Pharmacy Management Drug Policy

SUBJECT: Weight-Related Comorbidities: Overweight, Obesity, & Cardiovascular Disease
POLICY NUMBER: PHARMACY-03
EFFECTIVE DATE: 02/2012
LAST REVIEW DATE: 6/01/2026

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

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☐ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ 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, phentermine/topiramate ER and orforglipron 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.

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) is a 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-1and GIP receptors are present in several areas of the brain involved in appetite regulation. Tirzepatide increases feelings of satiety and decreases hunger.

Foundayo (orforglipron) 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. Orforglipron increases feelings of satiety and decreases hunger.

The FDA has approved orlistat, naltrexone/bupropion ER, phentermine/topiramate ER, semaglutide, tirzepatide, orforglipron 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 injection and tablets 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. Wegovy injection has also been approved for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults. The indication for MASH is approved under accelerated approval based on improvement of MASH and fibrosis, Continued approval for this indication may be contingent upon the verification and description of a clinical benefit in a confirmatory trial.

The FDA has approved Zepbound to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity in combination with a reduced calorie diet and increased physical activity.

General Policy Criteria – For Contrave, phentermine-topiramate ER, Foundayo, Qsymia, Saxenda, liraglutide, 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, liraglutide, Wegovy (For Weight loss only), Zepbound, Foundayo, 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 injection, Saxenda and liraglutide 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/m²)
   OR
   B. Class 2 Obesity (BMI 35 to 39.9kg/m²) 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)
      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**
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. Current BMI must not be less than 18.5 kg/m^2.
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.

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. Current BMI must not be less than 18.5 kg/m^2.
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) **OR** use chart below: **AND**

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

	Male	Female
Age (in years)	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. Current BMI must not be below the 5% percentile standardized for age and sex.
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 and generic liraglutide specific criteria:

1. Quantity limits:
   a. Saxenda and liraglutide are limited to a total of 15 mL (5 pens) per 30-days.
   b. Saxenda and liraglutide are limited to a total of fourteen (14) 30-day supplies or five (5) 90-day supplies (or a combination of these) per 365 days.
   c. For new starts only, the first 6 fills of liraglutide will be limited to a 30-day supply or less.
2. Saxenda and liraglutide 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 (Exenatide, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro) **AND**
3. For new starts on Saxenda or liraglutide, must have documentation of a trial and failure of Foundayo, unless a documented contraindication is provided. Failure of Foundayo is defined as one of the following (a,b,or c):
   a. Failure to achieve ≥ 5% total weight loss from baseline after ≥ 6 months of therapy despite appropriate dose titration and adherence **OR**
   b. For members who initially achieved ≥5% total weight loss, failure to achieve additional weight loss or experiencing minimal weight loss (< 0.5% per month) after at least 3 months at the maximum tolerated maintenance dose, with both of the following (i and ii):
      i. Documented adherence to medication and lifestyle changes (e.g., increasing exercise, adjusting caloric intake, increasing dietary protein and fiber) **AND**
      ii. Provider attestation additional weight loss is clinically indicated **OR**
   c. Documentation of severe adverse effects to Foundayo
      i. Gastrointestinal (GI) adverse effects associated with GLP-1 receptor agonists are a common class effect. They are usually transient, typically starting during the dose-escalation period and generally resolving shortly after the maintenance dose is reached, and, in most cases, they are mild to moderate in severity. Managing GI adverse effects via gradual dose titration and lifestyle guidance will help to prevent unnecessary therapy discontinuation. Occurrence of mild to moderate GI symptoms is not considered a treatment failure

ii. The following gastrointestinal (GI) adverse effects are considered severe adverse effects
    1. Clinically significant nausea, vomiting, diarrhea, constipation, or abdominal pain that meet one of the following (a,b,c,or d):
        a. Persists for ≥4–8 weeks at a stable dose and provider attests patient has tried mitigation measures, including slower titration, dietary adjustments, and dose adjustment strategies
        b. Prevents escalation to a therapeutic or maintenance dose
        c. Necessitates repeated dose reductions without symptom resolution, resulting in an inability to achieve or sustain a clinically effective dose
        d. Requires the need for urgent medical evaluation, intravenous fluids, or hospitalization

4. For patients new to therapy, initial coverage duration is 4 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 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. Current BMI must not be less than 18.5 kg/m^2.
6. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
7. The maximum daily dose is 3mg subcutaneously once daily according to the prescribing information.

For Adolescents:

1. Must be 12-17 years of age **AND**
2. Must have body weight ≥60kg (~132lbs) **AND**
3. Must have an initial BMI corresponding to 30 kg/m2 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^2	
	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

4. Will not be approved for use in combination with any other GIP and/or GLP-1 receptor agonist (Exenatide, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro) **AND**
5. For patients new to therapy, initial coverage duration is 5 months. After the initial coverage period, recertification will be required every 6 months.
6. For patients continuing drug therapy (recertification):
    a. Upon recertification the patient must be utilizing the 2.4mg or 3mg dose as maintenance therapy.
    b. 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.
   c. For continued 6-month recertifications, patient must have maintained initial 1% weight loss **OR** has continued to lose weight. Current BMI must not be below the 5% percentile standardized for age and sex.
7. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
8. Note, the manufacturer recommends the following
   a. Maintenance dosage of SAXENDA and liraglutide 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 or liraglutide if the patient cannot tolerate the 2.4 mg dose.
   b. Dose escalation for pediatric patients may take up to 8 weeks.
   c. 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.

1. Quantity Limits:
   a. Injection:
      i. The quantity limit for all strengths (0.25mg, 0.5mg, 1mg, 1.7mg, 2.4mg, Wegovy HD 7.2 mg) 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.).
      ii. Wegovy injection is limited to a total of fourteen (14) 28-day supplies or five (5) 84-day supplies (or a combination of these) per 365 days.
   b. Tablets:
      i. The quantity limit for all strengths (1.5mg, 4mg, 9mg, 25mg) is 30 tablets per 30 days.
      ii. Wegovy tablet is limited to a total of fourteen (14) 30-day supplies or five (5) 90-day supplies (or a combination of these) per 365 days.
   c. For new starts only, the first 6 fills of Wegovy will be limited to a 30-day supply or less.
   d. For new starts on Wegovy HD 7.2mg, the first 3 fills will be limited to a 28-day supply or less.
2. Wegovy will not be approved for non-FDA approved diagnoses.

For noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis in adults:

1. On August 15, 2025, Wegovy injection received FDA approval for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults. Patients with a BMI ≥ 35kg/m^2 and qualifying comorbidity, which includes metabolic dysfunction-associated fatty liver disease (MAFLD), a spectrum of liver disease that includes MASH, are eligible for coverage under our existing weight management policy. Based on the Health Plan's assessment of the available clinical literature, coverage eligibility for MASH patients with a BMI < 35 is not supported. Therefore, for patients with a BMI < 35, even in the presence of MAFLD/MASH, use of Wegovy injection is considered not medically necessary based on the following evidence-based considerations:
   a. In the pivotal ESSENCE trial, which evaluated Wegovy injection for biopsy-confirmed MASH with stage F2–F3 fibrosis, fewer than 3% of participants had a BMI < 27. Moreover, the trial enrolled a population with a mean BMI of 34.6. As such, subgroup efficacy in non-obese or

overweight (BMI < 35) populations has not been established; therefore, there is insufficient evidence to support efficacy of Wegovy injection in patients with MASH who are not obese
   b. The trial's primary outcomes were based on biopsy-confirmed changes in steatohepatitis and fibrosis. It did not evaluate progression to cirrhosis, liver-related hospitalizations, or mortality. Long-term outcomes data are not expected until 2029.
   c. The Wegovy group experienced an average weight loss of 10.5%, and histologic improvements strongly correlate with weight reduction rather than a proven drug-specific anti-fibrotic effect.

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 (Exenatide, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro) **AND**
3. For new starts on Wegovy, must have documentation of a trial and failure of Foundayo, unless a documented contraindication is provided. Failure of Foundayo is defined as one of the following (a,b,or c):
   a. Failure to achieve ≥ 5% total weight loss from baseline after ≥ 6 months of therapy despite appropriate dose titration and adherence **OR**
   b. For members who initially achieved ≥5% total weight loss, failure to achieve additional weight loss or experiencing minimal weight loss (< 0.5% per month) after at least 3 months at the maximum tolerated maintenance dose, with both of the following (i and ii):
      i. Documented adherence to medication and lifestyle changes (e.g., increasing exercise, adjusting caloric intake, increasing dietary protein and fiber) **AND**
      ii. Provider attestation additional weight loss is clinically indicated **OR**
   c. Documentation of severe adverse effects to Foundayo
      i. Gastrointestinal (GI) adverse effects associated with GLP-1 receptor agonists are a common class effect. They are usually transient, typically starting during the dose-escalation period and generally resolving shortly after the maintenance dose is reached, and, in most cases, they are mild to moderate in severity. Managing GI adverse effects via gradual dose titration and lifestyle guidance will help to prevent unnecessary therapy discontinuation. Occurrence of mild to moderate GI symptoms is not considered a treatment failure
      ii. The following gastrointestinal (GI) adverse effects are considered severe adverse effects
         1. Clinically significant nausea, vomiting, diarrhea, constipation, or abdominal pain that meet one of the following (a,b,c,or d):
            a. Persists for ≥4–8 weeks at a stable dose and provider attests patient has tried mitigation measures, including slower titration, dietary adjustments, and dose adjustment strategies
            b. Prevents escalation to a therapeutic or maintenance dose
            c. Necessitates repeated dose reductions without symptom resolution, resulting in an inability to achieve or sustain a clinically effective dose
            d. Requires the need for urgent medical evaluation, intravenous fluids, or hospitalization
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 1.7 mg, 2.4mg or 7.2 mg injection **OR** 25mg tablet dose.

   i. Wegovy HD 7.2 mg is only indicated for patients who have demonstrated tolerability to the 2.4 mg injection dosage for a minimum of 4 weeks and for whom additional weight loss is clinically indicated.
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. Current BMI must not be less than 18.5 kg/m^2.

6. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
7. The maintenance dose of Wegovy is 1.7mg or 2.4mg injection once weekly (or 7.2 mg injection if indicated – see below) **OR** 25 mg tablet once daily, 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 injection and 1.5mg, 4mg and 9mg tablet dosages are initiation and escalation dosages and are not approved as maintenance dosages for chronic weight management.

Recommended Dosage for Wegovy Injection for Adults

Treatment	Weeks	Once-weekly Subcutaneous Dosage
Initiation	1 though 4	0.25 mg
Escalation	5 through 8	0.5 mg
	9 though 12	1 mg
	13 through 16	1.7 mg
Maintenance	17 and onward	1.7 mg or 2.4 mg (recommended)
	21 and onward	1.7 mg, 2.4 mg, or Wegovy HD 7.2 mg* (*Wegovy HD 7.2 mg is **ONLY** indicated for patients who have tolerated 2.4 mg for at least 4 weeks and clinically require additional weight loss)

Recommended Dosage of Wegovy Tablets for Adults

	Days	Once Daily Tablet Dosage
Starting Dosage	1 through 30	1.5 mg
Dosage Escalation	31 through 60	4 mg
	61 though 90	9 mg
Maintenance Dosage	91 and onward	25 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) **OR** use chart below: **AND**

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

	Male	Female
Age (in years)	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 will not be approved for Wegovy tablets or Wegovy HD 7.2 mg injection as these products are only indicated for use in adults.
4. Will not be approved for use in combination with any other GIP and/or GLP-1 receptor agonist (Exenatide, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro) **AND**
5. For patients new to therapy, initial coverage duration is 7 months. After the initial coverage period, recertification will be required every 6 months.
6. For patients continuing drug therapy (recertification):
    a. Upon recertification the patient must be utilizing the 1.7mg or 2.4mg injection 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. Current BMI must not be below the 5% percentile standardized for age and sex.
7. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
8. Note, the manufacturer recommends the following:
    a. Maintenance dosage of Wegovy injection 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/m²
3. Prescriber must attest Wegovy is 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, and 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 (Exenatide, 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).
10. Requests will not be approved for Wegovy HD 7.2 mg as this dosage is not indicated for cardiovascular risk reduction in patients with established cardiovascular disease.
11. Initial approval will be for 7 months. After the initial coverage period, recertification will be required every 6 months.
12. Upon recertification the patient must:
    a. Be utilizing the 2.4mg **OR** the 1.7mg injection **OR** 25mg tablet 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.
13. The maintenance dose of Wegovy is 2.4mg **OR** 1.7mg injection once weekly **OR** 25mg tablet once daily, 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.

Recommended Dosage for Wegovy Injection for Adults

Treatment	Weeks	Once-weekly Subcutaneous Dosage
Initiation	1 though 4	0.25 mg
Escalation	5 through 8	0.5 mg
	9 though 12	1 mg
	13 through 16	1.7 mg
Maintenance	17 and onward	1.7 mg or 2.4 mg (recommended)

Recommended Dosage of Wegovy Tablets for Adults

	Days	Once Daily Tablet Dosage
Starting Dosage	1 through 30	1.5 mg
Dosage Escalation	31 through 60	4 mg
	61 though 90	9 mg
Maintenance Dosage	91 and onward	25 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. Current BMI must not be less than 18.5 kg/m^2.
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

Zepbound (tirzepatide) specific criteria:

1. Coverage criteria apply to the Zepbound pens only.
    a. Zepbound vials and Kwikpens are not a covered benefit as the vial and Kwikpen are not available through any pharmacy channels. Patients will still have an alternative means to obtain Zepbound vials or Kwikpens through the LillyDirect access program.
2. Quantity Limits:
    a. The quantity limit for all strengths (2.5mg, 5mg, 7.5mg, 10mg, 12.5mg 15mg) is 2ml (4 pens) per 28 days.
    b. Zepbound is limited to a total of fourteen (14) 28-day supplies or five (5) 84-day supplies (or a combination of these) per 365 days.
    c. For new starts only, the first 6 fills of Zepbound will be limited to a 28-day supply or less.
    d. 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 account 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 maintaining 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 (Exenatide, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro) **AND**
6. For new starts on Zepbound, must have documentation of a trial and failure of Foundayo, unless a documented contraindication is provided. Failure of Foundayo is defined as one of the following (a,b,or c):
    a. Failure to achieve ≥ 5% total weight loss from baseline after ≥ 6 months of therapy despite appropriate dose titration and adherence **OR**
    b. For members who initially achieved ≥5% total weight loss, failure to achieve additional weight loss or experiencing minimal weight loss (< 0.5% per month) after at least 3 months at the maximum tolerated maintenance dose, with both of the following (i and ii):

i. Documented adherence to medication and lifestyle changes (e.g., increasing exercise, adjusting caloric intake, increasing dietary protein and fiber) **AND**
ii. Provider attestation additional weight loss is clinically indicated **OR**

c. Documentation of severe adverse effects to Foundayo
   i. Gastrointestinal (GI) adverse effects associated with GLP-1 receptor agonists are a common class effect. They are usually transient, typically starting during the dose-escalation period and generally resolving shortly after the maintenance dose is reached, and, in most cases, they are mild to moderate in severity. Managing GI adverse effects via gradual dose titration and lifestyle guidance will help to prevent unnecessary therapy discontinuation. Occurrence of mild to moderate GI symptoms is not considered a treatment failure
   ii. The following gastrointestinal (GI) adverse effects are considered severe adverse effects
      1. Clinically significant nausea, vomiting, diarrhea, constipation, or abdominal pain that meet one of the following (a,b,c,or d):
         a. Persists for ≥4–8 weeks at a stable dose and provider attests patient has tried mitigation measures, including slower titration, dietary adjustments, and dose adjustment strategies
         b. Prevents escalation to a therapeutic or maintenance dose
         c. Necessitates repeated dose reductions without symptom resolution, resulting in an inability to achieve or sustain a clinically effective dose
         d. Requires the need for urgent medical evaluation, intravenous fluids, or hospitalization

7. For patients new to therapy, initial coverage duration is 7 months. After the initial coverage period, recertification will be required every 6 months.
8. For patients continuing drug therapy (recertification):
   a. Upon recertification the patient must utilize 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. Current BMI must not be less than 18.5 kg/m^2.
9. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
10. 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.

Foundayo (orforglipron) specific criteria:

1. Quantity limits:
   a. The quantity limit for all strengths (0.8mg, 2.5mg, 5.5mg, 9mg, 14.5mg, and 17.2mg) is 30 tablets per 30 days.

   b. Foundayo is limited to a total of fourteen (14) 30-day supplies or five (5) 90-day supplies (or a combination of these) per 365 days.
   c. For new starts only, the first 6 fills of Foundayo will be limited to a 30-day supply or less.
2. Foundayo will not be approved for non-FDA approved diagnoses.
3. Member must be 18 years of age or older **AND**
4. Will not be approved for use in combination with any other GIP and/or GLP-1 receptor agonist (Exenatide, Victoza, Ozempic, Rybelsus, Trulicity and Mounjaro) **AND**
5. For patients new to therapy, initial coverage duration is 7 months. After the initial coverage period, recertification will be required every 6 months.
6. For patients continuing drug therapy (recertification):
   a. Upon recertification the patient must be utilizing the 5.5mg, 9mg, 14.5mg or 17.2mg 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. Current BMI must not be less than 18.5 kg/m2.
7. Demonstration of failed efficacy by not meeting the continuation criteria above will preclude future coverage of the same drug.
8. The maintenance dose of Foundayo is 5.5mg, 9mg, 14.5mg or 17.2 mg tablet once daily, and is titrated according to the following schedule and recommendations:
   a. Starting dosage is 0.8mg once daily.
   b. After at least 30 days, increase dosage to 2.5mg once daily.
   c. After at least 30 days on the 2.5 mg dosage, increase dosage to 5.5 mg once daily.
   d. Dosage may be increased to the next dosage level (9 mg, 14.5 mg, or 17.2 mg once daily) after at least 30 days on the current dosage, based on treatment response and tolerability.
   e. Maximum dosage is 17.2mg once daily.
   f. The 0.8mg and 2.5mg tablet dosages are initiation and escalation dosages and are not approved as maintenance dosages for chronic weight management.

Collective GLP-1 Agonist ang GIP/GLP-1 Agonist Quantity Limits:

These limits apply cumulatively across all GLP-1 agonist and GLP-1/GIP agonist products, regardless of indication (diabetes, weight management, or weight-related comorbid condition), product, or strength.

Claim Frequency Limit

- One claim for one GLP-1 agonist or GLP-1/GIP agonist product at one strength may be approved for each 28-day or 30-day supply
  - Extended-day supplies are evaluated as multiples of standard monthly treatments (e.g., an 84-day supply equals three 28-day supplies; a 90-day supply equals three 30-day supplies)
- Claims for multiple strengths of the same product or for different GLP-1 agonist or GLP-1/GIP agonist products within the same or overlapping dispensing period will not be permitted.
  - An exception may be considered when a patient is transitioning from one product to another or from one strength to another, provided that the previous product or strength is discontinued, and no further claims will be submitted for the discontinued therapy

Annual Day-Supply Limits

- Maximum of 14-28 or 30-day fills per rolling 365 days OR maximum of 5-84 or 90-day fills per rolling 365 days
    - When multiple day-supply durations are used, eligibility is determined based on the total number of days supplied.
- Annual day-supply limits are cumulative across all GLP-1 agonist and GLP-1/GIP agonist products and dispensing patterns.
- Switching between products, strengths, or day-supply durations does not reset or bypass cumulative annual day-supply limits.
- Eligibility for additional fills is restored only as previously dispensed day-supply amounts fall outside the rolling 365-day period.

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 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, Foundayo, Saxenda and liraglutide. 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 ≥ 25 kg/m^2 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:

Date:	Revision:
06/01/2026	Revised
04/13/2026	Revised
04/02/2026	Revised
02/05/2026	Revised
01/07/2026	Revised
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08/28/2025	Revised
08/27/2025	Revised
08/14/2025	Reviewed / P&T Committee Approval
07/30/2025	Revised
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
08/15/2024	Reviewed / P&T Committee Approval
08/05/2024	Revised
04/22/2024	Revised
04/11/2024	Revised
1/26/2024	Revised
1/17/2024	Revised
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11/29/2023	Revised
10/25/2023	Revised
10/10/2023	Revised
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8/15/2023	Revised
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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
8/2020	Revised
03/20	Revised
02/20	Revised
9/19	P&T Committee Approval
08/19	Revised
06/19	Reviewed
08/18	Revised
06/18	Revised
8/17	Revised
9/16	Revised
12/15	Revised
4/15	Revised
9/14	Revised
7/14	Revised
2/14	Revised
6/13	Revised
1/13	Revised
10/12	Revised
7/12	Revised
5/99	Created

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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