



Wellmark Blue Cross and Blue Shield is an Independent Licensee of the Blue Cross and Blue Shield Association.

## DRUG POLICY

# Drugs for Weight Loss Management

**(Note: Drugs for Weight Loss Management are a standard exclusion for most benefits. Prior authorization review for medical necessity only applies when the member's prescription drug benefit language includes coverage for weight loss products with prior authorization. Benefits are subject to the terms and conditions of the member's contract. Please contact Wellmark customer service at the number on the member's ID card with benefit questions.)**

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

The intent of the Drugs for Weight Loss Management drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines for those select plans with specific benefit language that allow coverage of drugs for weight loss management when prior authorization criteria is met.

### FDA-APPROVED INDICATIONS

#### Benzphetamine

Benzphetamine is indicated in the management of exogenous obesity as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or higher who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. The limited usefulness of agents of this class should be weighed against possible risks inherent in their use. Benzphetamine is indicated for use as monotherapy only.

#### Limitations of Use:

- The effect on cardiovascular morbidity and mortality has not been established.
- The safety and effectiveness of these agents in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

#### Contrave (naltrexone HCl and bupropion HCl extended release)

Contrave is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obese), or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)

#### Limitations of Use

- The effect of Contrave on cardiovascular morbidity and mortality has not been established.
- The safety and effectiveness of Contrave in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

#### Diethylpropion

Diethylpropion is indicated in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index of 30 kg/m<sup>2</sup> or higher and who have not responded to an appropriate weight reducing regimen (diet and/or exercise) alone. The usefulness of agents of this class should be measured against possible risk factors inherent in their use. Diethylpropion is indicated for use as monotherapy only.

#### Limitations of Use:

- The effect on cardiovascular morbidity and mortality has not been established.
- The safety and effectiveness of these agents in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

#### Phendimetrazine

Phendimetrazine tartrate extended-release capsules are indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of greater than or equal to 30 kg/m<sup>2</sup> or greater than or equal to 27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia) who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. The limited usefulness of agents of this class should be weighed against possible risks inherent in their use. Phendimetrazine tartrate is indicated for use as monotherapy only.

Phendimetrazine tartrate is indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or higher who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. The limited usefulness of agents of this class should be weighed against possible risks inherent in their use. Phendimetrazine tartrate is indicated for use as monotherapy only.

#### Limitations of Use:

- The effect on cardiovascular morbidity and mortality has not been established.
- The safety and effectiveness of these agents in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

#### Phentermine

Phentermine is indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification, and caloric restriction, in the management of exogenous obesity for patients with an initial body mass index greater than or equal to 30 kg/m<sup>2</sup>, or greater than or equal to 27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use.

#### Limitations of Use:

- The effect on cardiovascular morbidity and mortality has not been established.
- The safety and effectiveness of these agents in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

#### **Qsymia (phentermine and topiramate extended-release)**

Qsymia is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:

1. Adult patients with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obese), or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia
2. Pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex.

#### Limitations of Use

- The effect of Qsymia on cardiovascular morbidity and mortality has not been established.
- The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription and over-the-counter drugs and herbal preparations have not been established.

#### **Saxenda (liraglutide injection)**

Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:

1. Adult patients with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obese), or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)
2. Pediatric patients aged 12 years and older with body weight above 60 kg and an initial BMI corresponding to 30 kg/m<sup>2</sup> or greater for adults (obese) by international cut-offs (Cole Criteria)

#### Limitations of Use:

- Saxenda contains liraglutide and should not be coadministered with other liraglutide-containing products or with any other GLP-1 receptor agonist.
- The safety and effectiveness of Saxenda in pediatric patients with type 2 diabetes have not been established.
- The safety and effectiveness of Saxenda in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

#### **Wegovy (semaglutide injection)**

Wegovy is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in:

1. Adults with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obesity), or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)
2. Pediatric patients aged 12 years and older with an initial BMI at the 95<sup>th</sup> percentile or greater standardized for age and sex (obesity)

#### Limitations of Use

- Wegovy contains semaglutide and should not be coadministered with other semaglutide-containing products or with any other GLP-1 receptor agonist.

- The safety and effectiveness of Wegovy in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Wegovy has not been studied in patients with a history of pancreatitis

### **Xenical (orlistat)**

Xenical is indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet. Xenical is also indicated to reduce the risk for weight regain after prior weight loss. Xenical is indicated for obese patients with an initial body mass index (BMI)  $\geq 30$  kg/m<sup>2</sup> or  $\geq 27$  kg/m<sup>2</sup> in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

### **OFF-LABEL USE**

#### **Anti-Diabetic Medications**

Certain anti-diabetic medications (e.g., GLP-1 receptor agonists and combination GLP-1 receptor agonist and GIP receptor agonist) are sometimes prescribed off-label for weight loss. While these agents may support weight loss, none have an FDA approved indication for chronic weight management under the same brand name that is FDA approved for the treatment of Type 2 Diabetes.

## **POLICY**

### **Criteria for Approval**

Note: criteria only applies to select plans with specific benefit language to allow coverage of weight loss management drugs when prior authorization criteria is met.

- I. Benzphetamine products, diethylpropion products, phendimetrazine products, and phentermine products (excluding Qsymia) will be covered with prior authorization when the following criteria are met:
  - The patient has not received 3 months of therapy with the requested drug within the past 365 days  
**AND**
  - The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications  
**AND**
    - The patient has a body mass index (BMI) greater than or equal to 30 kg per square meter  
**OR**
    - The patient has a body mass index (BMI) greater than or equal to 27 kg per square meter AND has additional risk factors (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)
  - AND**
  - If the request is for phentermine it will not be used in a patient who is also using Fintepla (fenfluramine)  
**AND**
  - The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**Approval will be for 3 months (90 days) per year.**

- II. Contrave (naltrexone HCl and bupropion HCl extended release) will be covered with prior authorization when the following criteria are met:

- The patient has completed at least 4 months of therapy with the requested drug  
**AND**
  - The patient lost at least 5 percent of baseline body weight OR the patient has continued to maintain their initial 5 percent weight loss. Documentation is required for approval.  
**AND**
    - The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications  
**AND**
      - The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy  
**AND**
  - The patient has a body mass index (BMI) greater than or equal to 30 kg per square meter  
**OR**
    - The patient has a body mass index (BMI) greater than or equal to 27 kg per square meter AND has additional risk factors (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)  
**AND**
      - The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications  
**AND**
        - The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**Approval** will be for **4 months** for initial approval and **36 months** for requests for continuation.

III. Qsymia (phentermine and topiramate extended-release) will be covered with prior authorization when the following criteria are met:

- The requested drug will not be used in a patient who is also using Fintepla (fenfluramine) or in combination with another targeted weight loss agent for the requested indication  
**AND**
  - The patient has not completed at least 12 weeks of therapy with Qsymia 7.5 mg/46 mg or 15 mg/92 mg  
**AND**
    - The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy  
**AND**
      - The patient is 18 years of age or older  
**AND**
        - The patient has a body mass index (BMI) greater than or equal to 30 kilogram per square meter  
**OR**
          - The patient has a body mass index (BMI) greater than or equal to 27 kilogram per square meter AND has at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)

**OR**

- The patient is 12 to 17 years of age  
**AND**
  - The patient has an initial body mass index (BMI) in the 95<sup>th</sup> percentile or greater standardized for age and sex

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**OR**

- The patient has completed at least 12 weeks of Qsymia 15 mg/92 mg therapy

**AND**

- The patient lost at least 5 percent of baseline body weight (for adults) or the patient experienced a reduction of at least 5 percent of baseline body mass index (BMI) (for pediatrics). Documentation is required for approval.

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The requested drug will not be used in a patient who is also using Fintepla (fenfluramine) or in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient has continued to maintain their initial 5 percent weight loss (for adults) or the patient has continued to maintain their initial reduction of 5 percent of baseline body mass index (BMI) (for pediatrics). Documentation is required for approval.

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The requested drug will not be used in a patient who is also using Fintepla (fenfluramine) or in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient has completed at least 12 weeks of Qsymia 7.5 mg/46 mg therapy

**AND**

- The patient lost at least 3 percent of baseline body weight (for adults) or the patient experienced a reduction of at least 3 percent of baseline body mass index (BMI) (for pediatrics). Documentation is required for approval.

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The requested drug will not be used in a patient who is also using Fintepla (fenfluramine) or in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient has continued to maintain their initial 3 percent weight loss (for adults) or the patient has continued to maintain their initial reduction of 3 percent of baseline body mass index (BMI) (for pediatrics). Documentation is required for approval.

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The requested drug will NOT be used in a patient who is also using Fintepla (fenfluramine) or in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient has not lost at least 3 percent of baseline body weight (for adults) or the patient has not experienced a reduction of at least 3 percent of baseline body mass index (BMI) (for pediatrics) OR the patient has not continued to maintain their initial 3 percent weight loss (for adults) or their initial reduction of 3 percent BMI (for pediatrics)

**AND**

- The patient's dose has been escalated to Qsymia 11.25 mg/69 mg and will follow the appropriate dose escalation schedule. Documentation is required for approval.

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The requested drug will NOT be used in a patient who is also using Fintepla (fenfluramine) or in combination with another targeted weight loss agent for the requested indication

**Approval** will be for **3 months** for initial approval and **36 months** for requests for continuation.

IV. Saxenda (liraglutide injection) will be covered with prior authorization when the following criteria are met:

- The patient is 18 years of age or older

**AND**

- The patient has completed at least 16 weeks of therapy with the requested drug AND
  - The patient lost at least 5 percent of baseline body weight OR the patient has continued to maintain their initial 5 percent weight loss. Documentation is required for approval.

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy

**AND**

- The patient has a body mass index (BMI) greater than or equal to 30 kg per square meter

**OR**

- The patient has a body mass index (BMI) greater than or equal to 27 kg per square meter AND has additional risk factors (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient is 12 to 17 years of age

**AND**

- The patient has completed at least 12 weeks of therapy on the maintenance dose of the requested drug **AND**
    - The patient has at least 1 percent reduction in body mass index (BMI) from baseline **OR** the patient has continued to maintain their initial 1 percent reduction in BMI from baseline. Documentation is required for approval.
- AND**
- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications
- AND**
- The patient will **NOT** be using the requested agent in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy
- **AND**
    - The patient has a body weight above 60 kilograms
- AND**
- The patient has an initial body mass index (BMI) corresponding to 30 kilograms per square meter or greater for adults by international cut-off points based on the Cole Criteria
- AND**
- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications
- AND**
- The patient will **NOT** be using the requested agent in combination with another targeted weight loss agent for the requested indication

**Approval** will be for **4 months** for initial approval (**5 months** for pediatric patients) and **12 months** for requests for continuation.

V. Wegovy (semaglutide injection) will be covered with prior authorization when the following criteria are met:

- The patient is 18 years of age or older

**AND**

- The patient has completed at least 3 months of therapy with the requested drug at a stable maintenance dose

**AND**

- The patient lost at least 5 percent of baseline body weight **OR** the patient has continued to maintain their initial 5 percent weight loss. Documentation is required for approval.

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The patient will **NOT** be using the requested agent in combination with another targeted weight loss agent for the requested indication

**OR**



- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy

**AND**

- The patient has a body mass index (BMI) greater than or equal to 30 kg per square meter

**OR**

- The patient has a body mass index (BMI) greater than or equal to 27 kg per square meter AND has at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity and behavioral modifications

**AND**

- The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient is 12 to 17 years of age

**AND**

- The patient has completed at least 3 months of therapy with the requested drug at a stable maintenance dose

**AND**

- The patient has at least 5 percent reduction in body mass index (BMI) from baseline OR the patient has continued to maintain their initial 5 percent reduction in BMI from baseline. Documentation is required for approval.

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy

**AND**

- The patient has an initial BMI at the 95<sup>th</sup> percentile or greater standardized for age and sex

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity and behavioral modifications

**AND**

- The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**Approval** will be for **7 months** for initial approval and **12 months** for requests for continuation.

VI. Xenical (orlistat) will be covered with prior authorization when the following criteria are met:

- The patient has completed at least 6 months of therapy with the requested drug AND
  - The patient lost at least 5 percent of baseline body weight OR the patient has continued to maintain their initial 5 percent weight loss. Documentation is required for approval.

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy

**AND**

- The patient has a body mass index (BMI) greater than or equal to 30 kg per square meter

**OR**

- The patient has a body mass index (BMI) greater than or equal to 27 kg per square meter AND has additional risk factors (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity and behavioral modifications

**AND**

- The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**Approval will be for 12 months.**

VII. The Off-Label use of anti-diabetic medications for chronic weight management will be covered with prior authorization when the following criteria are met:

- The patient is 18 years of age or older

**AND**

- The patient has completed at least 3 months of therapy with the requested drug at a stable maintenance dose

**AND**

- The patient lost at least 5 percent of baseline body weight (at least 10 percent for Mounjaro) OR the patient has continued to maintain their initial 5 percent weight loss (10 percent for Mounjaro). Documentation is required for approval.

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy

**AND**

- The patient has a body mass index (BMI) greater than or equal to 30 kg per square meter

**OR**

- The patient has a body mass index (BMI) greater than or equal to 27 kg per square meter AND has at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia)

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity and behavioral modifications

**AND**

- The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient is 12 to 17 years of age

**AND**

- The patient has completed at least 3 months of therapy with the requested drug at a stable maintenance dose

**AND**

- The patient has at least 5 percent reduction in body mass index (BMI) (at least 10 percent for Mounjaro) from baseline OR the patient has continued to maintain their initial 5 percent reduction in BMI from baseline (10 percent for Mounjaro). Documentation is required for approval.

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**OR**

- The patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy

**AND**

- The patient has an initial BMI at the 95<sup>th</sup> percentile or greater standardized for age and sex

**AND**

- The patient is currently on and will continue to be on a weight loss regimen of a reduced calorie diet, increased physical activity, and behavioral modifications

**AND**

- The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication

**Approval** will be for **8 months** for initial approval and **12 months** for requests for continuation.

The aforementioned drugs are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Strength + Dosage Form	Quantity Limit	Days Supply
Benzphetamine HCl	25 mg tab	180 tabs	30 days
	50 mg tab	90 tabs	30 days

Contrave (naltrexone HCl-bupropion HCl)	8-90 mg ER 12 HR tab	120 tabs	30 days
Diethylpropion HCl	25 mg tab	120 tabs	30 days
	75 mg ER tab	30 tabs	30 days
Mounjaro (tirzepatide)	All strengths	4 pens	28 days
Ozempic (semaglutide)	All strengths	1 pen	28 days
Phendimetrazine Tartrate	35 mg tab	180 tabs	30 days
	105 mg ER 24 HR cap	30 caps	30 days
Phentermine	8 mg tabs	90 tabs	30 days
	15 mg caps	30 caps	30 days
	30 mg caps	30 caps	30 days
	37.5 mg caps	30 caps	30 days
	37.5 mg tabs	30 tabs	30 days
Qsymia (phentermine HCl-topiramate)	3.75-23 mg ER 24 HR cap	30 caps	30 days
	7.5-46 mg ER 24 HR caps	30 caps	30 days
	11.25-69 mg ER 24 HR caps	30 caps	30 days
	15-92 mg ER 24 HR caps	30 caps	30 days
Rybelsus (semaglutide)	3 mg tabs	30 tabs	30 days
	7 mg tabs	30 tabs	30 days
	14 mg tabs	30 tabs	30 days
Saxenda (liraglutide)	18 mg/3 mL soln Pen-Inj	5 pens	30 days

Trulicity (dulaglutide)	All strengths	4 pens	28 days
Victoza (liraglutide)	18 mg/3 mL soln Pen-Inj	3 pens	28 days
Wegovy (semaglutide)	All strengths	4 pens	28 days
Xenical (orlistat)	120 mg caps	90 caps	30 days

## CLINICAL RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Guidelines state that the purpose of weight loss and weight maintenance is to reduce health risk. Weight loss programs should begin with a basic weight loss regimen consisting of a reduced-calorie diet and increased physical activity. The major role of medications is to help with patient compliance to a weight loss plan. Therefore, drugs should be used as part of a comprehensive weight loss program and should never be used without concomitant lifestyle modification. Drugs may be used as an adjunct to diet and physical activity for patients with a BMI that is greater than or equal to 30 kg/m<sup>2</sup> or greater than or equal to 27 kg/m<sup>2</sup> if other risk factors are present (e.g., hypertension, diabetes, dyslipidemia, sleep apnea, cardiovascular disease).

Benzphetamine products, diethylpropion products, phendimetrazine products, and phentermine products  
Anorectics are indicated as a short-term (a few weeks) adjunct to a reduced-calorie diet and increased physical activity, in the management of exogenous obesity for patients with an initial body mass index greater than or equal to 30 kg/m<sup>2</sup> or greater than or equal to 27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use.

Historically, the FDA announced the withdrawal of fenfluramine and dexfenfluramine (Fen-Phen) due to evidence about significant side effects associated with these products. Fenfluramine and dexfenfluramine are the likely cause of heart valve problems of the type that prompted FDA's two earlier warnings concerning "fen-phen," a combination of fenfluramine and phentermine. "Fen-phen" had been widely used off-label for the long-term management of obesity. In 2020, Fintepla (fenfluramine) was FDA-approved for Dravet syndrome. Due to well documented potential for serious adverse effects of the concurrent use of phentermine and fenfluramine, phentermine should not be used in a patient who is also using Fintepla (fenfluramine).

Sympathomimetic amine anorectic drugs have a narrow FDA labeling which reflects on the importance of prevention of inappropriate usage. The FDA approved indication for these agents is for short term treatment only. The safety of long-term anorexiant therapy has not been established conclusively beyond 12 weeks of administration. Therefore, coverage will be limited to a total of 3 months per year of each of the following: benzphetamine, diethylpropion, phendimetrazine or phentermine products.

### Contrave

Contrave is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obese), or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia). The safety and efficacy of coadministration of Contrave with other products intended for weight loss including prescription drugs, over-the-counter drugs, and herbal preparations have not been established. The effect of Contrave on cardiovascular morbidity and mortality has not been established.

Contrave will be approved initially for 4 months to allow for dose escalation to the maintenance dosage and 12 weeks of maintenance therapy. For renewal after 4 months of Contrave therapy, the patient must have lost at least 5% of baseline body weight or has continued to maintain their initial 5 percent weight loss. If a patient has not lost at least 5% of baseline body weight, Contrave should be discontinued as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.<sup>1</sup>

The optimal duration of treatment is unclear. Considering that drug discontinuation invariably leads to weight regain, if clinically significant weight loss is achieved, longer courses of treatment are reasonable to consider after the benefits and risks of treatment are re-reviewed with the patient and lack of long-term data is acknowledged.

### Qsymia

Qsymia is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obese), or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia. The effect of Qsymia on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription and over-the-counter drugs and herbal preparations have not been established.

Qsymia is to be taken once daily in the morning. Treatment should begin with Qsymia 3.75 mg/23 mg daily for 14 days. After 14 days, it is recommended to increase the dose to Qsymia 7.5 mg/46 mg. The patient should be evaluated at 12 weeks. If the patient has not lost 3 percent of baseline body weight on 7.5 mg/46 mg, Qsymia should be discontinued or the dose should be escalated as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss at the Qsymia 7.5 mg/46 mg dose. The dose should be escalated (if necessary), to Qsymia 11.25 mg/69 mg daily for 14 days, followed by Qsymia 15 mg/92 mg daily. The patient should then be evaluated after 12 weeks. If the patient has not lost at least 5 percent of baseline body weight, Qsymia treatment should be discontinued. Qsymia 3.75 mg/23 mg and Qsymia 11.25 mg/69 mg are for titration purposes only.

For renewal after 12 weeks of therapy, the patient must have lost at least 5 percent of their baseline body weight on the Qsymia 15 mg/92 mg daily dose or has continued to maintain their initial 5 percent weight loss. For renewal after 12 weeks of therapy, the patient must have lost at least 3 percent of their baseline body weight on the Qsymia 7.5 mg/46 mg dose or has continued to maintain their initial 3 percent weight loss. The duration of approval for continuation of therapy will be 12 months.

It is recommended that therapy be discontinued after 12 weeks if the patient does not meet this goal, as it is unlikely that the patient will be able to achieve and sustain clinically meaningful weight loss with continued treatment. Therefore, the duration of approval is 3 months for patients new to therapy or patients escalating the dose to Qsymia 11.25 mg/69 mg.

The optimal duration of treatment is unclear. Considering that drug discontinuation invariably leads to weight regain, if clinically significant weight loss is achieved, longer courses of treatment are reasonable to

consider after the benefits and risks of treatment are reviewed with the patient and lack of long-term data is acknowledged.

### Saxenda

Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients with a body weight above 60 kg and an initial BMI corresponding to 30 kg/m<sup>2</sup> or greater for adults (obese) by international cut-offs (Cole Criteria). Saxenda contains liraglutide and should not be coadministered with other liraglutide-containing products or with any other GLP-1 receptor agonist. The safety and effectiveness of Saxenda in pediatric patients with type 2 diabetes have not been established. The safety and effectiveness of Saxenda in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

Evaluate the change in body weight for adults 16 weeks after initiating Saxenda and discontinue Saxenda if the patient has not lost at least 4% of baseline body weight, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment. Evaluate the change in pediatric patients in BMI after 12 weeks on the maintenance dose and discontinue Saxenda if the patient has not had a reduction in BMI of at least 1% from baseline, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

For adult renewal after 16 weeks of Saxenda therapy, the patient must have lost at least 4% of baseline body weight or have continued to maintain their initial 4 percent weight loss. It is recommended that Saxenda therapy be discontinued after 16 weeks if the patient did not meet this goal, as it is unlikely that the patient will be able to achieve and sustain clinically meaningful weight loss with continued treatment.<sup>1</sup> Therefore, the duration of approval is 4 months for adult patients new to therapy.

For pediatric renewal after 20 weeks of Saxenda therapy, the patient must have at least 1 percent reduction in BMI from baseline or the patient has continued to maintain their initial 1 percent reduction in BMI from baseline. Dose escalation for pediatric patients may take up to 8 weeks until the maintenance dose is achieved. It is recommended that Saxenda therapy be discontinued after 12 weeks on the maintenance dose, if the patient did not meet this goal, as it is unlikely that the patient will be able to achieve and sustain clinically meaningful weight loss with continued treatment.<sup>1</sup> Therefore, the duration of approval is 5 months for pediatric patients new to therapy.

The International Obesity Task Force BMI Cut-offs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (Cole Criteria) shows a corresponding BMI for patients 12 years of age to 17.5 years of age that is equal to a 30 kg/m<sup>2</sup> BMI for adults. Therefore, a patient must be 18 years of age or older to be approved as an adult.

The optimal duration of treatment is unclear. Considering that drug discontinuation invariably leads to weight regain, if clinically significant weight loss is achieved, longer courses of treatment are reasonable to consider after the benefits and risks of treatment are reviewed again with the patient and lack of long-term data is acknowledged.

### Wegovy

Wegovy is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obese), or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) and pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity). The safety and efficacy of coadministration of Wegovy with other products intended for weight loss including prescription drugs, over-the-counter drugs, and herbal preparations have not been established.

The Endocrine Society Clinical Practice Guideline states that if a patient's response to a weight loss medication is deemed effective (weight loss at least 5% of body weight at 3 months) and safe, it is recommended that the medication be continued. If deemed ineffective (weight loss less than 5% at 3 months) or if there are safety or tolerability issues at any time, it is recommended that the medication be discontinued and alternative medications or referral for alternative treatment. The American Heart Association Guideline for the Management of Overweight and Obesity in Adults recommends that overweight and obese individuals who would benefit from weight loss participate for at least 6 months in a comprehensive lifestyle program that assists participants in adhering to a lower-calorie diet and in increasing physical activity through the use of behavioral strategies.

Wegovy will be approved initially for 7 months to allow for dose escalation (16 weeks) to the maintenance dosage and 12 weeks of maintenance therapy if the patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy. For renewal after 7 months of Wegovy therapy, the patient must have lost at least 5% of baseline body weight or has continued to maintain their initial 5 percent weight loss. If a patient has not lost at least 5% of baseline body weight, Wegovy should be discontinued as it is recommended that the medication be discontinued and alternative medications or referral for alternative treatment be initiated.

The optimal duration of treatment is unclear. Considering that drug discontinuation invariably leads to weight regain, if clinically significant weight loss is achieved, longer courses of treatment are reasonable to consider after the benefits and risks of treatment are re-reviewed with the patient and lack of long-term data is acknowledged.

#### Xenical

Xenical is indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet. Xenical is also indicated to reduce the risk for weight regain after prior weight loss. Xenical is indicated for obese patients with an initial body mass index (BMI) greater than or equal to 30 kg/m<sup>2</sup> or greater than or equal to 27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

The National Heart, Lung, and Blood Institute recommends the short-term goal of weight-loss therapy should be an approximately 5 to 10 percent loss or 1 to 2 lb per week of body weight from baseline during the initial six months of therapy. If no improvement in BMI after diet and exercise consider initiation of Xenical under care of an experienced physician for 6-12 months. Use of Xenical was associated with a significantly greater decrease in BMI and body weight from baseline after 1 year of treatment; absolute BMI was also lower in the Xenical treatment group.

Clinical trials for up to four years duration have shown that Xenical improves cardiovascular risk factors and reduces diabetes incidence in high-risk individuals, thus it may be especially useful in patients at high risk for developing type 2 diabetes, with high LDL-cholesterol concentrations, or with pre-existing cardiovascular disease. Of the patients who completed 1 year of treatment, 57% of the patients treated with Xenical (120 mg three times a day) and 31% of the placebo-treated patients lost at least 5% of their baseline body weight. Xenical treatment is safe and well tolerated over 4 years of treatment.

Therefore, initial requests will be approved for 12 months and long-term use of Xenical will be considered for patients who demonstrate continued weight loss or maintenance of original weight loss. For renewal after at least 6 months of therapy, the patient must have lost at least 5% of their baseline body weight or has continued to maintain their initial 5 percent weight loss.



The optimal duration of treatment is unclear. Considering that drug discontinuation invariably leads to weight regain, if clinically significant weight loss is achieved, longer courses of treatment are reasonable to consider after the benefits and risks of treatment are reviewed again with the patient and lack of long-term data is acknowledged.

### Anti-Diabetic Medications

GLP-1 receptor agonists that are FDA approved for Type 2 Diabetes management may be utilized off-label for weight loss as mean body weight reductions are reported as secondary outcomes in the GLP-1 receptor agonist's respective clinical trials. Most notably, Ozempic 1 mg monotherapy resulted in a mean baseline body weight change of -4.7 kg, Victoza 1.8 mg monotherapy produced an adjusted mean change in baseline body weight of -2.5 kg, and Trulicity 1.5 mg monotherapy resulted in a mean baseline body weight change of -2.3 kg.

Mounjaro (tirzepatide), a GLP-1 receptor agonist and GIP receptor agonist, is currently approved for Type 2 Diabetes by lowering glucose levels, enhancing glucose-dependent insulin secretion, slowing gastric emptying, and reducing postprandial glucagon and food intake. Due to its multifaceted mechanism of action, Mounjaro is commonly prescribed off-label for weight loss. An approved weight management indication is anticipated considering the positive clinical trial results. Participants in the trial were administered Mounjaro along with lifestyle interventions for 72 weeks (20 weeks for dose escalation) at which point a statistically significant mean change in weight of up to -20% in the tirzepatide groups versus -3% in the placebo group. Over 85% of patients in the Mounjaro treatment arm achieved a weight reduction of 5% or more by the conclusion of the trial.

Therefore, initial requests would be for 8 months to allow for dose escalation (20 weeks for Mounjaro) to the maintenance dosage and 12 weeks of maintenance therapy if the patient has participated in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing follow-up for at least 6 months prior to using drug therapy. For renewal after 8 months of off-label therapy with a GLP-1 receptor agonist or Mounjaro, the patient must have lost at least 5% (10% for Mounjaro considering the statistically significant clinical trial results) of baseline body weight or has continued to maintain their initial 5% (10% for Mounjaro) weight loss. If a patient has not lost at least 5% (10% for Mounjaro) of baseline body weight, off-label treatment with these agents should be discontinued as it is recommended that the medication be discontinued and alternative medications or referral for alternative treatment be initiated.

The optimal duration of treatment is unclear. Considering that drug discontinuation invariably leads to weight regain, if clinically significant weight loss is achieved, longer courses of treatment are reasonable to consider after the benefits and risks of treatment are re-reviewed with the patient and lack of long-term data is acknowledged.

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