<sup>42</sup> WAC prices from information accessed from the Texas Health and Human Services prescription drug price disclosure program. Retrieved August 17, 2023, from <https://www.dshs.texas.gov/prescription-drug-price-disclosure-program/data-overview>.

<sup>43</sup> Atlas SJ, Kim K, Beinfeld M, Lancaster V, Nhan E, Lien PW, Shah K, Touchette DR, Moradi A, Rind DM, Pearson SD, Beaudoin, FL. Medications for Obesity Management: Effectiveness and Value; Final Evidence Report. Institute for Clinical and Economic Review, October 20, 2022. Retrieved on August 23, 2023, from <https://icer.org/assessment/obesity-management-2022/>.

<sup>44</sup> Leach, J. et al., op cit.

<sup>45</sup> Wilding, J.P.H. et al., op cit.

Patient concerns about injections, potential treatment side effects (including nausea, vomiting, and diarrhea), or other complications related to GLP-1s may be mitigated by education and support by a medical provider and services. An initial demonstration of the injection process can create a more positive experience for the patient, and education around negative side effects, mitigation strategies, and typical improvement in side effects over time may help patients tolerate the initial discomfort.<sup>46</sup>

## Strategies for payers

The booming demand for GLP-1 drugs for weight loss and obesity requires that payers understand all aspects of this class of medications and develop a well-thought-out strategy regardless of whether or not they decide to offer coverage for these products. Below are key actions for payers to help develop such a strategy.

### 1. Evaluate coverage of obesity medications.

The following are important strategic questions payers can consider when evaluating coverage of obesity medications for weight loss management as part of the overall benefit design.

- Does the benefit design currently provide coverage for this class?
- How does coverage for this class align with the organization's broader benefits strategy, such as weight loss surgery?
- Can a coverage rider buy-up be added (adjustment or add-on to basic policy) for this class?
- What are the cost implications if the organization decides to cover these medications?
- If covering this class, are the most cost-effective medications covered, including the impact of formulary rebates?
- Is there a comprehensive care management plan for patients taking these medications?
- Are lifestyle modification benefits, such as counseling, diet, and exercise, also covered in conjunction with these medications?
- Are there medical benefit savings when obesity is reduced by these medications, and can those savings, if any, be quantified?

The answers to these questions and others are important inputs for payer consideration in developing coverage policies for these drugs.

### 2. Ensure appropriate utilization for benefit coverage decisions.

These medications are also used to treat diabetes under different brand names which are typically covered (e.g., semaglutide is marketed as Wegovy for the treatment of obesity and Ozempic for the treatment of diabetes). Plan sponsors that do not provide coverage for obesity medications should implement clinical edits or processes to ensure appropriate utilization of the versions indicated for diabetes to control off-label use. Review the plan's utilization management program to see whether diagnosis is confirmed prior to providing coverage for these medications. Consider a "smart prior authorization (PA)," if available, which allows claims to bypass the prior authorization edit when systematically confirming diagnosis with prior medication history or medical diagnosis information. Prior authorization denial rates vary significantly by PBM, therefore a one-size approach does not fit all.

For obesity coverage, plans should consider prior authorization criteria that follows FDA-approved labeling at a minimum. This will mitigate off-label use by individuals who are not eligible for treatment.

Whether these medications are covered for obesity or diabetes, payers should consider quantity limits to limit use to the appropriate dose. Plans should also consider verifying the effectiveness of the treatment for each patient with periodic assessments, applying an evaluation for continuation of coverage criteria after a set period.

Payers should review their plans and PBM edits for compounds to ensure the denial of coverage of compounds with these active ingredients unless and until appropriate compounding criteria are established.

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<sup>46</sup> Shomali, M. (January 2014). Optimizing the Care of Patients With Type 2 Diabetes Using Incretin-Based Therapy: Focus on GLP-1 Receptor Agonists. Clin Diabetes. Retrieved August 17, 2023, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4521427/>.

Payers should measure and keep track of GLP-1 patient medication adherence and persistency. To encourage medication adherence, consider implementing a financial incentive for patients to participate in an adjunctive lifestyle and nutritional counseling program or in a patient education and wellness program specific for GLP-1s. Patient outcomes should be studied, where costs are compared to attributed savings, if any, from maintained weight loss of patients that are adherent.

### 3. Develop a patient engagement strategy to ensure optimal value from this drug class.

*First-fill medication adherence education and counseling:* Prior to taking these medications, patients need to be educated on treatment expectations, administration, side effects, dosing escalation, and management strategies for potential adverse reactions. Throughout therapy, continuous engagement and management of issues as they arise are critical to ensuring patients stay compliant.

*Comprehensive behavioral change support:* In addition to counseling on medication, it is critical to provide guidance and support for patients in other areas, including nutrition and diet, physical activity, lifestyle changes, and mental health. This wraparound support is key to achieving and maintaining weight loss.

*Addressing potential socioeconomic inequities:* Payers should have a plan in place to remove or minimize potential barriers to treatment for those with social vulnerability challenges. It has been shown that there are racial inequities in the patient populations that receive these treatments, with many of those populations having higher incidence of major adverse cardiovascular events (MACE) that could potentially be reduced with weight loss.<sup>47</sup>

See Appendix 1 for a comprehensive framework of a patient engagement strategy.

### 4. Evaluate the pharmacy supply chain strategy to ensure optimal pricing and value for this category.

Payers should ensure that they are receiving optimal value for this drug category, evaluating all available purchase discounts, such as rebates and patient assistance programs. In addition, the formulary rebates eligibility criteria should be considered when implementing the utilization management protocols.

Payers may consider value-based contracts (VBCs) to help reduce waste and spend. Similar to other classes of drugs where medication persistency is low, a VBC may be designed to reimburse for expenses incurred for patients who do not continue therapy beyond the loading dose. This would require payers, PBMs, and pharmacies to have patient onboarding support programs implemented to enable this agreement.

Essential aspects that need development to effectively implement value-based agreements include:

- Reliable and credible total cost of care analytics and modeling capabilities to calculate and forecast return on investment (ROI) for use in the contracting process.
- Plan designs that maximize value by motivating and incentivizing optimal behaviors when patients enroll in adherence counseling, wellness, nutritional, or other supporting programs.
- Design agreements that address pain points or potential waste associated with therapy. Other classes such as multiple sclerosis have implemented VBC with low patient adherence and persistency drop-off. These agreements typically provide an incremental discount or additional rebate when agreed-upon measures are not met for an individual patient. They can include some sort of patient support program to help ensure a higher success rate.<sup>48</sup>

<sup>47</sup> Eberly, L.E. *ibid.*

<sup>48</sup> Kelly, C. (August 8, 2017). Biogen Ventures Into Value-Based Contracts In Multiple Sclerosis. Citeline. Retrieved August 17, 2023, from <https://pink.pharmaintelligence.informa.com/PS121212/Biogen-Ventures-Into-Value-Based-Contracts-In-Multiple-Sclerosis>.

## Conclusion

The GLP-1 agonist class of medications appears to offer a meaningful new opportunity to address obesity in the United States. At the same time, there are several complex clinical, economic, regulatory, and patient engagement considerations that must be addressed in order to maximize value from this class of medications.

Specifically, as the medication adherence and persistency data discussed in this paper confirm, achieving the expected benefits of this therapy will require a robust and strategic level of patient education and counseling support in order to achieve optimal adherence and therapeutic effectiveness of the medications.

In fact, given the high cost of these medications, coupled with existing suboptimal adherence rates, there is high potential for payers and patients alike to experience significant financial waste if medications are not taken exactly as prescribed. This paper provides a thoughtful care management framework with robust medication counseling and education, which are both considered essential for payers and relevant healthcare stakeholders if they choose to offer coverage for these medications.

## Methods

The values presented in Figure 2 were developed by Milliman using the Milliman MedInsight® Emerging Experience research data set, which is a database of nationwide de-identified healthcare claims data for over 70 million unique individuals with dates of service spanning 2017 to the current year. Approximately 75 healthcare organizations contribute monthly data to this research database, which is currently refreshed quarterly. The database provides a comprehensive view of services received by patients provided by any healthcare professional in any location or setting billed to insurance, including approximately 1.7 million medical professionals and 340,000 healthcare facilities. The study population included individuals enrolled from January 1, 2022, through February 28, 2023. Sources of coverage were categorized as commercial—health maintenance organization (HMO), preferred provider organization (PPO), ACA, and other—with upwards of 37 million; Medicare Part D stand-alone prescription drug plan, with upwards of 2 million; Medicare Advantage Part D prescription drug plan, with more than 2 million; and Medicaid (HMO, PPO, other) with more than 8 million enrollees.

National Drug Codes (NDC) for GLP-1s included Wegovy, Ozempic, Saxenda, Victoza, and Mounjaro. Findings were not risk- or acuity-adjusted.

## Caveats, limitations, and qualifications

We summarize administrative claims data, reflecting healthcare services paid by insurers. Our results do not capture claims that were denied or cash-paid by patients outside of insurer-paid healthcare encounters or events. The summarized data have not been geographically or demographically adjusted and reflect the observed populations and geographies represented in the Milliman MedInsight® Emerging Experience research data set.

The material in this report 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 report related to GLP-1 medications.

The information in this report is designed to provide an overview of the GLP-1s for weight loss for payers. 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 report that desires professional guidance should not rely upon Milliman's work product but should engage qualified professionals for advice appropriate to its specific needs.

The American Academy of Actuaries requires its members to identify their credentials in their work product. Deana Bell and Peter Heinen are consulting actuaries of Milliman, are members of the American Academy of Actuaries, and meet the qualification standards of the Academy to render the actuarial opinion contained herein. To the best of their knowledge and belief, this report is complete and accurate and has been prepared in accordance with generally recognized and accepted actuarial principles and practices.

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## Appendix A: Framework for a GLP-1 patient engagement and adjunctive lifestyle and nutritional counseling strategy

CARE MANAGEMENT COMPONENT	DEFINITION	TOOLS AND STRATEGIES
<b>Stratification</b>	Identify, segment, and prioritize, patient populations at highest risk who offer the greatest potential for improvements in health outcomes	<ul style="list-style-type: none"> <li>- Health risk assessments/surveys</li> <li>- Predictive models to identify high-risk opportunities for care management</li> <li>- Case finding (e.g., chart reviews, surveys)</li> <li>- Referrals (from member, provider, community)</li> <li>- Integrate health equity/social determinants of health considerations in all segmentation and prioritization activities</li> </ul>
<b>Analytics</b>	Utilize analytics capabilities to identify specific clinical opportunities and provide the intervention opportunities to appropriate healthcare professionals to execute engagement strategies	<ul style="list-style-type: none"> <li>- Ensure all analytics methodologies adhere to evidence-based guidelines</li> <li>- Integrate opportunities using technology where possible</li> <li>- Generate action-oriented intervention opportunities that are intuitive to the audience</li> </ul>
<b>Intervention</b>	Directly engage all relevant healthcare stakeholders, including the patient, provider, pharmacist, PBM, and payer, to maximize clinical outcomes and reduce costs	<ul style="list-style-type: none"> <li>- Create a comprehensive patient educational program around overall healthy habits, weight loss strategies, medication dosing, and side effects management</li> <li>- Develop an infrastructure and processes to engage with each healthcare stakeholder</li> <li>- Provide regular cadence consultation and counseling based on the individualized needs of the patient</li> <li>- Implement motivational interviewing techniques</li> </ul>
<b>Measurement</b>	Collaborate with all healthcare stakeholders to ensure that quality and savings metrics are relevant to each and useful for ongoing strategic decision-making	<ul style="list-style-type: none"> <li>- Leverage population management and care management applications to track all relevant key performance indicators (KPIs) and measures</li> <li>- Conduct periodic assessments of therapeutic impact and progress for each patient and take action as appropriate</li> <li>- Utilize newer, more sophisticated predictive modeling techniques to estimate reductions in total cost of care (if any) and other potential cost savings related to healthier patients</li> <li>- Identify opportunities for value-based care and outcomes-based contracting</li> </ul>



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