

### **EMPLOYER ACTION BRIEF**



# COVERING PRESCRIPTION WEIGHT LOSS THERAPIES TO ADDRESS OBESITY

#### **KEY TAKEAWAYS:**

- Obesity is a disease that affects 1 in 3 adults and has significant impact on health, productivity, and cost.
- Behavioral change programs (diet & exercise) do not work for all individuals with obesity.
- Utilizing a pharmacological weight loss therapy in conjunction with a lifestyle program can reduce body weight more than diet and exercise alone.
- There are currently five FDA approved weight loss therapies that could help employers' weight management and wellness strategies.
- Weight loss pharmacotherapy should be discontinued if there is not at least a 4% reduction in body weight within 12 weeks of therapy initiation.

Obesity is one of the leading chronic disease states in the United States, affecting more than 1 in 3 adults. Obesity in itself is a driver of health care utilization and cost and poorer health outcomes, is closely linked to increasing rates of diabetes, and affects incidence, prevalence, quality of life and other health outcomes, for many other chronic conditions including cardiovascular disease, musculoskeletal decline, and cancer.

Obesity is one of the biggest drivers of healthcare costs in the United States. When comparing overall healthcare cost burdens of obese adults vs. healthy adults, data shows that obese adults spend 42% more on direct health costs than adults who are a healthy weight. In addition, the per capita healthcare costs for severely obese adults (BMI >40) are 81% higher than for healthy weight adults. Obesity is also associated with lost productivity (indirect cost) - both absenteeism and presenteeism. The additional per capita indirect cost for workers with obesity is \$506 (per obese worker per year).

Given the significant impact of obesity on health, medical spending, and lost productivity, many employers have made achieving healthy weight and addressing obesity a top priority for their wellness initiatives and benefit strategies. Yet, the offering of a pharmacologic weight loss benefit (coverage of prescription weight loss drugs) as part of the pharmacy benefit is not common. A 2016 GPBCH employer survey found that while almost all responding employers offered behaviorally-focused weight loss programs (healthy eating, physical activity, stress management, etc.), and a bariatric surgery benefit, only one-third of employers were covering prescription weight loss drugs.

## Employers typically cover a full range of pharmacologic therapies to address hypertension and hyperlipidemia. Why is obesity treated differently?

By providing more improved healthcare options for obesity management, employers can help to reduce the likelihood of worsening complications and also reduce the overall employee cost burden associated with this disease. Pharmacological weight loss therapy, coupled with other lifestyle changes, has proven to be an effective therapy for obesity management. In this Action Brief, we shed light on why employers should consider supporting pharmacological weight loss therapies in their employee benefit packages.

## What Role Can Pharmacological Weight Loss Therapy Play in Obesity Therapy?

Losing as little as 5% of one's weight can provide significant benefits in overall health (blood pressure, blood sugar levels, sleep apnea, among others). It is widely understood that implementing a healthy eating and exercise plan are important components to maintaining a healthy overall weight. Generally, most pharmacotherapy weight loss initiatives encourage a healthy eating and exercise plan in conjunction with the pharmacotherapy plan. A limited number of studies have been done where researchers examined the effects of drug therapy alone in absence of any lifestyle modifications. The available data indicates that pharmacotherapy by itself does not result in as much weight loss as achieved by pharmacotherapy plus lifestyle therapy (healthy diet and exercise). These findings are in agreement with the 2016 American Association of Clinical Endocrinologists and the American College of Endocrinology Physicians clinical guidelines for treating patients with obesity; pharmacotherapy for obesity should only be used as an adjunct to lifestyle therapy, not alone.

#### Did you know?

Research shows that those who couple lifestyle therapy with a pharmacotherapy weight loss program lose between 3 - 9% more on average than those strictly focused on a lifestyle plan.

In fact, some individuals have lost 10% or more of their starting weight within 6 months of beginning the pharmacotherapy program. Since weight loss of 5 - 10% of one's initial body weight can help to reduce further health complications and improve overall outcomes, it is necessary to consider all available options.

## What Pharmacological Weight Loss Therapies Are Available and Are They Effective?

There are currently five FDA approved prescription medications for weight loss: Orlistat (Xenical, Alli), Lorcaserin (Belvig), Phentermine-Topiramate ER (Osymia), Naltrexone ER-Bupropion ER (Contrave), and Liraglutide (Saxenda). Orlistat causes weight loss by inducing fat malabsorption. Lorcaserin reduces appetite and food intake. Phentermine combined with topiramate ER has been shown to be effective in weight loss and weight loss maintenance by reducing appetite. The combination of Naltrexone ER and Bupropion ER works synergistically to suppress appetite. Liraglutide is the only subcutaneous therapy out of the five pharmacological therapies. When injected subcutaneously, Liraglutide reduces appetite and increases satiety. At lower doses, liraglutide has also been approved for the treatment of type 2 diabetes. The comparison table below shows the average body weight reduction of each pharmacological weight loss therapy when combined with diet and exercise vs. lifestyle alone, route of administration, and optimal dosing.





For additional information on how each drug works, the clinical indication(s), what specific population(s) they are approved for, common side effects, dosing, and Wholesale Acquisition Cost (WAC) for a 30-day supply of each medication, please see appendix 1.

Comparison Table		Average % body	Average % body
Drug Name	Route	weight reduction (drug dose + lifestyle)	weight reduction: placebo (lifestyle alone)
Orlistat (Xenical, Alli)	Oral	<b>7.4%</b> (for 120mg 3 times a day dose - Alli at 60mg)	4.1%
Lorcaserin (Belviq)	Oral	<b>5.15%</b> (for 10 mg twice a day dose)	2.15%
Phentermine- Topiramate ER (Osymia)	Oral	<b>8.55%, 11.3%</b> (for 7.5 mg/46 mg dose, for 15 mg/92 mg dose)	1.85%
Naltrexone ER- Bupropion ER (Contrave)	Oral	<b>5.7%</b> (Week 1: 8mg/90mg Bupropin daily. Week 4: 32mg/260 mg dose twice daily)	2.15%
Liraglutide (Saxenda)	Subcutaneous	<b>7%</b> (start w8ith 0.6mg/week; up to 3.0 mg/dose by week5)	1.4%

## What Are the Current Barriers to Utilizing Pharmacological Therapies?

Many experts worry that although these prescription weight loss therapies have shown clinical benefits for patients, experience with prior generations of weight loss drugs cast a pessimistic shadow over newer products. As with many drugs, the guidelines set forth by the healthcare provider may not always be routinely or appropriately followed by the patients. Using any drugs outside of their therapeutic means is always a cause for concern.

In addition, some drugs approved by the FDA in the past were linked to serious health problems. In 1997, the FDA recalled Fenfluramine (Pondimin) and Dexfenfluramine (Redux) due to concerns related to heart valve problems. The new pharmacological weight loss therapies are shown to have mild side effects; in fact, the mild side effects improve with continued use as prescribed. As a result, it is important to understand how to effectively use these therapies, what to expect when taking these therapies, and how long before seeing optimal outcomes.

Additional barriers include a lack of insurance coverage on the antiobesity drugs along with an inadequate education and training of employers, insurers, and providers to recognize obesity as a chronic disease in need of treatment.

#### Recommendations for Incorporating Weight Loss Therapies in Employer Insurance Benefit Designs

Upon review of the information compiled in this Action Brief we encourage employers to cover all five FDA approved weight loss therapies within their pharmacy plan. Employers should speak with health plans and PBMs to determine:



- How pharmacologically therapy can be effectively coupled with lifestyle change programs
- ➤ How these vendors will monitor to ensure that people who are receiving weight loss drugs meet BMI and other clinical eligibility criteria. The therapies should be made available employees with a BMI of 30 or greater or a BMI of 27 or greater with at least one weight related comorbid condition (hypertension, dyslipidemia, type 2 diabetes)
- How these vendors will monitor to ensure that people receiving prescription weight loss drugs are under a physician's care (a primary care provider, a weight loss specialist, an endocrinologist, or another appropriate provider)
- How adherence is monitored and addressed. Coverage could be discontinued for people who are non-adherent to drug therapy or lifestyle change program participation
- ➤ How plans monitor for clinical effectiveness and discontinue therapy for people who do not respond to therapy. The employer may consider having therapy discontinued after 12 weeks if at least a 4% reduction in body weight from baseline is not achieved, or whether bariatric surgery should be recommended for morbidly obese individuals who do not respond to behavioral and pharmacologic therapy





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#### Appendix 1: FDA Approved Anti-Obesity and Overweight Pharmacological Therapies

#### Orlistat (Xenical Rx)

Mechanism of Action/ How Does it Work Lipase inhibitor/ works in the gut to reduce the amount of fat absorption from meals.

Indication

**Rx Obesity management**: including weight loss and weight maintenance, when used in conjunction with a reduced- caloric diet. To reduce weight regain after prior weight loss. Limited to patients with a BMI of  $\geq$  30 kg/m<sup>2</sup> or  $\geq$  27 kg/m<sup>2</sup> with at least weight related comorbid condition (HTN, dyslipidemia, type 2 diabetes).

Who it is Approved For?

Adults and children 12 years or older.

**Common Side Effects** 

Diarrhea, gas, oily stools.

Dosina

**Xenical**: 120mg 3 times a day with each meal containing fat (during or up to 1 hour after meal). Omit dose if meal is skipped. Take a multivitamin to account for decrease of absorption.

Estimated WAC for 30-day supply

\$586

#### Lorcaserin (Belviq)

Mechanism of Action/ How Does it Work Acts on serotonin receptors to help feel fullness after eating smaller portions of food.

Indication

**Chronic Weight Management:** as an adjunct to a reduced caloric diet and increased physical activity with initial BMI of  $\geq$  30 kg/m<sup>2</sup> or  $\geq$  27 kg/m<sup>2</sup> with at least weight related comorbid condition (HTN, dyslipidemia, type 2 diabetes).

Who it is Approved For?

Adults only.

**Common Side Effects** 

Constipation, dizziness, dry mouth.

Dosing

**Extended release**: 20mg by mouth daily (max 20mg/day) **Immediate release**: 10mg by mouth twice a day (max 20mg/day)

Discontinuation of Therapy: Evaluate response after 12 weeks. Discontinue if body weight reduction is not

≥ 5%.

Estimated WAC for 30-day supply

\$280

#### ${\bf Phentermine\text{-}Topiramate} \ ({\bf Qsymia})$

Mechanism of Action/ How Does it Work Lessens your appetite and makes you feel full faster.

Indication

**Weight management:** Adjunct to a reduced-calorie diet and increased physical activity, in patients with either an initial body mass index (BMI) of  $\geq$  30 kg/m2 or an initial BMI of  $\geq$  27 kg/m2 and at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes)

Who it is Approved For?

Adults only.

**Common Side Effects** 

Constipation, dizziness, dry mouth.

Dosing

**Oral: Initial:** Phentermine 3.75 mg/topiramate 23 mg once daily for 14 days. Increase dose to phentermine 7.5 mg/topiramate 46 mg once daily for 12 weeks then evaluate weight loss. If 3% of baseline body weight has not been lost, discontinue use or increase dose to phentermine 11.25 mg/topiramate 69 mg once daily for 14 days, and then to phentermine 15 mg/topiramate 92 mg once daily. Evaluate weight loss after 12 weeks on phentermine 15 mg/topiramate 92 mg; if 5% of baseline body weight has not been lost at dose of phentermine 15 mg/topiramate 92 mg gradually discontinue therapy (eg, 1 dose every other day for at least 1 week).

Estimated WAC for 30-day supply

\$200

#### Appendix 1 (Continued): FDA Approved Anti-Obesity and Overweight Pharmacological Therapies

#### Naltrexone-Bupropion (Contrave)

Mechanism of Action/ How Does it Work Makes you feel less hungry and more full faster.

Indication

**Weight management:** Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of  $\geq$ 30 kg/m2 or  $\geq$ 27 kg/m2 in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, and/or dyslipidemia)

Who it is Approved For?

Adults only

**Common Side Effects** 

Constipation, dizziness, dry mouth, diarrhea.

Dosina

**Initial:** One tablet (naltrexone 8 mg/bupropion 90 mg) once daily in the morning for 1 week; at week 2, increase to 1 tablet twice daily administered in the morning and evening and continue for 1 week; at week 3, increase to 2 tablets in the morning and 1 tablet in the evening and continue for 1 week; at week 4, increase to 2 tablets twice daily administered in the morning and evening and continue for the remainder of the treatment course.

**Usual dosage:** Two tablets (naltrexone 16 mg/bupropion 180 mg) twice daily (maximum dose: naltrexone 32 mg/bupropion 360 mg/day).

**Discontinuation of therapy:** If the patient has not lost at least 5% of baseline body weight after 12 weeks at the maintenance dosage, discontinue therapy; clinically meaningful weight loss is unlikely with continued treatment.

Estimated WAC for 30-day supply

\$278

#### Liraglutide (Saxenda) Injection Only

Mechanism of Action/ How Does it Work Makes you feel less hungry and more full faster.

Indication

**Chronic weight management (Saxenda):** As an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index of 30 kg/m2 or greater (obese) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia)

Who it is Approved For?

Adults only.

**Common Side Effects** 

Nausea, diarrhea, constipation.

Dosing

**SubQ: Initial:** 0.6 mg once daily for one week; increase by 0.6 mg daily at weekly intervals to a target dose of 3 mg once daily. If the patient cannot tolerate an increased dose during dose escalation, consider delaying dose escalation for one additional week. If the 3 mg daily dose is not tolerated, discontinue use as efficacy has not been established at lower doses.

**Discontinuation of Therapy:** Evaluate change in body weight 16 weeks after initiation of therapy; discontinue if at least 4% of baseline body weight loss has not been achieved.

Estimated WAC for 30-day supply

\$1,200

#### Sources

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The Greater Philadelphia Business Coalition on Health (GPBCH) seeks to increase the value of health benefit spending for its employer members, by improving workforce and community health, increasing healthcare quality and safety, and reducing health care costs. The Coalition represents employer interests in working with health plans, health care providers, benefits consultants, suppliers and other system stakeholders to address population health priorities and to ensure that when health care is needed it is accessible, affordable, high-quality, and safe.



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