

# Pharmacy Management Drug Policy

**SUBJECT: Weight-Related Comorbidities: Overweight, Obesity, & Cardiovascular Disease**

**POLICY NUMBER: PHARMACY-03**

**EFFECTIVE DATE: 02/2012**

**LAST REVIEW DATE: 06/12/2025**

*If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:*

## Policy Application

<b>Category:</b>	<input checked="" type="checkbox"/> Commercial Group (e.g., EPO, HMO, POS, PPO)	<input type="checkbox"/> Medicare Advantage
	<input checked="" type="checkbox"/> On Exchange Qualified Health Plans (QHP)	<input type="checkbox"/> Medicare Part D
	<input checked="" type="checkbox"/> Off Exchange Direct Pay	<input checked="" type="checkbox"/> Essential Plan (EP)
	<input type="checkbox"/> Medicaid & Health and Recovery Plans (MMC/HARP)	<input type="checkbox"/> Child Health Plus (CHP)
	<input type="checkbox"/> Federal Employee Program (FEP)	<input type="checkbox"/> Ancillary Services
	<input type="checkbox"/> Dual Eligible Special Needs Plan (D-SNP)	

## DESCRIPTION:

Observational epidemiological studies have established a relationship between obesity and visceral fat and the risks for cardiovascular disease, type 2 diabetes, certain forms of cancer, gallstones, certain respiratory disorders, and an increase in overall mortality. These studies suggest that weight loss, if maintained, may produce health benefits for obese patients who have or are at risk of developing weight related co-morbidities.

Orlistat, liraglutide, semaglutide, naltrexone/bupropion ER, tirzepatide and phentermine/topiramate ER are indicated for the management of obesity, including weight loss and maintenance of weight loss, and should be used in conjunction with a reduced calorie diet.

Xenical (orlistat) is also indicated to reduce the risk of weight regain after prior weight loss. Orlistat is a reversible inhibitor of lipases. It exerts its therapeutic activity in the lumen of the stomach and small intestine by forming a covalent bond with the active serine residue site of gastric and pancreatic lipases. The inactivated enzymes are thus unavailable to hydrolyze dietary fat in the form of triglycerides into absorbable free fatty acids and monoglycerides. As undigested triglycerides are not absorbed, the resulting caloric deficit may have a positive effect on weight control.

Saxenda (liraglutide) is a glucagon-like peptide-1 (GLP-1) receptor agonist. GLP-1 is a regulator of appetite and calorie intake. GLP-1 receptors are present in several areas of the brain involved with appetite regulation. Liraglutide increases feelings of satiety and decreases hunger.

Wegovy (semaglutide) is a glucagon-like peptide-1 (GLP-1) receptor agonist. GLP-1 is a physiological regulator of appetite and caloric intake, and the GLP-1 receptor is present in several areas of the brain involved in appetite regulation. Semaglutide increases feelings of satiety and decreases hunger.

Contrave is a combination of two FDA-approved drugs, naltrexone, and bupropion, in an extended-release formulation. Naltrexone is approved to treat alcohol and opioid dependence. Bupropion is approved to treat depression and seasonal affective disorder and as an aid to smoking cessation treatment.

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Qsymia is a combination of phentermine, a sympathomimetic amine anorectic, and topiramate, an antiepileptic drug. The exact mechanism of action of these agents is not known. Phentermine likely releases catecholamines in the hypothalamus, resulting in reduced appetite and decreased food consumption. Topiramate leads to appetite suppression and satiety enhancement, possibly induced by a combination of pharmacologic effects.

Zepbound (tirzepatide) glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist. GIP and GLP-1 are physiological regulators of appetite, caloric intake, and insulin secretion and the GLP-1 and GIP receptors are present in several areas of the brain involved in appetite regulation. Tirzepatide increases feelings of satiety and decreases hunger.

The FDA has approved orlistat, naltrexone/bupropion ER, phentermine/topiramate ER, semaglutide, tirzepatide and liraglutide as adjuncts to caloric restriction, increased physical activity and behavior modification in the overall treatment of qualifying obesity. The medications are not approved as the sole therapeutic modality.

The FDA has approved Wegovy to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight in combination with a reduced calorie diet and increased physical activity.

**General Policy Criteria – For Contrave, phentermine-topiramate ER, Qsymia, Saxenda, Wegovy (For Weight loss only), Zepbound and Xenical/Orlistat only. Please refer to drug specific section for Wegovy requests for reduction of major cardiovascular events in patients with established cardiovascular disease:**

Based upon our review and assessment of peer-reviewed literature, Contrave, Xenical/Orlistat, Saxenda, Wegovy (For Weight loss only), Zepbound, Qsymia and phentermine-topiramate ER have been proven to be effective and are considered **medically necessary** for the treatment of Class II and Class III obesity, provided **all** the following criteria are met. This policy prioritizes patients with Class II and Class III obesity to address the highest risk of imminent medical and life-threatening complications (e.g., cardiovascular events).

Coverage requires documentation of the following criteria (1-6). Documentation must reflect the patient's clinical status (including weight, height, BMI, and comorbid conditions) at the time the drug was originally initiated, regardless of the date of the current coverage request.

1. For initial reviews, member must fall under **one** of the following: A or B. (Qsymia, phentermine-topiramate ER, Wegovy and Saxenda ages 12-17, please refer to drug specific policy below for clinical criteria for this step) **AND**

- A. Class 3 Obesity (BMI greater than or equal to 40 kg/m<sup>2</sup>)

**OR**

- B. Class 2 Obesity (BMI 35 to 39.9kg/m<sup>2</sup>) in the presence of *one or more co-morbidities* listed below:

- Cardiovascular Disease

- Dyslipidemia (ex. high LDL, TG, or low HDL)

- Gallstones

- Gynecological abnormalities

- Hypercholesterolemia

- Hypertension

- Metabolic Syndrome

- Metabolic Dysfunction-Associated Steatotic Liver Disease (MAFLD)

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Pulmonary Hypoventilation  
Obstructive Sleep Apnea  
Stress Incontinence  
Type 2 Diabetes  
Weight-Bearing Joint Arthropathy

2. **Documentation of current enrollment into a qualified comprehensive weight management program for at least the past 3 consecutive months.** (Please refer to addendum for program criteria.) **AND**

#### EXAMPLES OF APPROVED PROGRAMS

- Provider based counseling that meets guidelines for a comprehensive weight management program (see addendum at end of policy).
  - Weight Watchers, Curves Nutrition & Weight Management Program, or other programs that meet the guidelines for a comprehensive weight management program (see addendum at end of policy).
3. **For initial approvals - Proof of current and prior participation in a comprehensive weight management program (such as a receipt or certificate and dietary/exercise logs) will be required.**
4. Recertification of drug approval beyond the initial coverage period will require provider acknowledgement (via prior authorization form or provider progress note) of continued comprehensive weight management program enrollment.
5. The safety and efficacy of any anorexiant in combination with other weight loss drugs (including prescription, OTC, and herbal preparations) has not been established and therefore, combination therapy will not be approved.
6. Additional requirements for approval are listed in the Drug-Specific Policy criteria.

#### **Drug-Specific Policy:**

##### **Contrave (naltrexone/bupropion) specific criteria:**

1. Member must be 18 years of age or older
2. For patients new to therapy, initial coverage duration is 4 months. After initial coverage period, recertification will be required every 6 months.
3. For patients continuing drug therapy (recertification):
  - a. For initial recertification, patient must have a physician verified weight loss of 5% of initial weight by 4 months. Failure to lose 5% of weight at 4 months suggests that positive health outcome may not be realized, and drug therapy coverage will not be continued.
  - b. For continued 6-month recertifications, patient must have maintained initial 5% weight loss **OR** has continued to lose weight.
4. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
5. The maximum daily dose is Naltrexone 32 mg/bupropion 360 mg daily (two tablets twice daily) according to the prescribing information. According to the prescribing information, titration to this dose occurs over a 4-week period. Response to therapy should be evaluated after 3 months at the *maintenance* dosage.

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#### Qsymia and phentermine/topiramate ER specific criteria:

##### For Adults:

1. Member must be 18 years or older
2. Requests for brand name Qsymia will require documentation of use of generic phentermine/topiramate ER that lead to serious side effects or drug failure.
2. For patients new to therapy, initial coverage duration is 6 months. After the initial coverage period, recertification will be required every 6 months.
3. For patients continuing drug therapy (recertification):
  - a. For initial recertification, patient must have physician verified weight loss of 5% of initial weight by 6 months.
  - b. For continued 6-month recertifications, patient must have maintained initial 5% weight loss **OR** has continued to lose weight.
4. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
5. Note, the manufacturer recommends the following:
  - a. Discontinue or increase dose if 3% weight loss is not achieved after 12 weeks on the 7.5/46mg dose.
  - b. Discontinue phentermine-topiramate ER if 5% weight loss is not achieved after 12 weeks on maximum daily dose of 15mg/92mg.
  - c. Discontinue 15/92mg dose gradually to prevent possible seizure.

##### For Adolescents:

1. Must be 12-17 years of age **AND**
2. Must have an initial BMI in the 95th percentile or greater standardized for age and sex. (See CDC website for current BMI for age Growth Charts:  
[https://www.cdc.gov/healthyweight/assessing/bmi/childrens\\_bmi/about\\_childrens\\_bmi.html](https://www.cdc.gov/healthyweight/assessing/bmi/childrens_bmi/about_childrens_bmi.html)) **OR** use chart below: **AND**

BMI Percentiles by Age and Sex for Pediatric Patients Aged 12 Years and Older

Age (in years)	Male	Female
	95th Percentile BMI Value	95th Percentile BMI Value
12	24.2	25.3
12.5	24.7	25.8
13	25.2	26.3
13.5	25.6	26.8
14	26.0	27.3
14.5	26.5	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.6	28.9
16.5	27.9	29.3
17	28.3	29.6
17.5	28.6	30.0

3. Requests for brand name Qsymia will require documentation of use of generic phentermine/topiramate ER that lead to serious side effects or drug failure.
4. For patients new to therapy, initial coverage duration is 6 months. After the initial coverage period, recertification will be required every 6 months.
5. For patients continuing drug therapy (recertification):
  - a. For initial recertification, patient must have a physician verified BMI reduction of 5% of initial weight by 6 months. Failure to lose 5% of BMI at 6 months suggests that positive health outcome may not be realized, and drug therapy coverage will not be continued.
  - b. For continued 6-month recertifications, patient must have maintained initial 5% weight loss **OR** has continued to lose weight.

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6. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
7. Note, the manufacturer recommends the following:
  - a. Monitor the rate of weight loss in pediatric patients. If weight loss exceeds 2 lbs. (0.9 kg)/week, consider dosage reduction.
  - b. After 12 weeks of treatment with phentermine-topiramate ER 7.5 mg/46mg, if a pediatric patient has not experienced a reduction of at least 3% of baseline BMI, increase the dosage to phentermine-topiramate ER 11.25 mg/69 mg orally once daily for 14 days; followed by an increase in the dosage to phentermine-topiramate ER 15 mg/92 mg.
  - c. Discontinue phentermine-topiramate ER 15 mg/92 mg gradually by taking phentermine-topiramate ER 15 mg/92 mg once daily every other day for at least 1 week prior to stopping treatment altogether, due to the possibility of precipitating a seizure

#### **Saxenda (liraglutide) specific criteria:**

#### **As of 9/12/23 the following policy criteria will be applicable:**

As a result of unexpected demand that far exceeded the manufacturer's expectations, there is currently a supply shortage of Saxenda in the marketplace. Novo Nordisk, the manufacturer of Saxenda, stated there is a shortage of Saxenda, and they will not be able to meet demand for the medication for an extended period of time. Saxenda is available as a 6 mg/mL strength in a 3 mL pen that delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, or 3 mg. According to drug labeling, only the 3mg dose is utilized for maintenance. All other doses are for dose titration only. Due to the supply issues, titration, and maintenance to 3mg daily cannot be reliably and safely completed and puts patients at risk for requiring recurrent titration periods which have a lack of weight loss benefit or continuing maintenance dosing after a large gap in therapy which can lead to adverse effects. Effective immediately, request for patient's new to therapy with Saxenda will **NOT** be granted approval until the supply-chain is restored. A review for an alternative product contained within this policy can be requested.

#### **When supply of Saxenda is restored to adequate levels, the following criteria will then become active again for all requests.**

1. The quantity limit for Saxenda is 15 mL (5 pens) per 30-days. Saxenda is limited to a total of 14 fills per year (365 days). Requests for a quantity outside of these limits will not be approved.
2. Saxenda will not be approved for non-FDA approved diagnoses.

#### **For Adults:**

1. Member must be 18 years of age or older **AND**
2. Will not be approved for use in combination with any other GIP and/or GLP-1 receptor agonist (Byetta/Bydureon, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro) **AND**
3. For patients new to therapy, initial coverage duration is 4 months. After the initial coverage period, recertification will be required every 6 months.
4. For patients continuing drug therapy (recertification):
  - a. Upon recertification the patient must be utilizing the 3mg dose as maintenance therapy.
  - b. For initial recertification, patient must have physician verified weight loss of 5% of initial weight by 4 months.
  - c. For continued 6-month recertifications, patient must have maintained initial 5% weight loss **OR** has continued to lose weight.
5. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.



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- The maximum daily dose is 3mg subcutaneously once daily according to the prescribing information.

#### For Adolescents:

- Must be 12-17 years of age **AND**
- Must have body weight  $\geq 60\text{kg}$  (~132lbs) **AND**
- Must have an initial BMI corresponding to 30 kg/m<sup>2</sup> or greater for adults (obese) by international cut-offs (Cole Criteria; see table) **AND**

**Table 2: International Obesity Task Force BMI Cut-offs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (Cole Criteria)**

Age (years)	Body mass index 30 kg/m <sup>2</sup>	
	Males	Females
12	26.02	26.67
12.5	26.43	27.24
13	26.84	27.76
13.5	27.25	28.20
14	27.63	28.57
14.5	27.98	28.87
15	28.30	29.11
15.5	28.60	29.29
16	28.88	29.43
16.5	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84

- Will not be approved for use in combination with any other GIP and/or GLP-1 receptor agonist (Byetta/Bydureon, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro) **AND**
- For patients new to therapy, initial coverage duration is 5 months. After the initial coverage period, recertification will be required every 6 months.
- For patients continuing drug therapy (recertification):
  - Upon recertification the patient must be utilizing the 2.4mg or 3mg dose as maintenance therapy.
  - For initial recertification, patient must have a physician verified reduction in BMI of at least 1% by 5 months. Failure to reduce BMI by at least 1% at 5 months suggests that it is unlikely the patient will achieve and sustain clinically meaningful weight loss, and therefore coverage will not be continued.
  - For continued 6-month recertifications, patient must have maintained initial 1% weight loss **OR** has continued to lose weight.
- Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
- Note, the manufacturer recommends the following
  - Maintenance dosage of SAXENDA is 3 mg daily. Pediatric patients who do not tolerate 3 mg daily may have their maintenance dose reduced to 2.4 mg daily. Discontinue SAXENDA if the patient cannot tolerate the 2.4 mg dose.
  - Dose escalation for pediatric patients may take up to 8 weeks.
  - Evaluate the change in BMI after 12 weeks on the maintenance dose.

#### Wegovy (semaglutide) specific criteria:

#### The following policy criteria will be applicable to all indications of Wegovy.

- The quantity limit for all strengths (0.25mg, 0.5mg, 1mg, 1.7mg, 2.4mg) is 4 pens per 28 days. Requests for a quantity outside of these limits will not be approved (i.e., use of 0.25mg x4 pens to make a 1mg dose or use of 0.5mg x2 pens, etc.). Wegovy is limited to a total of 14 fills per year (365 days). Requests for a quantity outside of these limits will not be approved.
- Wegovy will not be approved for non-FDA approved diagnoses.

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#### Weight loss only criteria for Adults:

1. Member must be 18 years of age or older **AND**
2. Will not be approved for use in combination with any other GIP and/or GLP-1 receptor agonist (Byetta/Bydureon, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro) **AND**
3. For patients new to therapy, initial coverage duration is 7 months. After the initial coverage period, recertification will be required every 6 months.
4. For patients continuing drug therapy (recertification):
  - a. Upon recertification the patient must be utilizing the 2.4mg **OR** the 1.7mg dose as maintenance therapy.
  - b. For initial recertification, patient must have physician verified weight loss of 5% of initial weight by 7 months.
  - c. For continued 6-month recertifications, patient must have maintained initial 5% weight loss **OR** has continued to lose weight.
5. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
6. The maintenance dose of Wegovy is 2.4mg **OR** 1.7mg once weekly, and is titrated according to the following schedule and recommendations:
  - a. If patients do not tolerate a dose during dose escalation, consider delaying dose escalation for 4 weeks.
  - b. Consider treatment response and tolerability when selecting the maintenance dosage.
  - c. The 0.25 mg, 0.5 mg, and 1 mg once-weekly dosages are initiation and escalation dosages and are not approved as maintenance dosages for chronic weight management.

Table 3: Recommended Dosage Regimen for Adults

Treatment	Weeks	Once weekly Subcutaneous Dosage
Initiation	1 through 4	0.25 mg <sup>a</sup>
Escalation	5 through 8	0.5 mg <sup>a</sup>
	9 through 12	1 mg <sup>a</sup>
	13 through 16	1.7 mg
Maintenance	17 and onward	1.7 mg or 2.4 mg

#### Weight loss only criteria for Adolescents:

1. Must be 12-17 years of age **AND**
2. Must have an initial BMI in the 95th percentile or greater standardized for age and sex. (See CDC website for current BMI for age Growth Charts: [https://www.cdc.gov/healthyweight/assessing/bmi/childrens\\_bmi/about\\_childrens\\_bmi.html](https://www.cdc.gov/healthyweight/assessing/bmi/childrens_bmi/about_childrens_bmi.html)) **OR** use chart below: **AND**

BMI Percentiles by Age and Sex for Pediatric Patients Aged 12 Years and Older

Age (in years)	Male	Female
	95th Percentile BMI Value	95th Percentile BMI Value
12	24.2	25.3
12.5	24.7	25.8
13	25.2	26.3
13.5	25.6	26.8
14	26.0	27.3
14.5	26.5	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.6	28.9
16.5	27.9	29.3
17	28.3	29.6
17.5	28.6	30.0

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3. Will not be approved for use in combination with any other GIP and/or GLP-1 receptor agonist (Byetta/Bydureon, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro) **AND**
4. For patients new to therapy, initial coverage duration is 7 months. After the initial coverage period, recertification will be required every 6 months.
5. For patients continuing drug therapy (recertification):
  - a. Upon recertification the patient must be utilizing the 1.7mg or 2.4mg dose as maintenance therapy.
  - b. For initial recertification, patient must have a physician verified reduction in BMI of at least 5% by 7 months. Failure to reduce BMI by at least 5% at 7 months suggests that it is unlikely the patient will achieve and sustain clinically meaningful weight loss, and therefore coverage will not be continued.
  - c. For continued 6-month recertifications, patient must have maintained initial 5% weight loss **OR** has continued to lose weight.
6. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
7. Note, the manufacturer recommends the following:
  - a. Maintenance dosage of WEGOVY is 2.4 mg weekly.
  - b. Dose escalation for pediatric patients may take up to 16 weeks.

#### **Reduction of major cardiovascular events in patients with established cardiovascular disease criteria:**

1. Must be at least 18 years old
2. Must have a BMI of at least 27 kg/m<sup>2</sup>
3. Prescriber must attest that Wegovy is be prescribed by or in consultation with a cardiologist or neurologist.
4. Must have progress notes submitted demonstrating established cardiovascular disease defined as: Prior myocardial infarction, Prior stroke, Symptomatic peripheral arterial disease, as evidenced by an intermittent claudication with ankle-brachial index <0.85, Prior peripheral arterial revascularization procedure or Amputation due to atherosclerotic disease.
5. Documentation must be provided that demonstrates:
  - a. The patient is currently a non-smoker (defined as someone who has not smoked in the past 6 months)
  - b. The patient is partaking in a heart healthy diet.
  - c. The patient is engaging in physical activity (at their level of ability)
  - d. The patient will continue to participate in the above lifestyle modifications while on Wegovy therapy.
6. There must be supportive documentation that demonstrates that the patient is optimized, according to the prescriber, on standard of care treatment for prevention of secondary cardiovascular events. Standards of care may include: lipid lowering therapies, blood pressure lowering therapy, SGLT2 inhibitors when appropriate, antiplatelet therapy when appropriate.
7. Must not have been diagnosed with diabetes mellitus, end stage renal disease or New York Heart Association Class IV heart failure symptoms.
  - a. Please note, for patients with type 2 diabetes you can consider GLP1 receptor agonists that are FDA approved to reduce the risk of major adverse cardiovascular in adults with type 2 diabetes mellitus and established cardiovascular disease.
8. Will not be approved for use in combination with any other GIP and/or GLP-1 receptor agonist (Byetta/Bydureon, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro)
9. Will not be approved for use in combination with any weight loss drugs (including prescription, OTC, and herbal preparations).



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10. Initial approval will be for 7 months. After the initial coverage period, recertification will be required every 6 months.
11. Upon recertification the patient must:
  - a. Be utilizing the 2.4mg **OR** the 1.7mg dose as maintenance therapy.
  - b. Must have proven adherence to Wegovy defined as a threshold of 80% PDC (Percent Days Covered) since last approval.
  - c. Must have documentation that demonstrates the patient is still a non-smoker, is partaking in a heart healthy diet and is engaging in physical activity (at their level of ability).
  - d. Not have developed type 2 diabetes, ESRD or New York Heart Association Class IV heart failure symptoms.
12. The maintenance dose of Wegovy is 2.4mg **OR** 1.7mg once weekly, and is titrated according to the following schedule and recommendations:
  - a. If patients do not tolerate a dose during dose escalation, consider delaying dose escalation for 4 weeks.
  - b. Consider treatment response and tolerability when selecting the maintenance dosage.

Table 3: Recommended Dosage Regimen for Adults

Treatment	Weeks	Once weekly Subcutaneous Dosage
Initiation	1 through 4	0.25 mg <sup>a</sup>
Escalation	5 through 8	0.5 mg <sup>a</sup>
	9 through 12	1 mg <sup>a</sup>
	13 through 16	1.7 mg
Maintenance	17 and onward	1.7 mg or 2.4 mg

#### **Xenical and generic orlistat specific criteria:**

1. Member must be 12 years of age or older
2. Requests for brand Xenical will require documentation of serious side effects or drug failure with generic orlistat.
3. For patients new to therapy, initial coverage duration is 6 months. After the initial coverage period, recertification will be required every 6 months.
4. For patients continuing drug therapy (recertification):
  - a. For initial recertification, patient must a physician verified weight loss of 5% of initial weight by 6 months. Failure to lose 5% of weight at 6 months suggests that positive health outcome may not be realized, and drug therapy coverage will not be continued.
  - b. For continued 6-month recertifications, patient must have maintained initial 5% weight loss **OR** has continued to lose weight.
5. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
6. The maximum daily dose is one 120mg capsule by mouth three times a day with each main meal containing fat (during or up to 1 hour after the meal) according to the prescribing information.
7. Quantity Limit of 90 capsules/30 days

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#### Zepbound (tirzepatide) specific criteria:

1. Coverage criteria applies to the Zepbound pens only.
  - a. Zepbound vials are not a covered benefit as the vial is not available through any pharmacy channels. Patients will still have an alternative means to obtain Zepbound vials through the LillyDirect access program.
2. The quantity limit for all strengths (2.5mg, 5mg, 7.5mg, 10mg, 12.5mg 15mg) is 2ml (4 pens) per 28 days. Zepbound is limited to a total of 14 fills per year (365 days). Requests for a quantity outside of these limits will not be approved
  - a. The 2.5mg strength will be limited to 2ml/365 days to allow for titration to maintenance dosing. It is not intended to be used chronically; therefore, it will not be covered beyond the initial 4-week titration period.
3. On December 20, 2024, Zepbound received FDA approval for the treatment of Obstructive Sleep Apnea (OSA) in adult patients with obesity. Based on the Health Plan's assessment of the available literature, it has been determined that the clinical efficacy of Zepbound in obstructive sleep apnea (OSA) is inherently dependent on weight loss. Therefore, the Health Plan will integrate this indication into our existing weight management criteria, which already accounts for OSA as a comorbid condition. As such, enrollment in a comprehensive weight management program for this diagnosis remains essential, as it provides structured support for lifestyle modifications (including diet and exercise) while improving adherence, which is critical to obtaining and maintain clinical efficacy.
4. Member must be 18 years of age or older **AND**
5. Will not be approved for use in combination with any other GIP and/or GLP-1 receptor agonist (Byetta/Bydureon, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro) **AND**
6. For patients new to therapy, initial coverage duration is 7 months. After the initial coverage period, recertification will be required every 6 months.
7. For patients continuing drug therapy (recertification):
  - a. Upon recertification the patient must be utilizing the 5mg, 7.5mg, 10mg, 12.5mg or 15mg dose as maintenance therapy.
  - b. For initial recertification, patient must have physician verified weight loss of 5% of initial weight by 7 months.
  - c. For continued 6-month recertifications, patient must have maintained initial 5% weight loss **OR** has continued to lose weight.
8. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
9. Approved Dosing: Please refer to the prescribing information for dosing related to the FDA-approved indications
  - a. Note: For patients unable to tolerate one of the approved maintenance doses, a lower maintenance, minimum of 5 mg once weekly, will be covered.

#### POLICY GUIDELINES:

1. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
2. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
3. Organic causes of obesity such as hypothyroidism should be excluded before prescribing weight loss medications.
4. Victoza (liraglutide) will not be authorized at a dose of greater than 1.8mg once daily, as there is an

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active formulation of liraglutide (Saxenda) that is FDA approved for chronic weight management. Ozempic (semaglutide) will not be authorized at a dose greater than 2mg once weekly, as there is an active formulation of semaglutide that is FDA approved for chronic weight management.

5. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, and imaging.
  - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.
6. Upon recertification, maintenance dosing per FDA labeling will be required for continued use of Wegovy, Zepbound and Saxenda. Dosing below FDA approved maintenance dosing will not be allowed after adequate dose titration (per medication package insert) has occurred.
7. Patients who have not received treatment within the past 4 months (i.e., last dose taken more than 4 months ago) will be considered new to therapy.
8. For off-label use requests of the medications listed in this policy, that satisfy the criteria outlined in our Off-Label Use of FDA Approved Medications Policy (Pharmacy-32), where the efficacy is not independent of weight loss and/or the requested use was studied as part of an extension trial of an original obesity/weight loss trial (e.g. pre-diabetes extension trial of SURMOUNT-1 for tirzepatide [Zepbound]), all applicable weight management criteria will apply (BMI requirements and participation in a comprehensive weight management program, etc.).
9. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
10. BMI thresholds may be adjusted for ethnicity (e.g., Asian population) on a case-by-case basis. Obesity definitions using BMI thresholds do not apply similarly to all populations. For example, BMI thresholds should be adjusted in the Asian population such that a BMI  $\geq 25$  kg/m<sup>2</sup> suggests clinical obesity, and as such, consideration for pharmacological treatment should be given.
11. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.

#### **UPDATES:**

<b>Date:</b>	<b>Revision:</b>
06/12/2025	Revised
04/04/2025	Revised
03/06/2025	Revised
01/31/2025	Revised
01/21/2025	Revised
01/02/2025	Revised
01/01/2025	Revised (Updates approved at 11/21/2024 P&T); Formerly named Weight Management Policy – Policy name changed to Weight-Related Comorbidities Policy – Overweight, Obesity, Cardiovascular Disease
10/31/2024	Revised
09/13/2024	Revised
08/28/2024	Revised
08/26/2024	Revised

## Pharmacy Management Drug Policy

### Weight-Related Comorbidities - Overweight, Obesity, & Cardiovascular Disease

08/15/2024	Reviewed / P&T Committee Approval
08/05/2024	Revised
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9/12/2023	Revised
9/5/2023	Revised
8/24/2023	P&T Committee Approval
8/15/2023	Revised
6/28/2023	Revised
6/21/2023	Revised
5/24/2023	Revised
04/01/2023	Revised
1/2023	Revised
10/2022	Revised
8/2022	Revised
07/14/2022	Reviewed & Approved P&T Committee
7/2022	Revised
1/2022	Revised
9/2021	Revised
7/2021	Revised/P&T Committee Approval
6/21	Revised
2/21	Revised
12/20	Revised
11/2020	Revised
9/16/2020	P&T Committee Approval
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03/20	Revised
02/20	Revised
9/19	P&T Committee Approval
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06/19	Reviewed
08/18	Revised
06/18	Revised
8/17	Revised
9/16	Revised
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4/15	Revised
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1/13	Revised
10/12	Revised

## Pharmacy Management Drug Policy

### Weight-Related Comorbidities - Overweight, Obesity, & Cardiovascular Disease

7/12	Revised
5/99	Created

#### **REFERENCES:**

1. US Food and Drug Administration. CDER Report to Nation: 2003. Found in <http://www.fda.gov/cder/reports/rtn/2003/rtn2003-1.HTM>
2. Fitchet M, et al. Meta-analysis of weight loss in three dose ranging studies [abstract], *Int J Obes* 1996; 20:156. .
3. Xenical Prescribing information. Cheplapharm; revised 08/2017. Accessed online 05/31/19.
4. Clinical Guidelines on the Indication, Evaluation, and Treatment of Overweight and Obesity in Adults. National Institute of Health. National Heart, Lung & Blood Institute 1998
5. Heshka S, et al. Weight Loss with Self-help Compared with a Structured Commercial Program: A Randomized Trial, *JAMA* April 9, 2003;289(14): 1792-1798
6. Diet, Drugs and Surgery for Weight Loss, Treatment Guidelines from The Medical Letter, December 2003; Vol1 (Issue 16):101-106
7. Ogden C, et al. Prevalence of Overweight and Obesity in the United States 1999-2004 *JAMA* April 5, 2006; 295: 1549-1555
8. Issued by Leade Health Inc: Radosevich T, Voss D. Excellus Outcomes Report --Weight Management Program September 2001 through March 2003; Leade Health Inc, Ann Arbor, Michigan May 2003
9. Christakis NA, Fowler JH The Spread of Obesity in a Large Social Network over 32 Years *JAMA* July 26, 2007 357:370-379
10. Redmon, JB, et al Two-Year outcome of a Combination of Weight Loss Therapies for Type 2 Diabetes *Care* 2005;28(6):1311-1315
11. Snow V; Barry P; Fitterman N; Qaseem A; Weiss K Pharmacologic and surgical management of obesity in primary care: a clinical practice guideline from the American College of Physicians *Ann Intern Med* 2005 Apr 5;142(7):525-31
12. USPSTF Screening for Obesity Release date Dec 2003 Accessed at [www.ahrq.gov/clinic/uspstfix.htm](http://www.ahrq.gov/clinic/uspstfix.htm)
13. [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm198221.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm198221.htm) - 31k - 2010-01-21
14. <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm228830.htm>
15. Wadden TA, et al A two-year randomized trial of obesity treatment in primary care practice *N Engl J Med*. 2011 Nov 24;365(21):1969-79. Epub 2011 Nov 14.
16. Garcia Diaz E et al Systematic review of the clinical efficacy of sibutramine and orlistat in weight loss, quality of life and its adverse effects in obese adolescents *Nutr Hosp*. 2011 Jun;26(3):451-7.
17. Thomas EL Pragmatic study of orlistat 60 mg on abdominal obesity *Eur J Clin Nutr*. 2011 Nov;65(11):1256-62. doi: 10.1038/ejcn.2011.108. Epub 2011 Jun 22.
18. Chanoine JP et al Early weight loss and outcome at one year in obese adolescents treated with orlistat or placebo *Int J Pediatr Obes*. 2011 Apr;6(2):95-101. Epub 2010 Sep 22.
19. CDC website <http://www.cdc.gov/obesity/data/trends.html> accessed 4/17/12
20. Saxenda prescribing information. Novo Nordisk; Revised 12/2020. Accessed online 12/23/2020.
21. Contrave prescribing information. Orexigen Therapeutics, Inc.; Revised 04/2019. Accessed online: 05/31/19.
22. Qsymia prescribing information. Vivus, Inc.; Revised 06/2022. Accessed online: 08/09/2022.
23. U.S. Department of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute. (2000). The Practical Guide. Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. NIH Publication No. 00-4084. Retrieved from:



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### Weight-Related Comorbidities - Overweight, Obesity, & Cardiovascular Disease

- [https://www.nhlbi.nih.gov/files/docs/guidelines/prctgd\\_c.pdf](https://www.nhlbi.nih.gov/files/docs/guidelines/prctgd_c.pdf)
24. Michael D. Jensen, Donna H. Ryan, Caroline M. Apovian, Jamy D. Ard, Anthony G. Comuzzie, Karen A. Donato, Frank B. Hu, Van S. Hubbard, John M. Jakicic, Robert F. Kushner, Catherine M. Loria, Barbara E. Millen, Cathy A. Nonas, F. Xavier Pi-Sunyer, June Stevens, Victor J. Stevens, Thomas A. Wadden, Bruce M. Wolfe and Susan Z. Yanovski; 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults, *Circulation*, 12 November 2013, <http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437739.71477.ee>
  25. Caroline M. Apovian, Louis J. Aronne, Daniel H. Bessesen, Marie E. McDonnell, M. Hassan Murad, Uberto Pagotto, Donna H. Ryan, Christopher D. Still, Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 100, Issue 2, 1 February 2015, Pages 342–362, <https://doi.org/10.1210/jc.2014-3415>
  26. W. Timothy Garvey, MD, FACE; Jeffrey I. Mechanick, MD, FACP, FACE, FACN, ECNU; Elise M. Brett, MD, FACE, CNSC, ECNU; Alan J. Garber, MD, PhD, FACE; Daniel L. Hurley, MD, FACE5; Ania M. Jastreboff, MD, PhD; Karl Nadolsky, DO; Rachel Pessah-Pollack, MD; Raymond Plodkowski, MD; and Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines; American Association Of Clinical Endocrinologists And American College Of Endocrinology Comprehensive Clinical Practice Guidelines For Medical Care Of Patients With Obesity; *Endocrine Practice*, Volume 22 (Suppl 3) July 2016. <https://www.aace.com/files/final-appendix.pdf>
  27. Wegovy™ subcutaneous injection [prescribing information]. Novo Nordisk; Revised 6/2022. Accessed online: 1/3/2023.
  28. Beales PL, Elcioglu N, Woolf AS, *et al* New criteria for improved diagnosis of Bardet-Biedl syndrome: results of a population survey *Journal of Medical Genetics* 1999;36:437-446.
  29. Grunvald E, Shah R, Hernaez R, *et al*. AGA Clinical Practice Guideline on Pharmacological Interventions for Adults with Obesity *Gastroenterology* 2022; 163,5:1198-1225.
  30. Zepbound™ subcutaneous injection, tirzepatide subcutaneous injection. Eli Lilly and Company (per FDA), Indianapolis, IN, 2023. Accessed online November 2023
  31. National Heart, Lung, and Blood Institute (NHLBI). (2013). *Managing Overweight and Obesity in Adults: Systematic Evidence Review From the Obesity Expert Panel*. U.S. Department of Health and Human Services, National Institutes of Health. [Management of Overweight and Obesity in Adults: Guidelines From the Expert Panel, 2013](#)

## Pharmacy Management Drug Policy

### Weight-Related Comorbidities - Overweight, Obesity, & Cardiovascular Disease

#### **Addendum:**

#### **Guidelines for Comprehensive Weight Management Program**

This document outlines the minimum standards that will be applied in the evaluation of a comprehensive Weight Management Program.

#### **Purpose**

The proliferation and availability of weight management support programs without widespread evidence of value provides a challenge to our members and health care programs. The availability of the internet, with unlimited and untested offerings, numerous alternative health care approaches as well as a multitude of self-professed “experts”, demands establishment of a set of standards that can be applied consistently in the evaluation of these programs. This document describes the standards that will be applied in the evaluation of a comprehensive Weight Management Program for weight loss medications Wegovy, Xenical, Orlistat, Contrave, Saxenda, Zepbound and Qsymia.

#### **Weight Management Programs**

The Weight management program guidelines combine coverage of medication with participation in a “comprehensive weight management program”. The comprehensive program includes nutritional counseling, behavior modification and the importance of lifestyle changes, including exercise. The program provides individual assessment, coaching, and information and helps to develop an action plan and establish goals and process to achieve sustained and significant weight loss.

#### **Minimum Standards for a Weight Management program:**

The comprehensive weight management program must:

- Include diet modification, meal-planning and/or a nutrition education component
- Include an exercise component (at a minimum documentation of oversight/education to increase physical activity)
- Address Behavior modifications
- Provide intensive individual coaching or group sessions on an ongoing basis and regularly scheduled sessions. (Monthly minimum)
- Have the capability to provide verification of program enrollment and individual session attendance/participation.
- Weight management programs conducted via the internet or telehealth will be given consideration. However, these programs must still comply with the required components of a qualified comprehensive weight management program as described above.

#### **Programs not qualifying:**

- Stand-alone Internet based programs (such as calorie or step tracking apps; ex. myfitnesspal). Internet programs/apps can be used to supplement a qualifying comprehensive program as above.
- Isolated dietician visits or referrals.
- Exercise only based programs.
- Programs that offer only weekly enrollment commitments
- Nutritional supplement-oriented programs (e.g., Optifast).

#### **Review process**

- All programs will be reviewed against these criteria.
- The clinical team will contact the program and obtain information if needed