

Managing Obesity: Strategic Considerations for Payers




Lomaira™
(phentermine HCl)
8 mg tablets

 **KVK** | **TECH**

Sponsored by KVK Tech, Inc.
Developed by Strategic Healthcare Alliance

Dear Payer:

The ongoing obesity epidemic has generated immense concern among patients, providers, employers, and payers. Given the scope of obesity and its impact on our society, the Centers for Disease Control and Prevention and the Obesity Society have classified it as one of the United States' most pressing healthcare crises.¹

Obesity is associated with numerous complex and costly comorbidities, such as diabetes, hypertension, heart disease, and stroke. Obese individuals have significantly higher medical costs and incur increased healthcare expenditures, both of which rise considerably based on obesity classification and number of comorbidities.

GLP-1s have substantially changed the obesity treatment landscape. However, their escalated demand has overwhelmed the healthcare system—triggering overutilization and costs—despite unanswered questions regarding their efficacy, safety, and potential for weight regain after discontinuation.

As you explore options to satisfy your customers and members, we urge you to consider Lomaira™ (phentermine HCl) 8 mg tablets, CIV. Lomaira is a prescription medicine used for a short period of time (a few weeks) for weight reduction and should be used together with regular exercise and a reduced-calorie diet. Lomaira is for adults with an initial BMI of 30 or more (obese) or 27 or more (overweight) with at least one weight-related medical condition such as controlled high blood pressure, diabetes, or high cholesterol.

Lomaira is a flexible treatment option, offering ideal utilization in numerous clinical situations, including before and after GLP-1s and/or bariatric surgery. When used in conjunction with lifestyle modification (diet and exercise), Lomaira is an effective and cost-efficient agent that suppresses appetite when patients need it most.

We hope you find this information, including the strategic considerations for health plans and draft obesity medical policies, to be helpful as you navigate this ever-evolving landscape. And, if you haven't done so already, we hope you will consider adding Lomaira to your formulary.

If you would like more information, or have any questions, please don't hesitate to contact me.

Sincerely,



VP, Business Development & Brand Marketing
KVK Tech, Inc.
kivepuri@kvktech.com

Please see the Lomaira Indication and Important Safety Information on page 25. To view the full prescribing information, visit https://lomaira.com/Prescribing_Information.pdf.

Reference: 1. OneDigital. 2025 *Workforce Insights Guide*. <https://view.onedigital.com/2025-workforce-insights-guide#page=1>.

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What Is Obesity?

An Ongoing Crisis

Obesity is a common, serious, and costly chronic disease influenced by a complex interplay of genetic, environmental, and behavioral factors. These include family history, unhealthy eating, stress, and conditions such as depression.¹⁻³

The American Medical Association classified obesity as a disease in 2013.⁴ Despite preventive efforts, the incidence and prevalence of obesity continue to grow, making obesity a major public health crisis that has reached epidemic proportions.

Currently, the measures of “healthy” versus “unhealthy” weight are categorized based on a patient’s body mass index (BMI). Each category covers a specific BMI range and is used to quantify normal weight and overweight. These categories also encompass several different classes of obesity (Table 1).⁵

Table 1—Current Weight Classifications by BMI Ranges⁵

BMI, ^a (kg/m ²)	Classification
18.5-24.9	Normal weight
25-29.9	Overweight
30-34.9	Class 1 obesity
35-39.9	Class 2 obesity
≥40	Class 3 obesity

BMI, body mass index.
^aBMI values are not dependent upon age or sex. Values may not correspond to the same amount of adiposity in different populations, including certain ethnic groups (specifically South Asian, Southeast Asian, and East Asian adults).

Among US adults aged ≥20 years, the prevalence of obesity, and those considered to be severely obese (BMI ≥40 kg/m²) has grown considerably within a 10-year period. According to the Centers for Disease Control and Prevention (CDC), the 2013-2014 age-adjusted obesity rate was 37.7%; 7.7% of these adults were classified as being severely obese.⁶ From 2021-2023, these rates increased to 40.3% and 9.7%, respectively.⁶ In that same 10-year period, the prevalence of obesity in specific age groups also experienced dramatic changes, particularly among adults aged 40 to 59 years (Figure 1).^{6,7}

Due to this growing prevalence, many professional organizations, including the CDC and the Obesity Society, have classified obesity as one of the United States’ most pressing healthcare crises.⁹

One study predicts that by 2050, two in three US adults aged ≥25 years will be obese.⁸

Obesity Overview

Obesity is a major public health crisis that has reached epidemic proportions

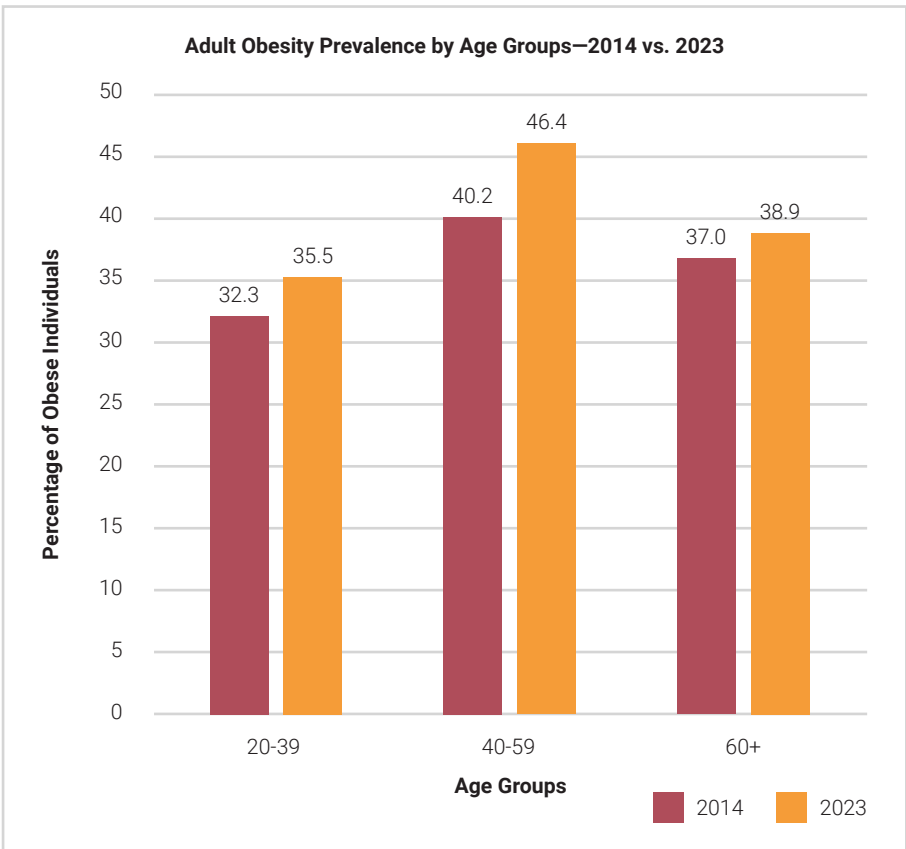
The CDC and Obesity Society have classified obesity as one of the most pressing healthcare crises in the US

Obesity impacts every body system, leading to multiple comorbidities

Obesity-related complications lead to excess healthcare utilization and direct medical expenditures, which increase based on severity

An advisory panel noted that, over a 10-year period, government spending for obesity-related costs would be approximately \$4.1 trillion

Figure 1—The growing prevalence of obesity by age.^{6,7}

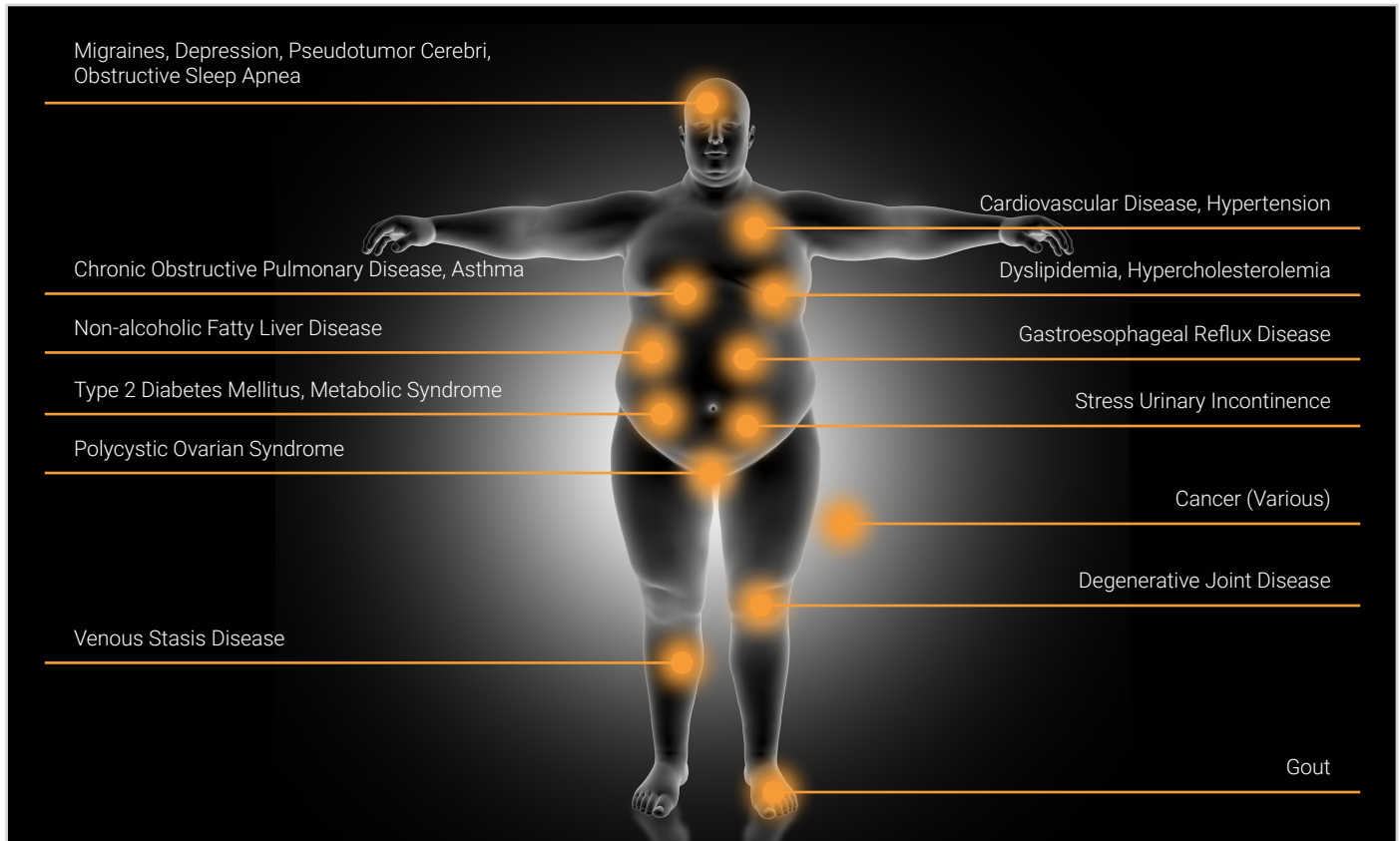


What Is Obesity?

Comorbidities of Obesity

Obesity is associated with a myriad of comorbidities; its physical impact affects virtually every aspect of the human body (**Figure 2**).¹⁰

Figure 2—The effects of obesity and its impact on the body's systems.¹⁰



It has been documented that obesity and its inflammatory markers pose significant risks for developing diabetes, hypertension, heart disease, stroke, and many other chronic conditions.^{11,12}

Obesity-related complications also play a significant role in driving increased healthcare utilization and costs, as the mean cost of obesity-related complications was higher than those for non-obese individuals.^{13,14}

The Financial Impact of Obesity

According to the CDC, obesity accounted for nearly \$173 billion in medical expenditures in 2019.¹ A 2023 report from the Joint Economic Committee (JEC), a bipartisan advisory panel composed of both Democratic and Republican lawmakers, estimated that government spending for obesity-related direct healthcare costs would total \$283 billion in 2023.¹⁵ Over a 10-year period, spending on obesity costs is projected to total approximately \$4.1 trillion.¹⁵

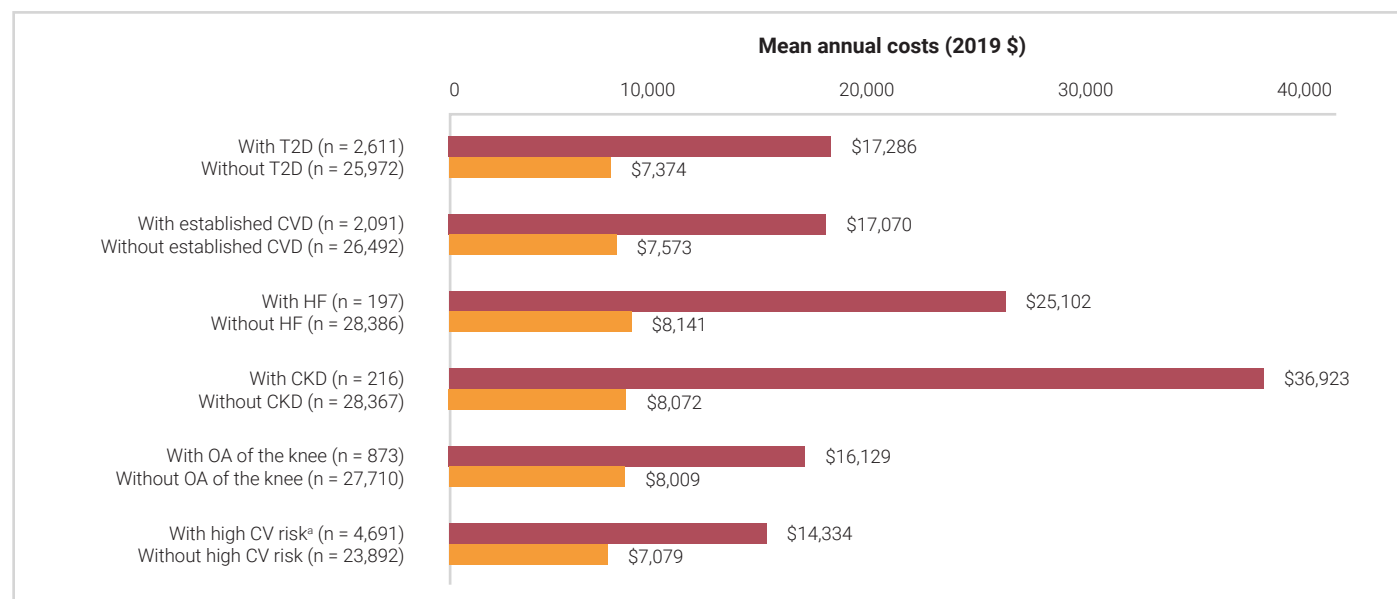
Data also show that individuals with obesity incur significantly higher medical costs than individuals without obesity, both overall and for most major categories of health expenditures, such as inpatient and outpatient costs and prescription drugs.¹⁶ According to the JEC, the average excess medical costs for obese individuals were estimated at \$5,155 per person.¹⁵

Additionally, the presence of obesity-related complications leads to greater healthcare resource utilization (HCRU) and costs (**Figure 3**).¹⁷ As a result, the mean annual costs for obese patients may total ~\$37,000 compared to ~\$8,100 for those at a healthy weight.¹⁷

The cost burden associated with some obesity-related comorbidities can be 2 to 4.5 times higher compared to those at a healthy weight.¹⁷

What Is Obesity?

Figure 3—Mean annual adjusted healthcare costs for individuals with and without obesity-related complications.¹⁷



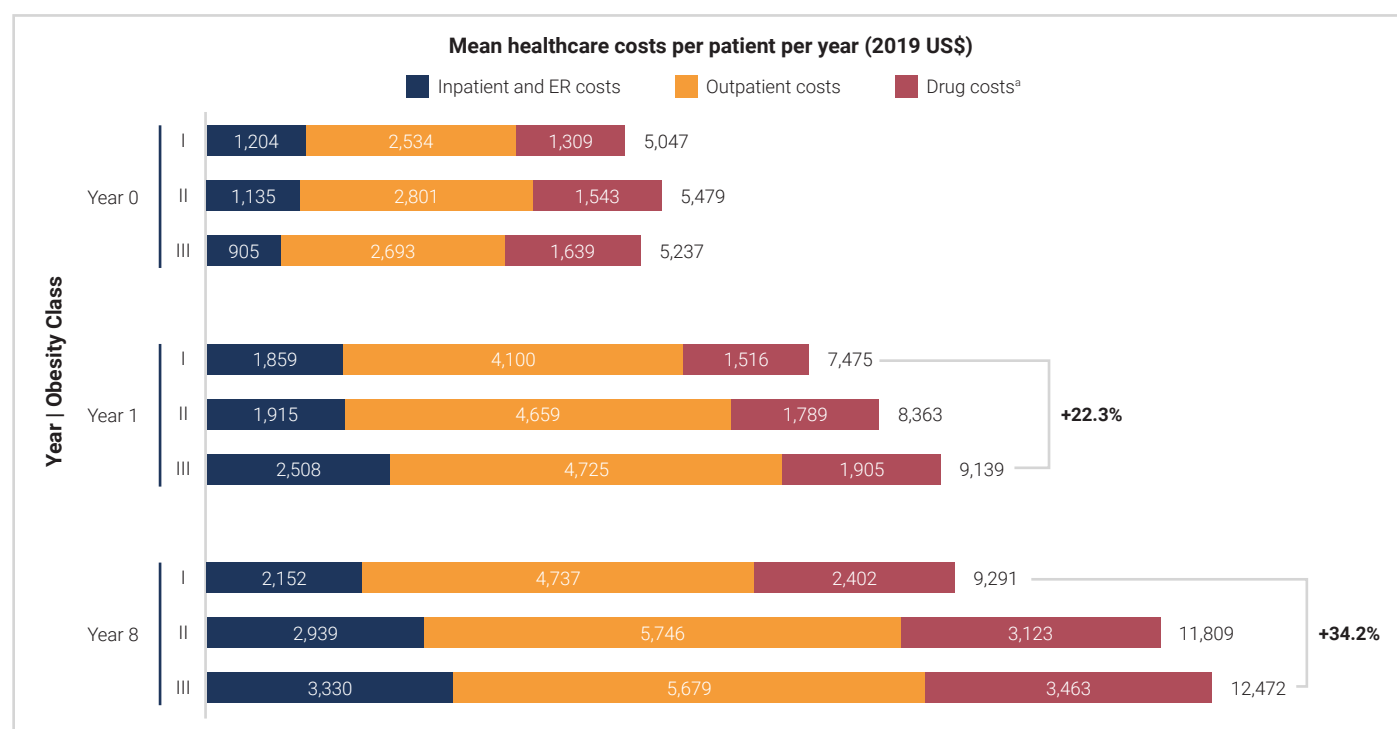
T2D, type 2 diabetes; CVD, cardiovascular disease; HF, heart failure; CKD, chronic kidney disease; OA, osteoarthritis.

*High CV risk: ≥ 2 risk factors out of hypertension, dyslipidemia and type 2 diabetes/prediabetes.

Used with permission from Pearson-Studdard J, et al. *Int J Obes.* 2023;47(12):1239-1246.

The severity of obesity is another influential factor that can exponentially increase direct treatment costs. An 8-year, retrospective, observational study looked at the direct healthcare costs associated with 5 obesity-related complications (cardiovascular disease [CVD], heart failure, type 2 diabetes, chronic kidney disease, and osteoarthritis of the knee) and their impact according to obesity class. The study included the health records of 28,583 adults aged ≥ 18 years with a BMI in the range of 30 to <70 kg/m². Over the 8-year study period, the investigators found that the mean annual total healthcare costs (adjusted to 2019 US dollars) increased considerably for inpatient, emergency room (ER), and outpatient visits, as well as for drug costs. There was also a progressive increase in this difference over time (**Figure 4**).¹⁸

Figure 4—Specific medical expenditures related to obesity-related complications.¹⁸



Adapted from Evans M, et al. *Diabetes Obes Metab.* 2023;25(2):536-544.

*Year 0 refers to the baseline year. Class I obesity: BMI ≥ 30 to <35 kg/m² (n = 17,892); class II obesity: BMI ≥ 35 to <40 kg/m² (n = 6,550); class III obesity: BMI ≥ 40 to <70 kg/m² (n = 4,141).

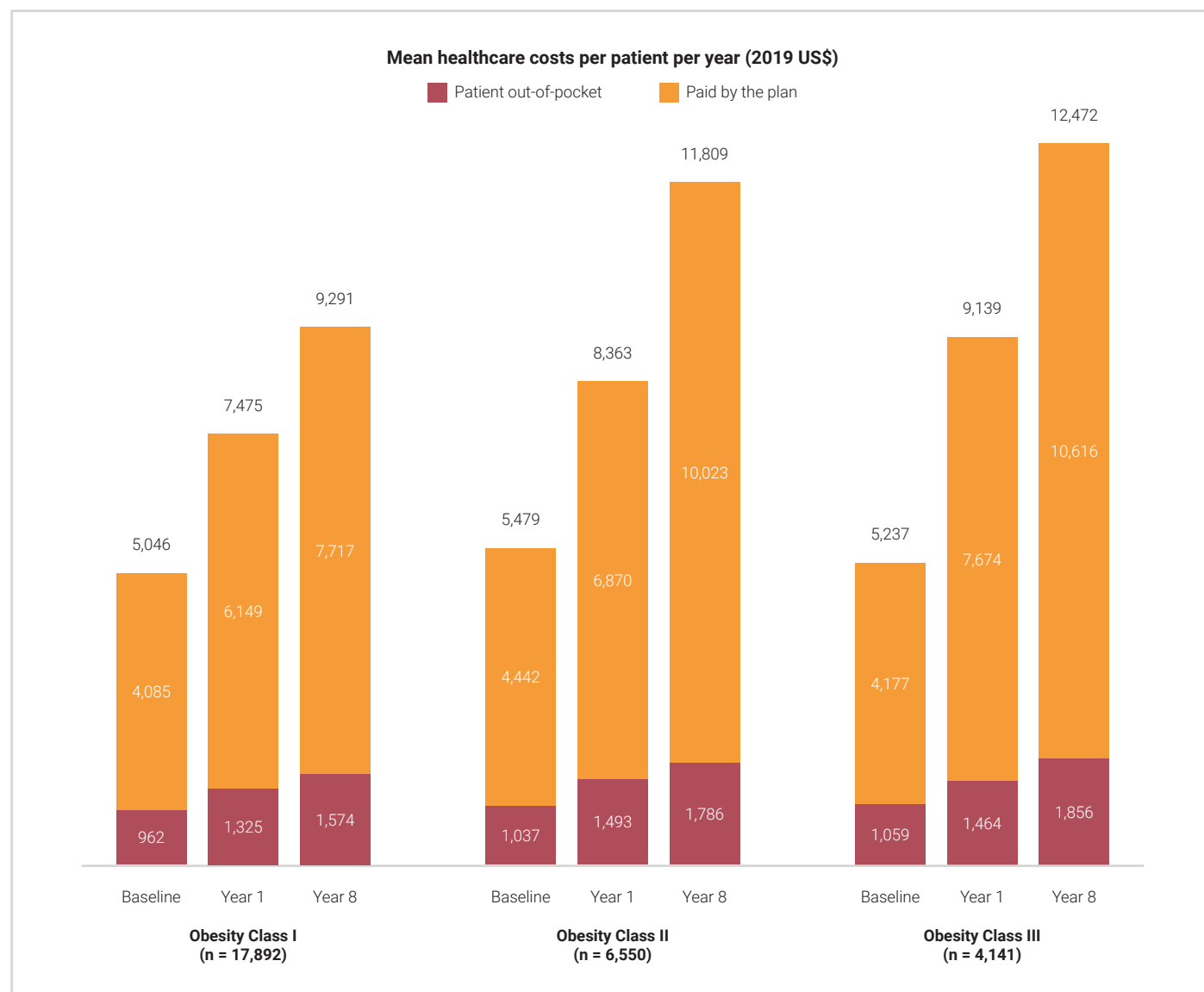
*Excluded Health care Common Procedure Coding System (HCPCS) drug costs.

What Is Obesity?

Additionally, the study investigators noted that the mean yearly direct costs from obesity-related complications increased patients' and plans' financial burden over time (Figure 5). Again, these direct costs were greater based on the severity of obesity.²⁰

People with obesity-related comorbidities have a decreased functional status, quality of life, and health outcomes. They also use ambulatory and inpatient care more frequently than those without comorbidities.¹⁹

Figure 5. Mean annual direct costs paid over 8 years by patient and plan.²⁰



Obesity has a detrimental impact on employers. Annual obesity-related absenteeism costs employers an average of \$1,755, while obese employees also experience an average of 3.2 more missed workdays per year compared to those at a healthy weight. Additionally, obesity-related presenteeism costs employers \$2,427 per employee per year, and those who are obese have a mean productivity loss of 2.6%.²¹

The clinical and economic consequences of obesity will continually threaten our healthcare system as it is estimated that 50.5% of the adult US population will qualify as obese by 2033.¹⁵ Therefore, obesity must be managed and treated as aggressively as other chronic conditions.

What Is Obesity?

Conclusion

Obesity is a common, serious, and costly chronic disease influenced by a complex interplay of genetic, environmental, and behavioral factors, including family history, unhealthy eating, stress, and conditions such as depression.

The American Medical Association classified obesity as a disease in 2013. Despite preventive efforts, the incidence and prevalence of obesity continue to grow, making obesity a major public health crisis that has reached epidemic proportions.

Obesity has a negative effect on multiple body systems, which increases the risk for comorbidities, including CVD, type 2 diabetes, hypertension, heart disease, and stroke.

Obesity-related complications also play a significant role in driving increased healthcare utilization and costs, as the mean cost of obesity-related complications was higher than those for non-obese individuals. As a result, the mean annual costs for obese patients may total ~\$37,000 compared to ~\$8,100 for those at a healthy weight.

An 8-year, retrospective, observational study looked at the direct healthcare costs associated with 5 obesity-related complications (CVD, heart failure, type 2 diabetes, chronic kidney disease, and osteoarthritis of the knee) and their impact according to obesity class. The investigators found that the mean annual total healthcare costs (adjusted to 2019 US dollars) increased considerably for inpatient, ER, and outpatient visits, as well as for drug costs, with a progressive increase in the difference between obesity classes over time. For employers, obesity-related absenteeism costs an average of \$1,755/year, while obesity-related presenteeism costs \$2,427 per employee per year.

As such, obesity needs to be managed and treated aggressively, as it is a continuous existential threat to our healthcare system.

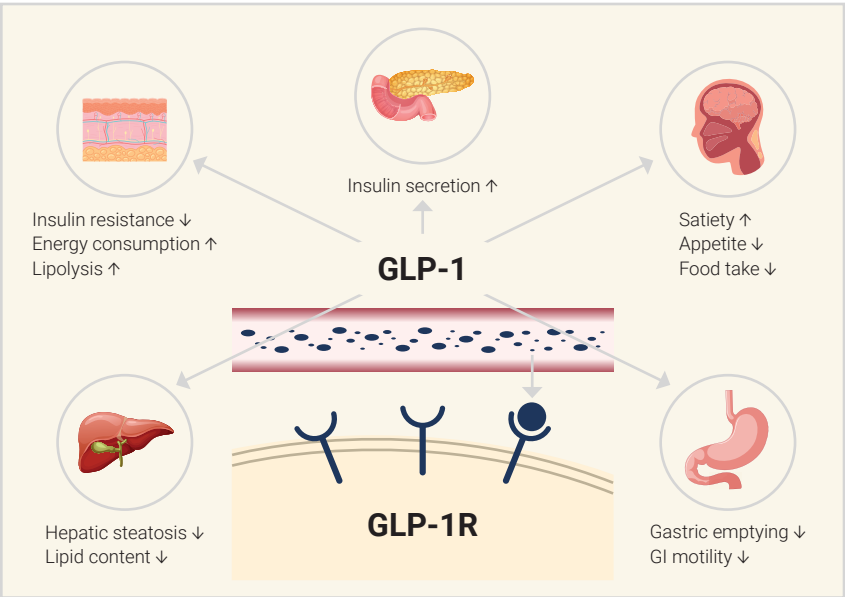
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GLP-1s and Obesity

What Are GLP-1s?

Glucagon-like peptide 1 receptors (GLP-1Rs) are widely present on various cells and binds to GLP-1 to regulate blood glucose and lipid metabolism.¹ Glucagon-like peptide-1 (GLP-1) agonists mimic the action of endogenous GLP-1 by activating GLP-1R and enhancing insulin secretion, inhibiting glucagon release, delaying gastric emptying, and reducing food intake through central appetite suppression (**Figure 1**).^{1,2}

Figure 1—How GLP-1s work with various body organs to promote weight loss.²



GLP-1 Overview

Originally approved to treat type 2 diabetes, many GLP-1s are often used off-label for obesity

While GLP-1s are effective for weight loss, they are associated with serious side effects and high discontinuation rates due to GI adverse events

Weight regain after stopping GLP-1 therapy is common and can negatively impact cardiometabolic parameters

Despite their high costs, employees still want their employers to cover GLP-1s

For employers, the financial impact of GLP-1s is the biggest deterrent to access

Limited evidence of long-term benefit and the high cost of GLP-1s has caused payers to implement cost-containment strategies to limit access and utilization

Byetta (exenatide) was the first FDA-approved GLP-1 indicated for the treatment of type 2 diabetes. The success of exenatide spurred the development of other potent GLP-1 analogs, such as liraglutide and semaglutide, and also unlocked their vast potential to treat various systemic diseases (**Table 1**).^{1,3-12}

Table 1—Currently approved GLP-1s³⁻¹²

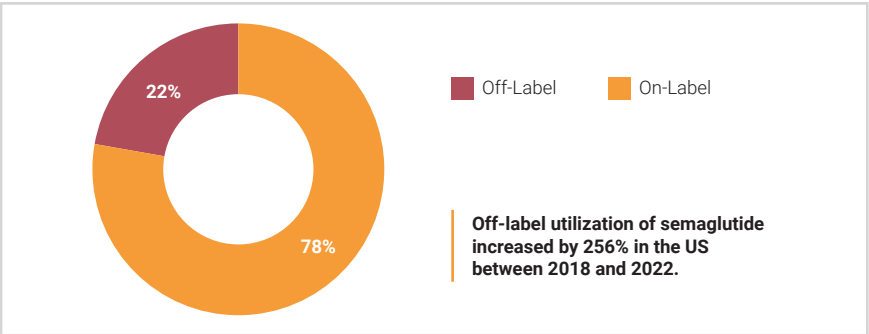
Name	Manufacturer	Indication(s)	Approval Year
Byetta (exenatide)	Amylin	Type 2 Diabetes	2005
Victoza (liraglutide)	Novo Nordisk	Type 2 Diabetes	2010
Trulicity (dulaglutide)	Eli Lilly	Type 2 Diabetes	2014
Saxenda (liraglutide)	Novo Nordisk	Chronic Weight Management	2014
Adlyxin (lixisenatide)	Sanofi	Type 2 Diabetes	2016
Ozempic (semaglutide)	Novo Nordisk	Type 2 Diabetes, Chronic Kidney Disease, CVD	2017; 2025; 2025
Rybelsus (semaglutide)	Novo Nordisk	Type 2 Diabetes	2019
Wegovy (semaglutide)	Novo Nordisk	Chronic Weight Management, CVD	2021; 2024
Mounjaro (tirzepatide)	Eli Lilly	Type 2 Diabetes	2022
Zepbound (tirzepatide)	Eli Lilly	Chronic Weight Management, Obstructive Sleep Apnea (OSA)	2023; 2024

GLP-1s and Obesity

GLP-1s for the Treatment of Obesity

While Saxenda, Wegovy, and Zepbound are FDA approved for obesity, Ozempic and Mounjaro are often prescribed off-label.^{6,10,12,13} According to one analysis, off-label utilization of semaglutide increased by 256% in the US between 2018 and 2022 (Figure 2), accounting for more than 1 in 5 prescriptions in 2022.¹⁴

Figure 2—Off-label utilization of semaglutide in the US, 2022.¹⁴



Efficacy of GLP-1s

Following clinical observations of modest weight losses (2% to 5%) among type 2 diabetes patients, investigators started to evaluate GLP-1s for treating obesity.¹⁵ Research has shown that GLP-1s reduce appetite and hunger, lower preference for energy-dense foods, alter food reward pathways, decrease food cravings, and improve eating control.¹⁶ Table 2 reviews the GLP-1s that are currently approved for weight loss in adults.^{6,10,12}

Table 2. An Overview of Currently Approved GLP-1s for Weight Loss^{6,10,12}

GLP-1 and GIP/GLP-1 Receptor Agonists For Chronic Weight Management		
Drug	Indications	Dosing Schedule
GLP-1 Receptor Agonists		
Liraglutide — Saxenda (Novo Nordisk) 18 mg/3 mL pens	<ul style="list-style-type: none">Adults with obesity or overweight with ≥ 1 weight-related comorbidityChildren 12-17 years old who weigh ≥ 60 kg with a BMI corresponding to 30 kg/m² for adults	Initial Dose: 3 mg SC once/day Titration: 0.6 mg once/day x 7 days; increase in 0.6-mg increments each week to 3 mg once/day
Semaglutide — Wegovy (Novo Nordisk) 0.25, 0.5, 1 mg/0.5 mL; 1.7, 2.4 mg/0.75 mL pens	<ul style="list-style-type: none">Adults with obesity or overweight with ≥ 1 weight-related comorbidityChildren 12-17 years old with obesity	Initial Dose: 1.7 or 2.4 mg SC once/week Titration: 0.25 mg once/week x 4 weeks, then 0.5 mg once/week x 4 weeks, then 1 mg once/week x 4 weeks, then 1.7 mg once/week for 4 weeks; then increase to 2.4 mg once/week (if needed)
GIP/GLP-1 Receptor Agonist		
Tirzepatide — Zepbound (Lilly) 2.5, 5, 7.5, 10, 12.5, 15 mg/0.5 mL pens	<ul style="list-style-type: none">Adults with obesity or overweight with ≥ 1 weight-related comorbidity	Initial Dose: 5, 10, or 15 mg SC once/week Titration: 2.5 mg SC once/week x 4 weeks, then 5 mg once/week x 4 weeks, then increase the dose in 2.5-mg increments every 4 weeks as needed (max 15 mg once/week)

GLP-1s and Obesity

Although the efficacy of GLP-1s in producing weight loss among type 2 diabetes patients treated with has been well established, these data among obese or overweight populations are only now becoming available.

A recently published model of 8 randomized controlled trials compared the cumulative benefit vs cumulative harm (adverse events) of 3 GLP-1s for weight loss in 8,847 patients with a BMI of ≥ 30 kg/m² or ≥ 27 kg/m² with at least 1 weight-related comorbidity (i.e., hypertension, dyslipidemia, obstructive sleep apnea, or cardiovascular disease [CVD]).¹⁷

Over a 2-year period, the number of individuals achieving a weight-loss target of $\geq 5\%$ and $\geq 10\%$ from baseline was significantly higher in the GLP-1 groups than placebo. Semaglutide showed a relatively larger effect, followed by tirzepatide and liraglutide in achieving a weight loss of $\geq 10\%$, with a similar effect for participants who had a weight loss of $\geq 5\%$.¹⁷

Adverse events, such as abdominal pain, constipation, diarrhea, eructation, hypoglycemia, nausea, and vomiting, were significantly higher in GLP-1–treated participants vs placebo. The incidence of most harm outcomes was consistent across the GLP-1s, but some were treatment specific (i.e. alopecia for tirzepatide-treated patients). Additionally, discontinuation rates due to adverse events were more than 2 times higher among those taking GLP-1s compared to placebo.¹⁷

Overall, GLP-1s offered a net benefit when there were weight losses of $\geq 10\%$; however, a $\geq 5\%$ weight loss was not large enough to outweigh the risks associated with these treatments.¹⁸

Current evidence suggests that GLP-1s may initially be effective for weight loss along with lifestyle interventions. However, randomized controlled trials have shown that any weight reduction stabilizes after 1 or 2 years of treatment.¹⁷ This prompts a very important question: which is most beneficial to the individual's overall health—discontinue GLP-1 therapy and experience a high risk for weight rebound or continue GLP-1 therapy without further potential weight loss.

Safety of GLP-1s

While GLP-1s have the potential to help those with obesity, their long-term benefit-to-harm ratio is uncertain. However, their approved package inserts indicate the potential for serious adverse events (SAEs) (**Table 3**).^{6,10,12}

Table 3—Potential SAEs of GLP-1s for Obesity Based on Approved Product Labeling^{6,10,12}

	ZEPBOUND® (tirzepatide)	WEGOVY® (semaglutide)	SAXENDA® (liraglutide)
Pulmonary Aspiration ^a	YES	YES	YES
AKI	YES	YES	NO
Acute Pancreatitis	YES	YES	YES
Acute Gallbladder Disease	YES	YES	YES
Suicidal Behavior/Ideation	YES	YES	YES
Hypoglycemia	YES	YES	YES
Complication of Diabetic Retinopathy	YES	YES	NO

^aDuring general anesthesia/deep sedation.

Additionally, GLP-1s' approved package inserts include black box warnings regarding the risk for developing thyroid C-cell tumors.^{6,10,12} The most common side effects with GLP-1s are gastrointestinal (GI) in nature, with one study noting that up to 90% of patients experienced nausea and vomiting in the first 8 weeks of treatment.¹⁸ GLP-1 users also demonstrated higher discontinuation rates due to negative GI side effects, including nausea, vomiting, diarrhea, constipation, and abdominal pain.^{6,10,12}

A retrospective medical records analysis of 125,474 adults found that 53.6% of overweight or obese patients overall discontinued liraglutide, semaglutide, or tirzepatide after 1 year, and 72.2% discontinued treatment after 2 years.¹⁹ The investigators noted higher discontinuation rates for older patients (those aged ≥ 65 years), those without type 2 diabetes, lower income patients ($\leq \$30,000$ year), and those not achieving an on-treatment weight loss of 1%. Moderate or severe GI AEs were cited as the most frequent reasons for discontinuation.¹⁹

The overall high rate of GLP-1 discontinuation observed in this study is consistent with other analyses, where discontinuation rates have ranged from 37% to 81%.¹⁹

A medical records analysis found that 53.6% of overweight or obese patients overall discontinued liraglutide, semaglutide, or tirzepatide after 1 year, and 72.2% discontinued treatment after 2 years.¹⁹

GLP-1s and Obesity

Challenges of GLP-1s for Weight Loss

After discontinuing GLP-1 treatment, weight loss maintenance can be challenging. The Semaglutide Treatment Effect in People with obesity (STEP 1) trial was a 68-week, randomized, double-blind, placebo-controlled study assessing percentage change in body weight in 1,961 overweight or obese patients taking once-weekly subcutaneous semaglutide 2.4 mg or placebo as adjuncts to lifestyle intervention.²⁰ The STEP 1 extension evaluated a subset of 333 overweight or obese participants from the original trial to determine changes in body weight and cardiometabolic risk during a 1-year off-treatment follow-up period.²¹

The STEP 1 extension found that patients in the semaglutide 2.4 mg plus lifestyle intervention group had regained two-thirds of their weight loss after 1 year, along with negative changes in blood pressure, total cholesterol, very low density cholesterol, triglycerides, and C-reactive protein. The investigators also noted that subgroups with greater weight losses tended to have numerically greater weight regains in the 52-week off-treatment extension.²¹

The extended use of GLP-1s and the potential for future complications is concerning to many healthcare professionals.²²

Barriers to GLP-1 Utilization

One of the most significant challenges to GLP-1 use is their high out-of-pocket (OOP) costs, which impedes both treatment initiation and adherence.³¹ For the GLP-1s approved for obesity, current wholesale acquisition costs (WACs) vary, with a median cost of approximately \$1,350 per patient per month, not accounting for insurance coverage or savings programs (Figure 3).^{32,33}

Employer and Employee Perspectives on GLP-1s

Despite the acquisition cost of GLP-1s, there is a growing demand among employees for their coverage. According to a December 2024 survey, 54% of people in the US use or want to use a GLP-1, up 6% from the previous year.³⁴ Results also showed that 31% of employees would consider changing jobs to gain access to these medications.³⁴ Additionally, 73% of employees now cite GLP-1 coverage as a critical factor in job retention or acceptance, up from 67% in 2023.³⁴

OVERVIEW OF BARIATRIC SURGERY

Bariatric surgery is another weight loss treatment option. In many instances, patients are required to have a BMI ≥ 40 kg/m² or a BMI ≥ 35 kg/m² with at least 1 obesity-related comorbidity to qualify for bariatric surgery.²³

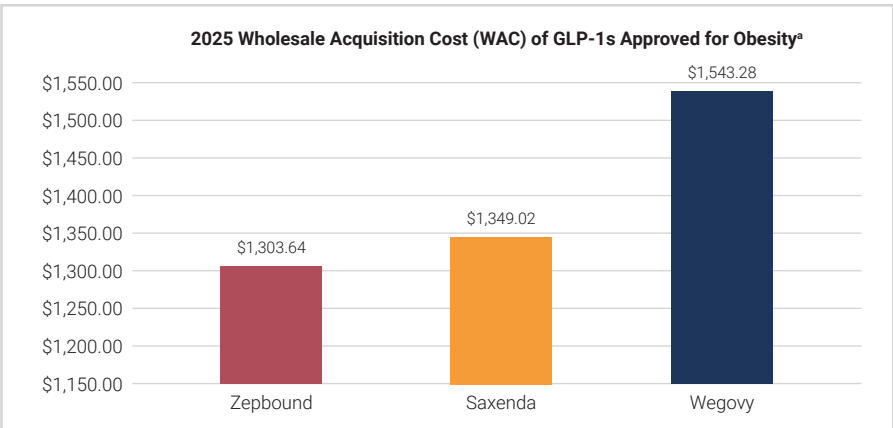
Through The Centers of Medicare & Medicaid Services (CMS), the federal government has enacted several regulations, including a 2006 national bariatric surgery coverage policy to reduce significant obesity-related health risks, including death and disability. CMS modified its policy in 2009 to specify type 2 diabetes as a consideration for determining coverage.²⁴

Currently, 24 US states, including Washington, Colorado, and Minnesota, are drafting legislation to include bariatric surgery coverage for obese individuals. Other states, such as New Jersey and New York, are going farther by requiring coverage for not only bariatric surgery, but all FDA-approved obesity treatments, including GLP-1s.²⁵

A significant decline in bariatric surgery has been seen in recent years. An analysis of 809 hospitals nationwide found that bariatric surgery procedures decreased by more than 32% from August 2022 to August 2024.²⁶ This decline corresponded with a substantial increase in semaglutide prescriptions, which jumped 442% between January 2021 and December 2023, according to a JAMA study.²⁷

Similar to GLP-1 users, bariatric surgery patients often struggle to maintain their weight loss.²⁸ Although these rates can vary, one study found that up to 50% of patients experienced weight regain post-surgery.²⁹ A review study noted several factors that influenced patient weight regain, including type of bariatric surgery, amount of weight loss achieved, and time to weight regain post-surgery. These rates ranged from as low as 5.7% after 1 year to 76% after 6 years.³⁰ Weight regain after bariatric surgery may also lead to recurrence of obesity-related comorbidities including type 2 diabetes, hypertension and dyslipidemia.³⁰

Figure 3—2025 WAC prices for GLP-1s approved for treating obesity.^{32,33}



^aWAC pricing for Wegovy has been averaged due to varying formulation costs. Sources: Data on file; KVK Tech, Inc. and Novo Nordisk.

GLP-1s and Obesity

For employers, the financial impact of GLP-1s is the largest deterrent to access.³⁵ One health plan noted that to include GLP-1 weight loss coverage would increase employers' drug coverage premiums by approximately 30%.³⁶ Another employer challenge is having a clearer value proposition for covering GLP-1s, since it may take many years before seeing a return on their investment.³⁵

Despite these concerns, coverage discussions continue as employers know that benefit enhancements, including those for obesity, play a vital role in attracting and retaining key employees as well as in reducing turnover and its related costs.³⁷

In a 2024 survey, 44% of employer groups with ≥500 employees offered GLP-1 coverage compared to 41% in 2023. For employers with ≥20,000 employees, 64% offered GLP-1s in 2024, up sharply from 56% in 2023.³⁸ The American Medical Association (AMA) is also urging insurance companies to cover obesity medications. In 2023, the AMA voted to adopt a policy supporting health insurance coverage parity for obesity treatments, including GLP-1s, without exclusions or additional carve-outs.³⁹

Health Plan Management of GLP-1s

Health plans are working to devise coverage strategies for obesity; however, these barriers to treatment are multifactorial and often interrelated. From a legislative perspective, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 prohibits Medicare Part D from covering weight-loss medications, even those approved by the FDA to treat obesity. As a result, most health plans limit weight loss/management to counseling in the primary care setting and weight-loss surgery to individuals with severe obesity. Despite these limitations, and because of pressure from various stakeholders, payers are now looking to balance coverage and affordability.⁴⁰

Unfortunately, the limited evidence of long-term benefit and the high cost of GLP-1s has caused payers to implement cost-containment strategies to limit access and utilization. A cost-effectiveness analysis found that although tirzepatide and semaglutide provided improvements in life expectancy, they were not cost-effective at the \$100,000/QALY (quality-adjusted life-year) benchmark because of their high lifetime treatment costs. With estimated incremental cost-effectiveness ratios per QALY of \$467,676 for semaglutide and \$197,023 for tirzepatide, prices would need to be reduced by 81.9% and 30.5%, respectively, to meet the \$100,000 threshold.⁴¹

Regardless of the many conflicting issues surrounding GLP-1 utilization, payers need to rethink their perspectives about obesity and its coverage due to the rising prevalence of this condition, as well as the myriad preventable health-related issues that could be prevented with aggressive management. Some progressive plans are reconsidering obesity management and assessing how to best integrate all tools in the obesity management toolbox. By changing coverage criteria elements for traditional anti-obesity agents, GLP-1s, and bariatric surgery (BMI, documentation requirements, etc.), some plans have created a de facto stepwise approach to obesity management. Lomaira, in conjunction with behavior modification, is the ideal agent for obese patients due to its low cost, low dose, and potential to suppress appetite when patients need it most. Lomaira is a flexible treatment option, making it ideal for utilization in numerous clinical situations, including before and after GLP-1s and/or bariatric surgery.

When used in conjunction with behavior modification, oral agents like Lomaira are ideal for utilization before and after GLP-1s and/or bariatric surgery.

Conclusion

GLP-1s mimic the action of endogenous GLP-1 by activating GLP-1R and enhancing insulin secretion, inhibiting glucagon release, delaying gastric emptying, and reducing food intake through central appetite suppression.

While their weight-loss effectiveness is well-established among patients with type 2 diabetes, evidence regarding their benefit among overweight or obese populations is still ongoing. However, that has not prevented their off-label use in these populations, with off-label utilization of semaglutide increasing by 256% over a 4-year period.

Although current evidence suggests that GLP-1s may initially be effective in achieving weight losses of ≥5% and ≥10%, randomized controlled trials have shown that any weight reduction stabilizes after 1 or 2 years of treatment. Additionally, there are concerns regarding the long-term adverse consequences of GLP-1s, including the potential for serious adverse events such as acute kidney injury, acute pancreatitis, acute gallbladder disease, and hypoglycemia. These treatments also have black box warnings regarding the risk for developing thyroid C-cell tumors. The most common side effects with GLP-1s are gastrointestinal, such as nausea, vomiting, diarrhea, constipation, and abdominal pain, and these often lead to early drug discontinuation.

The issue of weight regain after discontinuing GLP-1 treatment is another challenge. A study found that patients regained two thirds of their weight loss after stopping treatment and experienced negative changes in blood pressure, total cholesterol, very low density cholesterol, triglycerides, and C-reactive protein.

GLP-1s and Obesity

One of the greatest barriers to GLP-1 utilization for all stakeholders is cost. Currently, the median acquisition cost GLP-1s approved for obesity is approximately \$1,350 per patient per month, not accounting for insurance coverage or savings programs. Despite the costs, employees want coverage for GLP-1s, with 73% saying GLP-1 coverage is a critical factor in job retention or acceptance, and 31% saying they would consider changing jobs to gain access to them.

As plans reconsider this category, some are revising coverage criteria to favor traditional anti-obesity agents. When used in conjunction with behavior modification, oral agents like Lomaira are ideal for utilization before and after GLP-1s and/or bariatric surgery.

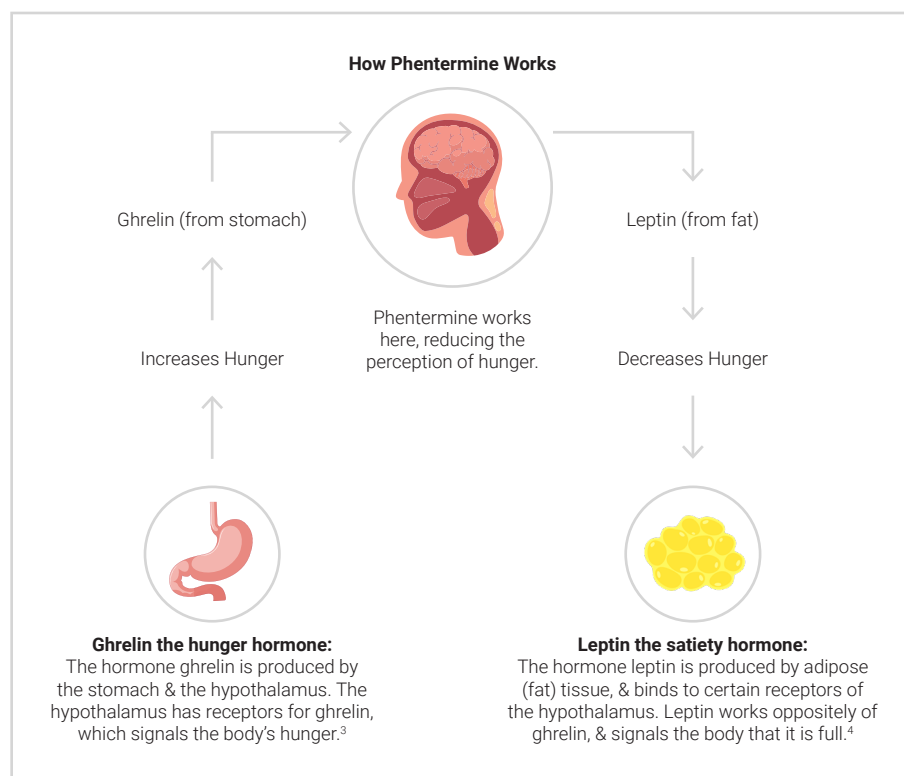
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Product Overview

Approved by the FDA in 2016, Lomaira (phentermine HCl) 8 mg tablets, CIV, are indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity in patients with an initial body mass index (BMI) greater than or equal to 30 kg/m², or greater than or equal to 27 kg/m² in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia).¹

Lomaira is a natural monoamine alkaloid derivative and a sympathomimetic stimulant that causes the hypothalamic release of norepinephrine, which reduces hunger sensation. It also causes the release of epinephrine or adrenaline outside the brain, resulting in the break down of stored fat.² **Figure 1** shows how Lomaira helps to reduce hunger pangs and promote satiety.

Figure 1—Phentermine increases endogenous leptin to reduce hunger cravings.



Phentermine has been prescribed in the United States for more than 60 years,⁵ making it the agent with the most real-world anti-obesity experience. The recommended dosing for phentermine is 15 mg to 37.5 mg orally taken once daily in the morning, with a standard adult dose of 37.5 mg once daily.⁵

In contrast, low-dose Lomaira can be taken up to 3 times a day, enabling dosing flexibility based on individual patient need to suppress appetite, while minimizing exposure to stimulatory effects and reducing adverse events. Additionally, the Lomaira 8 mg tablet is scored to facilitate administering half of the usual dosage for patients not requiring the full dose (**Figure 2**), enabling them to obtain an adequate response with the lowest effective dose.

Why Lomaira™ (phentermine HCl)?

When used in conjunction with lifestyle modification, Lomaira is the ideal agent for obese patients due to its low cost, low dose, and potential to suppress appetite when patients need it most

Lomaira can be taken up to 3 times a day, enabling dosing flexibility based on individual patient need

Lomaira has been effective in percent total body weight loss, body weight reduction, and change in body mass index

Lomaira has a safety profile comparable to placebo and did not adversely affect heart rate or diastolic and systolic blood pressure

Since 2022, Lomaira prescriptions have grown by 55%, making it the fastest growing oral anti-obesity medication on the market

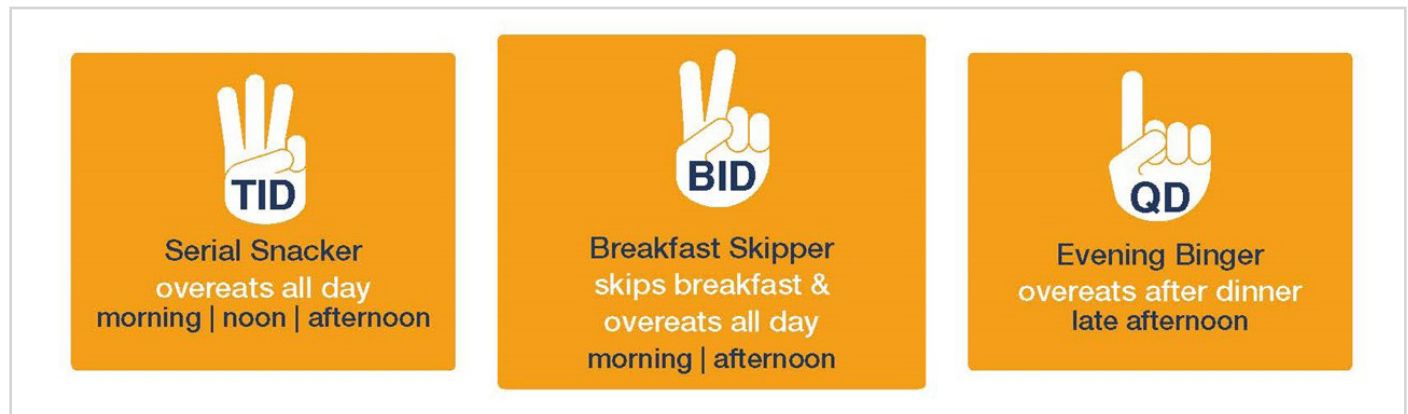
Lomaira is priced 4 to 27 times lower than other anti-obesity medications

Figure 2—Lomaira is provided as a butterfly-shaped tablet for tailored dosing.



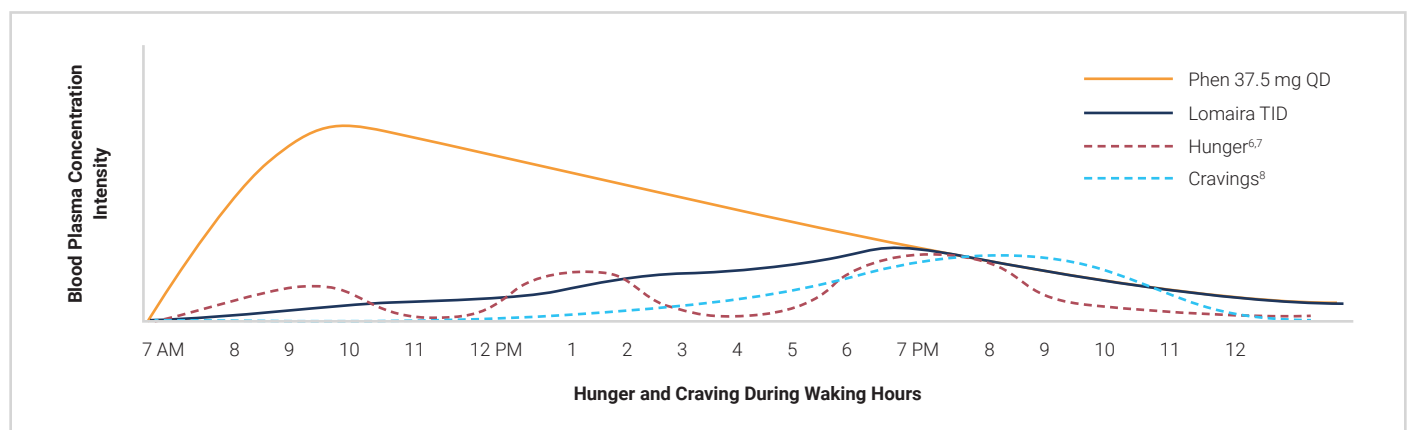
Another advantage of Lomaira is that it can be tailored to fit individual profiles, with a dose as low as 4 mg, and by dosing when patients need help with appetite most (**Figure 3**).

Figure 3—Lomaira offers dosing flexibility to meet a patient's individual needs.



Low-dose Lomaira can also be given up to three times daily, in relation to the hunger and cravings of the average population by time of day (**Figure 4**).⁶⁻⁸

Figure 4—Lomaira TID suppresses hunger and cravings throughout the day.⁶⁻⁸



This is a hypothetical representation and is not representative of all patients.

Clinical Trials—Efficacy

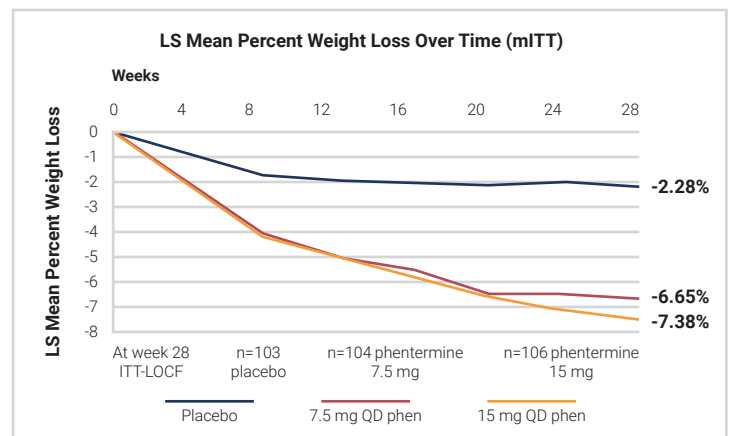
Study 1—Aronne LJ, et al. (2013)^a

28-week, randomized, controlled trial comparing placebo, low-dose phentermine (7.5 mg and 15 mg QD), topiramate ER, and combination phentermine and topiramate.⁹ Results at week 28 showed the phentermine doses of 7.5 mg and 15 mg were more effective in lowering body weight compared to placebo (**Figure 5**).⁹

Additionally, a greater percentage of those in the phentermine 7.5-mg and 15-mg groups were able to achieve weight losses of $\geq 5\%$ and $\geq 10\%$ (**Figure 6**).⁹

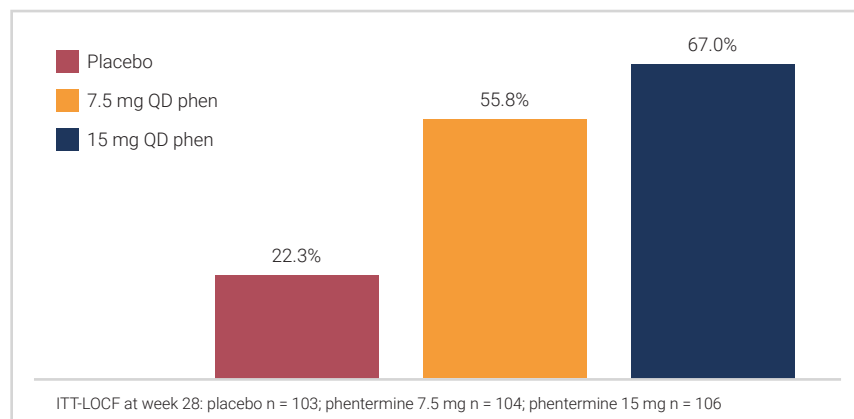
^aNOTE: This study was not performed or sponsored by KVK Tech, Inc.

Figure 5—Mean weight loss change for phentermine vs placebo.⁹



Adapted with permission from Aronne LJ, et al. *Obesity (Silver Spring)*. 2013;21(11):2163-2171.

Figure 6—Percent of patients achieving weight loss of at least ≥5% at week 28.⁹



Greater reductions in diastolic and systolic blood pressure were also achieved at week 28 in both phentermine treatment groups (**Table 1**).⁹

Study 2—Bartelt K, et al. (2024)

A study of 7,773 patients found that 88% of those who had lost less than 20 pounds on a GLP-1 and subsequently prescribed phentermine experienced a greater weight loss than when they took a GLP-1.¹⁰ Additionally, patients prescribed phentermine were less likely to experience total weight regain 1 year after discontinuing GLP-1s compared to those not prescribed phentermine (19.3% vs. 27.3% respectively).¹⁰

Table 1—Change in Diastolic and Systolic Blood Pressure Rates With Phentermine⁹

LS Mean Change in Blood Pressure from Baseline to Week 28 in the ITT-LOCF Population			
	Placebo (n = 103)	Phentermine 7.5 mg (n = 104)	Phentermine 15 mg (n = 106)
Diastolic Blood Pressure	-0.7	-1.5	-0.9
Systolic Blood Pressure	-1.8	-3.3	-3.5

Study 3—Garcia et al. (2025)

14-week, double-blind, prospective, randomized, controlled trial conducted at an academic medical center that compared weight loss with low-dose Lomaira (8 mg; n = 32) or placebo (n = 21) prior to bariatric surgery.¹¹ Patients were instructed to take their treatment 3 times daily, while gradually increasing the number of pills consumed.¹¹ Following the initial consult visit, patients were scheduled for study visits after 4 and 8 weeks, and all patients attended a standard of care preoperative clinic visit prior to surgery.¹¹ The primary outcome for this study was weight loss at the second study visit.¹¹

Results of the study showed that those taking phentermine had significant improvements in % total weight loss (%TWL), weight change, and BMI at visit 2 (week 14) compared to placebo (**Figures 7-9**).¹¹

Figure 7—Comparison of total percent weight loss with Lomaira vs. placebo.¹¹

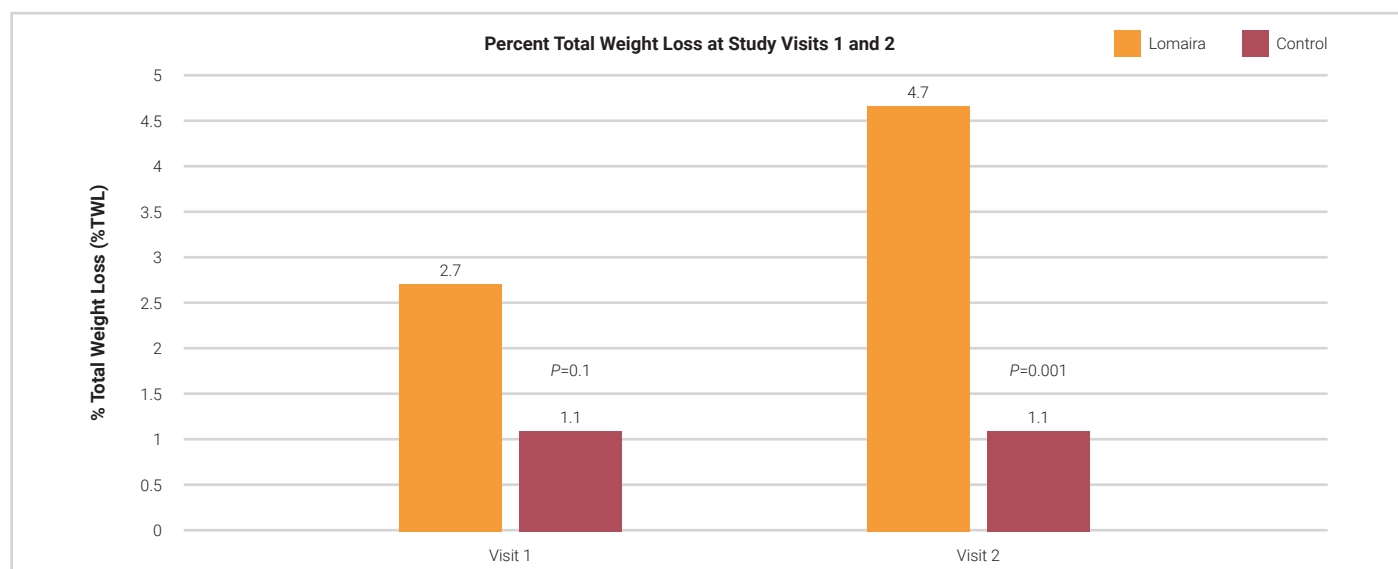


Figure 8—Weight change among participants receiving Lomaira vs. placebo.¹¹

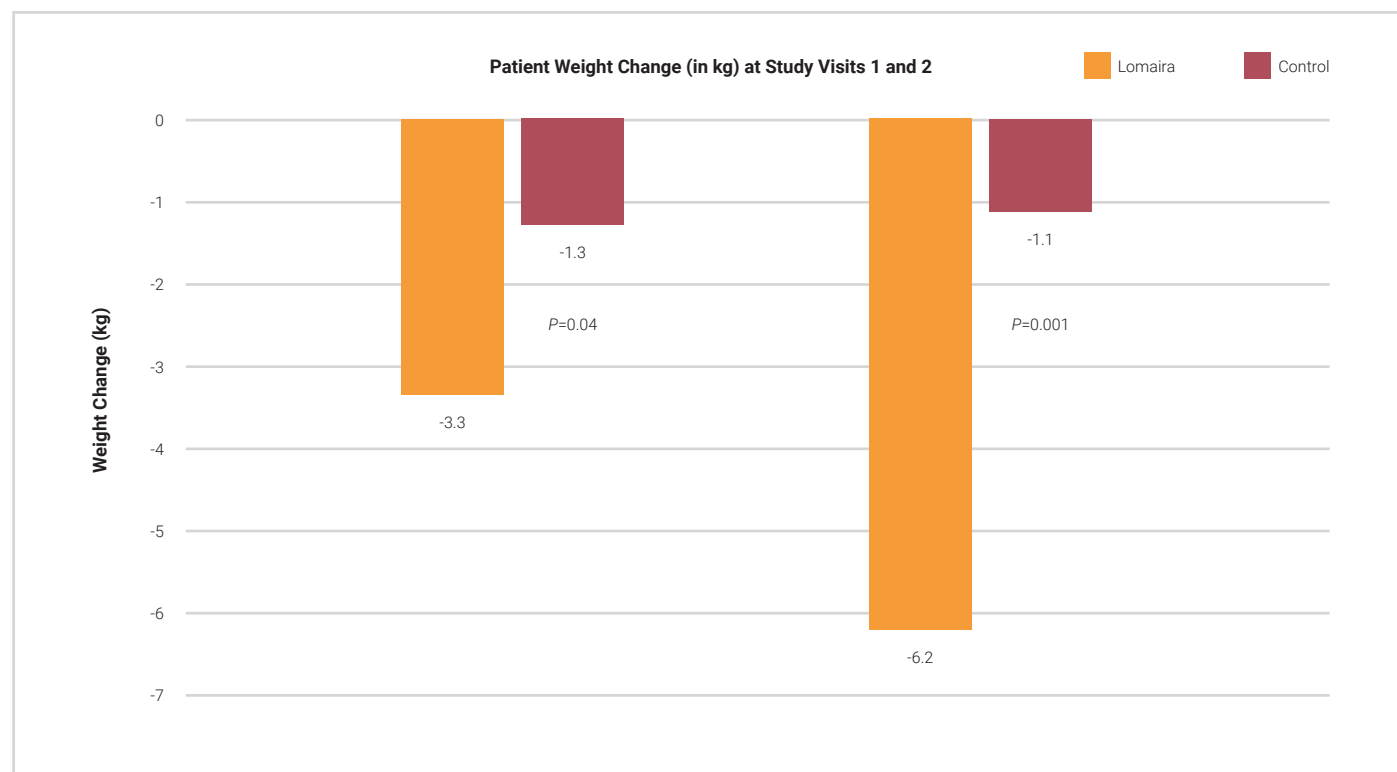
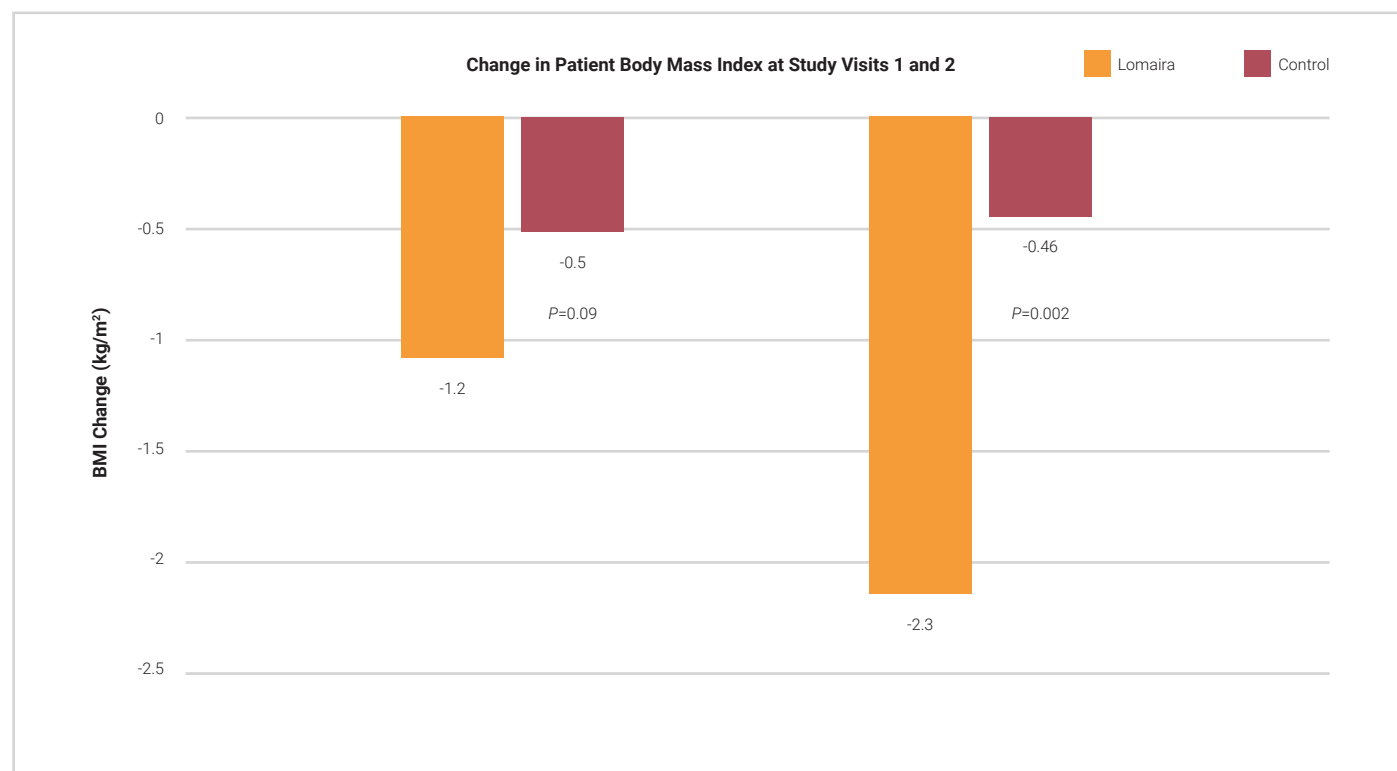


Figure 9—Change in BMI for Lomaira patients vs. placebo.¹¹



Clinical Trials—Safety

In a clinical trial, treatment-associated adverse events with low-dose Lomaira were comparable to placebo ($\geq 5\%$ of subjects in any treatment group; **Table 2**).⁹

Table 2—Treatment Emergent Adverse Events (TEAEs) With Phentermine vs. Placebo⁹

TEAE, n (%)	Placebo (n = 109)	Phentermine 7.5 mg (n = 109)	Phentermine 15 mg (n = 108)
Headache	14 (12.8)	14 (12.8)	11 (10.2)
Upper respiratory tract infection	12 (11.0)	9 (8.3)	9 (8.3)
Nasopharyngitis	11 (10.1)	6 (5.5)	10 (9.3)
Constipation	9 (8.3)	4 (3.7)	9 (8.3)
Fatigue	7 (6.4)	3 (2.8)	6 (5.6)
Cough	7 (6.4)	2 (1.8)	6 (5.6)
Back Pain	6 (5.5)	9 (8.3)	0 (0.0)
Insomnia	6 (5.5)	7 (6.4)	12 (11.1)
Sinusitis	6 (5.5)	3 (2.8)	8 (7.4)
Vision blurred	5 (4.6)	6 (5.5)	7 (6.5)
Irritability	2 (1.8)	6 (5.5)	2 (1.9)
Dry mouth	0 (0.0)	8 (7.3)	13 (12.0)

Adapted from Aronne LJ, et al. *Obesity (Silver Spring)*. 2013;21(11):2163-2171.

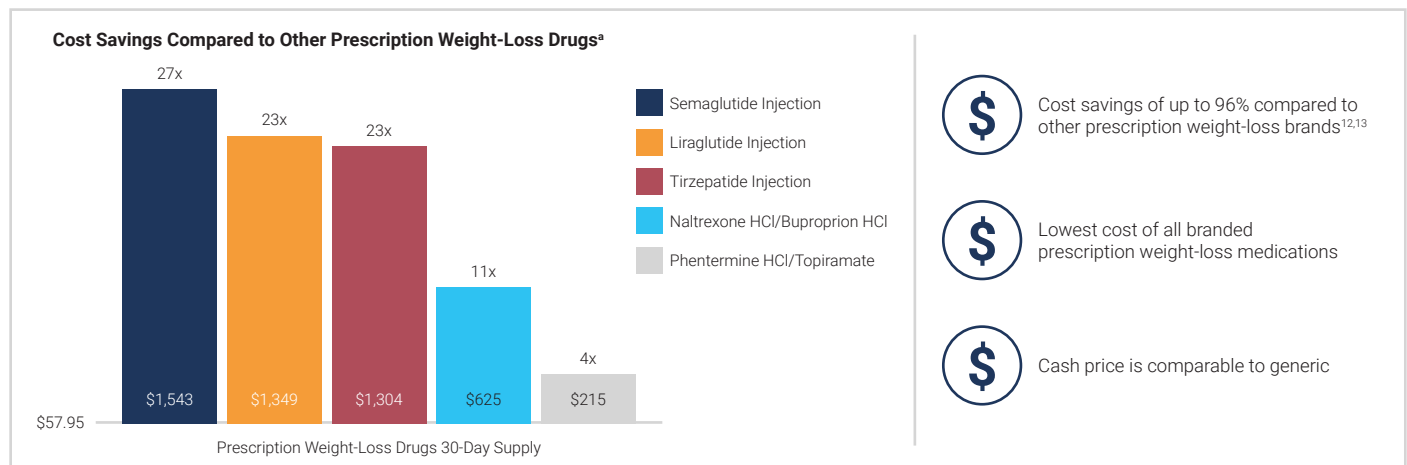
In the same study, heart rate changes among patients taking Lomaira 7.5 mg and 15 mg were comparable to placebo at week 28 (0.9, 1.1, and -1.9 beats per minute, respectively).⁹

Lomaira Place in Therapy

When used in conjunction with lifestyle modification (diet and exercise), Lomaira is the ideal agent for obese patients due to its low cost, low dose, and potential to suppress appetite when patients need it most, while minimizing exposure to stimulatory effects and reducing adverse events. Lomaira is an effective and cost-efficient treatment option that provides flexibility of use in numerous clinical situations.

Since 2022, the number of Lomaira prescriptions overall has grown by 55%—with more than 200,000 prescriptions written in 2024.¹² Additionally, the cost of Lomaira is significantly lower than its competitors (**Figure 10**).^{12,13}

Figure 10—Lomaira is reasonably priced compared to other weight-loss drugs.^{12,13}



^aWAC pricing for semaglutide injection and phentermine HCl/topiramate have been averaged due to varying formulation costs. Sources: Data on file; KVK Tech, Inc. and Novo Nordisk.

Conclusion

Lomaira is a flexible treatment option in the overall management of obesity, which enables its utilization in numerous clinical situations, including before and after GLP-1s and/or bariatric surgery. Research has shown that phentermine is effective for continued weight loss after stopping GLP-1 therapy.

Lomaira can be taken up to 3 times a day, enabling dosing flexibility based on individual patient need. Additionally, the Lomaira 8 mg tablet is scored to facilitate administering half of the usual dosage for patients not requiring the full dose, enabling them to obtain an adequate response with the lowest effective dose. Lomaira has also demonstrated a safety profile similar to placebo, with most adverse events being mild-to-moderate in severity. Changes in heart rate were also comparable between patients taking Lomaira and placebo.

Since 2022, the number of Lomaira prescriptions overall has grown by 55%—with more than 200,000 prescriptions written in 2024. Additionally, the cost of a 30-day supply of Lomaira is 4 to 27 times lower than other anti-obesity medications.

Lomaira is the ideal first-line agent for obese patients due to its low cost, low dose, and potential to suppress appetite when patients need it most.

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Payer Management Strategies

Impact of Obesity

The obesity epidemic continues unabated, with projections suggesting that by 2050, two-thirds of US adults aged 25 and over will be classified as obese.¹ As obesity has a negative effect on multiple body systems, the risk of comorbid conditions such as cardiovascular disease (CVD), type 2 diabetes, hypertension, heart disease and stroke, among others increase accordingly.²⁻⁴ A recent analysis found for a hypothetical firm with 10,000 employees (plus dependents), the annual costs for obesity were \$22 million, with average costs of \$6,472 per employee with obesity, and \$1,514 per adult dependent with obesity.⁵

Beyond medical costs, there are significant indirect costs to society, including decreased productivity, lower educational attainment, and reduced quality of life.⁶ These direct and indirect costs contribute to rising insurance rates, costing businesses, employees, and society overall.⁶

Aggressive management of obesity has been shown to reduce costs. In a hypothetical firm of 10,000 employees, a 5% weight loss would yield \$153.3 billion in medical savings over 5 years, while a 25% weight loss would yield \$326.1 billion.⁵

As the obesity crisis continues to grow, the need to balance practical solutions that improve long-term outcomes while considering costs of care is paramount. Although payers have faced previous pressure to address the obesity epidemic in their policies, the advent of glucagon-like peptide 1 (GLP-1) agonists has renewed calls to action from employers and members. According to December 2024 survey, 54% of people in the US use or want to use a GLP-1, up 6% from the previous year.⁷ Results also showed that 31% of employees would consider changing jobs to gain access to these medications.⁷ Additionally, 73% of employees now cite GLP-1 coverage as a critical factor in job retention or acceptance, up from 67% in 2023.⁷ The advent of GLP-1s has changed the landscape of managing obesity, offering promise but also numerous questions regarding their long-term viability.

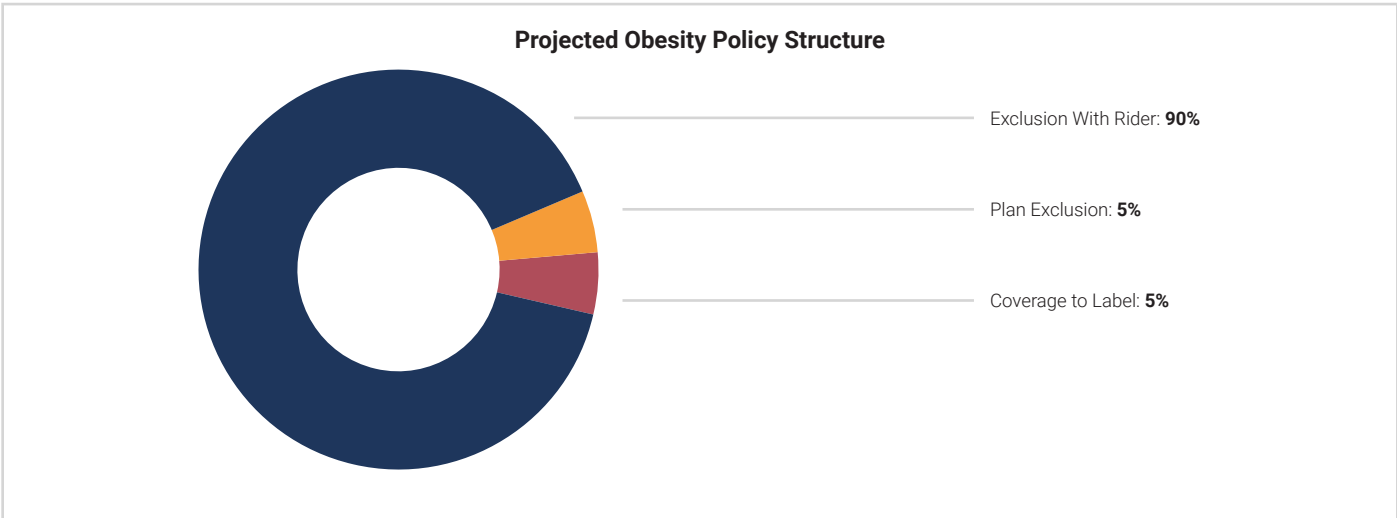
Rethinking Obesity Management

- The ongoing obesity crisis requires aggressive management
- The advent of GLP-1s has renewed calls to action from employers and members
- A comprehensive stepwise approach for obesity would allow the right patients to get the right drug at the right time, while better controlling costs associated with coverage
- Whether a plan opts to cover obesity as a standard benefit or via rider coverage, utilizing a stepwise approach provides numerous advantages including cost predictability, customer satisfaction, and improved long-term outcomes

Evolving Payer Coverage Policies

Understandably, the limited evidence of long-term benefit and high cost of GLP-1s has caused many payers to implement cost-containment strategies. Interviews with payers have identified three strategies that plans across the country are utilizing or considering (**Figure 1**).⁸

Figure 1—Payer strategies for future obesity management.⁸



While each strategy has several pros and cons (**Table 1**), payers interviewed indicated that within the next 12 months, a majority of plans will gravitate to exclude obesity coverage while offering a rider/addendum to employers.

Payer Management Strategies

Table 1. Obesity Coverage Strategies

Coverage Strategy	Potential Pros	Potential Cons
Exclusion of all obesity coverage	<ul style="list-style-type: none"> • Maintain costs and premiums • Ability to focus resources on other conditions and member groups where needed • Avoid administrative claims burden • Ability to limit member utilization through medical exception (self-funded plans with closed formularies) 	<ul style="list-style-type: none"> • Poor long-term member outcomes • Increased claims and cost burden for obesity-related comorbidities • Employer and member dissatisfaction • Customer migration to other plans that cover obesity • Potentially reduced HEDIS scores for member satisfaction • Loss of rebate revenue
Cover all obesity medications to label	<ul style="list-style-type: none"> • Employer and member satisfaction • Enables more members to manage their obesity • May improve or mitigate long-term consequences (CVD, type 2 diabetes, knee/hip surgeries), garnering long-term savings • Will receive rebate revenue 	<ul style="list-style-type: none"> • Assumption of full risk of increased category costs • Increased premiums • Need to manage adherence/persistence to drive long-term savings • Employer or member health plan migration may limit long-term return on investment • Improved HEDIS scores for member satisfaction
Exclusion of obesity coverage with rider/addenda offering	<ul style="list-style-type: none"> • Employer and member satisfaction • Enables more members to manage their obesity • Allows for cost sharing with customers who desire coverage • May improve or mitigate long-term consequences (CVD, type 2 diabetes, knee/hip surgeries), garnering long-term savings 	<ul style="list-style-type: none"> • Likely loss of rebate revenue • Increase in premiums for employers who implement rider coverage

Integrating Treatment Strategies

In recent years, obesity management strategies have been siloed and driven by the need to manage GLP-1s. However, some progressive plans are reconsidering obesity management and assessing how to best integrate all the tools in their toolbox.

Traditionally, non-exclusionary medical policies for obesity have focused on a specific drug category, providing coverage to label, or medical necessity of a procedure. However, considering the multitude of treatment approaches and products available for obesity, a comprehensive stepwise approach may be warranted. This would allow the right patients to get the right drug at the right time, while better controlling costs associated with coverage.

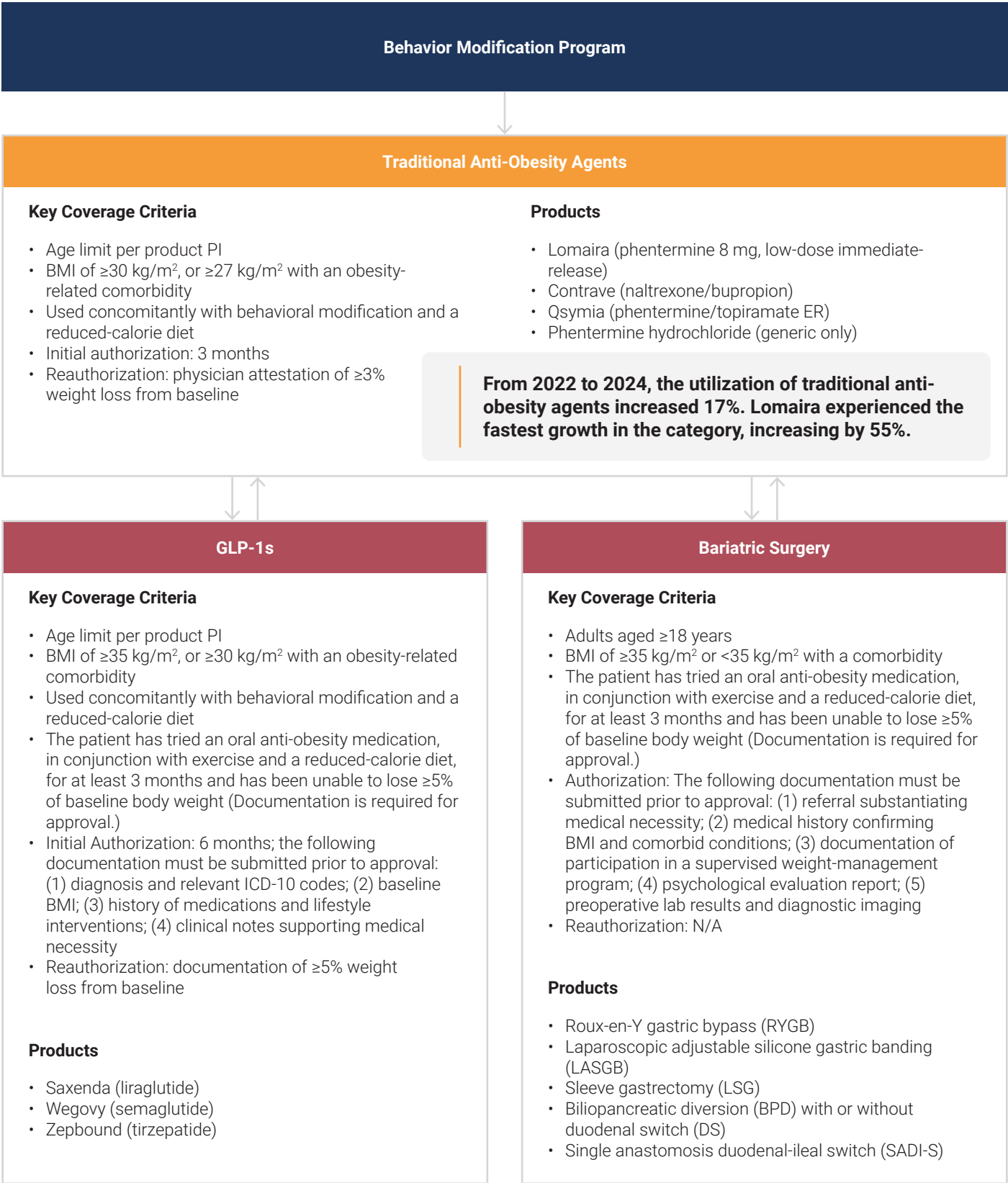
The foundation of any weight-loss regimen is behavior modification. In the past decade, particularly during the lockdown necessitated by the COVID-19 pandemic, behavior modification approaches have largely moved from in-person delivery to online programs designed to remind and reinforce healthy behaviors.⁹ These remote forms of treatment delivery reduce several logistical hurdles (e.g., travel time, costs); however, despite these developments, <5% of Americans annually participate in a formal weight-loss program of any type.⁹ Many health plans still do not cover behavior modification programs, while those that do often have restrictive criteria.⁹ A comprehensive medical policy should include a review of programs that drive behavioral modification and the development of a robust communication plan touting its availability.

Considering the multitude of treatment approaches and products available for obesity, a comprehensive stepwise approach may be warranted. This would allow the right patients to get the right drug at the right time, while better controlling costs associated with coverage.

Payer Management Strategies

For members who have participated in a behavior modification program and had limited success, adjunctive therapy should be considered. **Figure 2** provides a potential stepwise approach for the treatment of obesity.

Figure 2—A stepwise treatment approach to manage obesity.



Payer Management Strategies

Whether a plan opts to cover obesity as a standard benefit or via rider coverage, utilizing a stepwise approach provides numerous advantages including cost predictability, customer satisfaction, and improved long-term outcomes.

Inclusion of Lomaira (phentermine HCl) 8 mg tablets on formulary allows obese patients to have an effective and cost-efficient weight-management option that is ideal for utilization before and after GLP-1 therapy and/or bariatric surgery.

Conclusion

The ongoing obesity crisis requires aggressive management strategies to promote weight loss among eligible populations (i.e., those with a body mass index ≥ 30 kg/m² or ≥ 27 kg/m² and ≥ 1 obesity-related comorbidity). However, these strategies must be tempered by considerations such as efficacy, safety, adherence, impact on obesity-related comorbidities, and costs. Payers are ideally positioned to set parameters for cost-effective obesity management. Utilizing a stepwise approach that consistently emphasizes behavior modification can enable the right patient to receive the right treatment at the right time.

To view specific plan medical policies, please see the supplemental section of this document.

References: **1.** Ng M, Dai X, Cogen RM, et al for the GBD 2021 US Obesity Forecasting Collaborators. *Lancet*. 2024;404(10469):2278-2298. **2.** Bariatrix Florida. What is comorbidity? <https://drwizman.com/obesity-comorbidities/>. **3.** Wang H, Cai W, Zeng H, et al. *Sci Rep*. 2025;15(1):8505. doi: 10.1038/s41598-025-92733-y. **4.** National Institute of Diabetes and Digestive and Kidney Diseases. Health risks of overweight and obesity. <https://www.niddk.nih.gov/health-information/weight-management/adult-overweight-obesity/health-risks>. **5.** Dall TM, Sapra T, Natale Z, et al. *Nutr Diabetes*. 2024;14(1):96. doi: 10.1038/s41387-024-00352-9. **6.** Anekwe CV, Jarrell AR, Townsend MJ, et al. *Curr Obes Rep*. 2020;9(3):272-279. **7.** Garduño S. GLP-1 coverage becomes key in job retention in the US. <https://mexicobusiness.news/health/news/glp-1-coverage-becomes-key-job-retention-us>. **8.** Data on file. KVK Tech, Inc. **9.** Schumacher LM, Ard J, Sarwer DB. *Front Public Health*. 2023;11:1205880. doi: 10.3389/fpubh.2023.1205880.

Supplemental Information

Supplemental Information

Medical Policy: Traditional Anti-Obesity Agents

Policy Number:

Effective Date:

Review Date

Approval Date:

I. Policy Statement

Traditional anti-obesity agents are approved for obesity and chronic weight management in patients when prescribed as an adjunct to a comprehensive weight-management program that includes nutritional counseling, increased physical activity, and behavioral modification. Coverage is subject to the medical necessity criteria outlined in this policy.

II. Medications Covered

Traditional anti-obesity agents currently approved for chronic weight management include, but are not limited to:

- i. LOMAIRA™ (phentermine 8 mg, low-dose immediate-release)
- ii. CONTRAVE® (naltrexone/bupropion)
- iii. QSYMIA® (phentermine/topiramate ER)
- iv. Phentermine hydrochloride (generic only)

III. Coverage Criteria

Weight Loss (Adult) – LOMAIRA, CONTRAVE, QSYMIA, Phentermine Hydrochloride

Authorization may be granted when the requested drug is used with a reduced-calorie diet and increased physical activity for chronic weight management, and ALL of the following criteria are met:

- i. The patient is 18 years of age or older.
- ii. The patient has a baseline body mass index (BMI) of ≥ 30 kg/m², or ≥ 27 kg/m² with a comorbidity (e.g., controlled hypertension, type 2 diabetes mellitus, hyperlipidemia).
- iii. The patient has participated in a comprehensive weight-management program that encourages behavioral modification, reduced-calorie diet, and increased physical activity with continuing follow-up for at least 3 months prior to using drug therapy. (Documentation is required for approval.)
- iv. The medication is used concomitantly with behavioral modification and a reduced-calorie diet.
- v. Patient has no prior history of the following:
 - a. Seizure disorders
 - b. Anorexia nervosa or bulimia
 - c. Excessive utilization of alcohol, benzodiazepines, or barbiturates
- vi. Dose escalation per manufacturer recommendations

Weight Loss (Pediatric) – QSYMIA ONLY

Authorization may be granted when the requested drug will be used with a reduced-calorie diet and increased physical activity for chronic weight management, and ALL of the following criteria are met:

- i. The patient is 12 to 17 years of age.
- ii. The patient has participated in a comprehensive weight-management program that encourages behavioral modification, a reduced-calorie diet, and increased physical activity, with continuing follow-up for at least 3 months prior to using drug therapy. (Documentation is required for approval.)
- iii. The medication is used concomitantly with behavioral modification and a reduced-calorie diet.

IV. Exclusions and Limitations – LOMAIRA, CONTRAVE, QSYMIA, Phentermine Hydrochloride

The following exclusion and limitation criteria apply to all traditional anti-obesity agents listed in this policy. Traditional anti-obesity agents are not considered medically necessary and are not covered under the following conditions:

- i. Uncontrolled hypertension
- ii. History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension)
- iii. Seizure disorders, anorexia nervosa or bulimia, or undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs

Supplemental Information

- iv. Concomitant use of other anti-obesity products
- v. Chronic opioid use or history of drug abuse
- vi. Taking or within 14 days of having taken monoamine oxidase inhibitors (MAOI)
- vii. Hyperthyroidism
- viii. Pregnant or nursing mothers
- ix. History of suicidal ideation
- x. Initial authorization: 3 months

V. Reauthorization Criteria

For continued coverage beyond the initial 3 months, the following criteria must be met:

- i. Physician attestation of $\geq 3\%$ weight loss from baseline.
- ii. Patient remains adherent to medication and lifestyle modifications. Reauthorization: requires continued behavioral modification program participation and continued benefits.
- iii. No serious adverse effects warranting discontinuation.

VI. Billing and Coding

- i. ICD-10 Codes:
 - a. Z68.30-Z68.45 – BMI classification codes (adult)
 - b. Z68.51-Z68.56 – BMI classification codes (pediatric)

VII. No other drugs are approved under this policy for the treatment of obesity and chronic weight management.

IX. Sources

LOMAIRA [package insert]. Newtown, PA: KVK-Tech; December 2023.

CONTRAVE [package insert]. Morristown, NJ: Nalpropion/Currax; May 2024.

QSYMIA [package insert]. Mountain View, CA: Vivus; September 2024.

Daily Med. Label: Phentermine HCl capsule. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=375bfe83-c893-3ea7-e054-00144ff88e88>.

Supplemental Information

Medical Policy: GLP-1s

Policy Number:

Effective Date:

Review Date

Last Revision Date:

I. Policy Statement

Glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP)/glucagon-like peptide-1 (GLP-1) receptor agonists are approved for chronic weight management in patients who are obese or overweight with at least 1 weight-related comorbidity (e.g., type 2 diabetes mellitus, hypertension, dyslipidemia). Coverage is subject to the medical necessity criteria outlined in this policy.

II. Medications Covered

GLP-1 and GIP/GLP-1 receptor agonists currently approved for chronic weight management include, but are not limited to:

- i. Saxenda® (liraglutide)
- ii. Wegovy® (semaglutide)
- iii. Zepbound® (tirzepatide)

III. Exclusions and Limitations

The GLP-1 and GIP/GLP-1 receptor agonists listed are not considered medically necessary and are not covered under the following conditions:

- i. Saxenda
 - a. Saxenda contains liraglutide and should not be coadministered with other liraglutide-containing products or with any other GLP-1 receptor agonist.
 - b. The safety and effectiveness of Saxenda in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- ii. Wegovy
 - a. Wegovy contains semaglutide. Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended.
- iii. Zepbound
 - a. Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any other GLP-1 receptor agonist is not recommended.

IV. Coverage Criteria

Chronic Weight Management of Obesity (Adult) – Saxenda, Wegovy, and Zepbound

Authorization may be granted when the requested drug will be used in combination with a reduced calorie diet and increased physical activity for chronic weight management, when ALL of the following criteria are met:

- i. The patient is 18 years of age or older.
- ii. The patient has participated in a comprehensive weight-management program that encourages behavioral modification, reduced-calorie diet, and increased physical activity, with continuing follow-up for at least 3 months prior to using drug therapy. (Documentation is required for approval.)
- iii. The medication is used concomitantly with behavioral modification and a reduced-calorie diet.
- iv. The patient has a baseline body mass index (BMI) ≥ 35 kg/m², or ≥ 30 kg/m² with a comorbidity (e.g., controlled hypertension, type 2 diabetes mellitus, hyperlipidemia). (Documentation is required for approval.)
- v. The patient has tried an oral anti-obesity medication, in conjunction with exercise and a reduced-calorie diet, for at least 3 months and has been unable to lose $\geq 5\%$ of baseline body weight. (Documentation is required for approval.)
- vi. Provider agrees to monthly follow-up visits for 1 year.

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Chronic Weight Management (Pediatric) – Saxenda and Wegovy ONLY

Authorization may be granted when the requested drug will be used with a reduced-calorie diet and increased physical activity for chronic weight management when ALL of the following criteria are met:

- i. The patient is 12 to 17 years of age.
- ii. The patient has participated in a comprehensive weight-management program that encourages behavioral modification, a reduced-calorie diet, and increased physical activity, with continuing follow-up for at least 3 months prior to using drug therapy. (Documentation is required for approval.)
- iii. The patient has tried an oral anti-obesity medication, in conjunction with exercise and a reduced-calorie diet, for at least 3 months and has been unable to lose $\geq 5\%$ of baseline body weight. (Documentation is required for approval.)
- iv. The medication is used concomitantly with behavioral modification and a reduced-calorie diet.
- v. If the request is for Saxenda (liraglutide), then ALL of the following criteria must be met:
 - a. The patient has a baseline BMI corresponding to 30 kg/m² or greater for adults by international cut-off points based on the Cole Criteria. (Documentation is required for approval.)
- vi. If the request is for Wegovy (semaglutide), then the following criterion must be met:
 - a. The patient has a baseline BMI in the 95th percentile or greater that is standardized for age and sex (obesity). (Documentation is required for approval.)

V. Dosing and Duration

- i. Coverage is limited to FDA-approved dosages for each indication.
- ii. Initial authorization: 6 months
- iii. Reauthorization requires documentation of continued behavioral modification program participation and sustained benefit (e.g., $\geq 5\%$ weight loss).

VI. Required Documentation

The following documentation must be submitted from a healthcare provider before approval:

- i. Diagnosis and relevant ICD-10 codes
- ii. Baseline BMI
- iii. Previous treatment history (lifestyle interventions, medications)
- iv. Clinical notes supporting medical necessity

VII. Billing and Coding

- i. HCPCS Code:
 - a. J3490 – Unclassified drugs (for non-specific billing)
- ii. ICD-10 Codes:
 - a. Z68.30-Z68.45 – BMI classification codes (adult)
 - b. Z68.51-Z68.56 – BMI classification codes (pediatric)

VIII. No other GLP-1 or GIP/GLP-1 receptor agonists are approved under this policy for the treatment of obesity and chronic weight management.

IX. Sources

Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; April 2023.
Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; March 2024.
Zepbound [package insert]. Indianapolis, IN: Lilly USA, LLC; March 2024.

Supplemental Information

Medical Policy: Bariatric Surgery

Policy Number:

Effective Date:

Review Date

Approval Date:

I. Policy Statement

Bariatric surgery is approved for patients with clinically severe obesity who have not achieved or maintained adequate weight loss through conservative medical interventions. Severe obesity for adults is defined as a body mass index (BMI) of $\geq 35 \text{ kg/m}^2$ or $< 35 \text{ kg/m}^2$ in the presence of at least 1 obesity-related comorbid condition. For pediatric patients, severe obesity is defined as a BMI of $\geq 40 \text{ kg/m}^2$. Coverage is subject to the medical necessity criteria outlined in this policy.

II. Eligible Bariatric Procedures

The following bariatric surgical procedures may be considered medically necessary for the treatment of obesity when all the criteria are met:

- i. Roux-en-Y Gastric Bypass (RYGB)
- ii. Laparoscopic Adjustable Silicone Gastric Banding (LASGB)
- iii. Laparoscopic Sleeve Gastrectomy (LSG)
- iv. Biliopancreatic Diversion (BPD) with or without Duodenal Switch (DS)
- v. Single Anastomosis Duodenal-Ileal Switch (SADI)
- vi. Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S)

III. Indications for Coverage

Bariatric surgery may be considered medically necessary for severe obesity when the patient meets ALL of the following criteria:

- i. BMI Criteria
 - a. Adults (18 years of age and older):
 - i. BMI $\geq 35 \text{ kg/m}^2$ prior to the preoperative preparatory program; OR
 - ii. BMI $< 35 \text{ kg/m}^2$ prior to the preoperative preparatory program, accompanied by at least 1 of the following obesity-related comorbid conditions:
 - a. Type 2 diabetes mellitus
 - b. Clinically significant obstructive sleep apnea (confirmed by polysomnography)
 - c. Coronary heart disease (with documentation – by exercise stress test, radionuclide stress test, pharmacologic stress test, stress echocardiography, CT angiography, coronary angiography, heart failure, or prior myocardial infarction)
 - d. Medically refractory hypertension (blood pressure greater than 140 mm Hg systolic and/or 90 mm Hg diastolic despite concurrent use of 3 anti-hypertensive agents from different therapeutic classes).
 - e. Hyperlipidemia
 - f. Nonalcoholic fatty liver disease (NAFLD) or nonalcoholic steatohepatitis (NASH)
 - g. Osteoarthritis or degenerative joint disease affecting weight-bearing joints
 - h. Metabolic syndrome
 - b. Adolescents (post-bone growth, generally ≥ 13 years for girls and ≥ 15 years for boys):
 - i. BMI $\geq 40 \text{ kg/m}^2$
- ii. Previous Weight Management Efforts
 - a. Participation in an intensive multicomponent behavioral intervention within the past two years, meeting the following criteria:
 - i. Duration: At least 12 sessions on separate dates
 - ii. Format: In-person or remote, group or individual sessions
 - iii. Content: Focus on nutrition, physical activity, and behavioral modification
 - iv. Documentation: Records demonstrating compliance and progress (weight loss of $\geq 5\%$ from baseline)
 - b. The patient has tried an oral anti-obesity medication, in conjunction with exercise and a reduced-calorie diet, for at least 3 months and has been unable to lose $\geq 5\%$ of baseline body weight. (Documentation is required for approval.)
- iii. Psychological Evaluation
 - a. A comprehensive preoperative psychological assessment must confirm the absence of significant mental health conditions that could impair postoperative compliance.
- iv. Smoking and Substance Use
 - a. Patient must be tobacco-free for at least 6 months prior to surgery.
 - b. No active substance abuse (including alcohol or illicit drugs) for at least 1 year before surgery.

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IV. Exclusions and Limitations

The bariatric surgery procedures listed in this policy are not considered medically necessary and are not covered for patients with:

- i. Uncontrolled psychiatric disorders (e.g., untreated severe depression, schizophrenia, eating disorders)
- ii. Active malignancy requiring treatment
- iii. Pregnancy (Surgery should be deferred.)
- iv. Severe cardiopulmonary disease where surgical risk is excessive
- v. Noncompliance with medical care or follow-up
- vi. Experimental or investigational procedures
- vii. Revision surgeries unless medically necessary due to surgical failure or complications
- viii. Cosmetic procedures related to weight loss (e.g., skin removal surgery)

V. Required Documentation

The following documentation must be submitted for review before surgery approval:

- i. Physician Referral: Outlining the medical necessity of the procedure
- ii. Medical History and Physical Examination: Confirming BMI and comorbid conditions
- iii. Weight Management Records: Documentation from a supervised weight-management program OR healthcare provider (including a dietitian or physician)
- iv. Psychological Evaluation Report: Supporting surgical candidacy
- v. Preoperative Lab Results and Diagnostic Imaging: If applicable

VI. Billing and Coding

- i. ICD-10 Codes:
 - a. Z68.30-Z68.45 – BMI classification codes (adult)
 - b. Z68.51-Z68.56 – BMI classification codes (pediatric)

VII. Postoperative Follow-Up

- i. Patients must commit to a structured postoperative care program including nutritional counseling, exercise, vitamin supplementation, and routine follow-up visits.
- ii. Lifelong monitoring for nutritional deficiencies and metabolic complications is required.

VIII. Appeals Process

If coverage is denied, patients may submit an appeal with additional supporting documentation. Appeals will be reviewed on a case-by-case basis.

IX. Sources

American Society for Metabolic and Surgery. Bariatric surgery procedures. <https://asmbs.org/patients/bariatric-surgery-procedures/>.
Inova. Types of bariatric weight loss surgery and other procedures. <https://www.inova.org/our-services/inova-weight-loss-surgery-program/types-procedures>.
Mayo Clinic. Bariatric surgery. <https://www.mayoclinic.org/tests-procedures/bariatric-surgery/about/pac-20394258>.

INDICATION

Lomaira™ (phentermine hydrochloride USP) 8 mg tablets, CIV is a prescription medicine used for a short period of time (a few weeks) for weight reduction and should be used together with regular exercise and a reduced-calorie diet. Lomaira is for adults with an initial BMI* of 30 or more (obese) or 27 or more (overweight) with at least one weight-related medical condition such as controlled high blood pressure, diabetes, or high cholesterol. The limited usefulness of this drug class (anorectics), including Lomaira, should be measured against possible risk factors inherent in their use.

IMPORTANT SAFETY INFORMATION

Don't take Lomaira™ if you have a history of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure or uncontrolled high blood pressure); are taking or have taken a monoamine oxidase inhibitor drug (MAOI) within the past 14 days; have overactive thyroid, glaucoma (increased pressure in the eyes), agitation or a history of drug abuse; are pregnant, nursing, or allergic to the sympathomimetic amines such as phentermine or any of the ingredients in Lomaira.

Taking phentermine with other drugs for weight loss is not recommended. Primary pulmonary hypertension (PPH), a rare fatal lung disease, has been reported in patients who had taken a combination of phentermine and fenfluramine or dexfenfluramine for weight loss. The possible association between phentermine use alone and PPH cannot be ruled out. Patients should report immediately if they experience any decrease in the amount of exercise that they can normally tolerate, shortness of breath, chest or heart pain, fainting or swelling in the lower legs.

Serious heart valve problems or disease have been reported in patients taking a combination of phentermine and fenfluramine or dexfenfluramine for weight loss. The possible role of phentermine has not been established, therefore the possibility of an association between heart valve disease and the use of phentermine alone cannot be ruled out.

If your body becomes adjusted to the maximum dose of phentermine so that its effects are experienced less strongly, the maximum dose should not be exceeded in an attempt to increase the effect.

Caution is advised when engaging in potentially hazardous activity such as driving or operating machinery while taking phentermine. Phentermine has the potential to be abused. Keep Lomaira in a safe place to prevent theft, accidental overdose, misuse or abuse. Using alcohol with phentermine may result in an adverse drug reaction.

Phentermine can cause an increase in blood pressure. Tell your doctor if you have high blood pressure, even if it's mild. If you are taking medicines for type 2 diabetes, your doctor may have to adjust these medicines while taking phentermine.

Some side effects of phentermine that have been reported include pulmonary hypertension, valvular heart disease, palpitations, increased heart rate or blood pressure, insomnia, restlessness, dry mouth, diarrhea, constipation and changes in sexual drive. These are not all of the potential side effects of phentermine. For more information, ask your doctor or pharmacist.

To report negative side effects of prescription drugs, contact FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

*Body Mass Index (BMI) measures the amount of fat in the body based on height and weight. BMI is measured in kg/m².


Lomaira™^{IV}
(phentermine HCl)
8 mg tablets

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