Drugs for Weight Loss Management

(Note: Drugs for weight loss management or weight related comorbidities are a standard exclusion for most benefit plans. When the member's prescription drug benefit language includes coverage for weight loss products, prior authorization review for medical necessity will be applied. 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 or for weight related comorbidities 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^2 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.

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^2 or greater (obese), or 27 kg/m^2 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^2 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.

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^2 or greater than or equal to 27 kg/m^2 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^2 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.

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^2, or greater than or equal to 27 kg/m^2 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.

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^2 or greater (obese), or 27 kg/m^2 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/m2 or greater (obese), or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)
2. Pediatric patients aged 12 years and older with body weight above 60 kg and an initial BMI corresponding to 30 kg/m2 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 in combination with a reduced calorie diet and increased physical activity:

1. 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
2. To reduce excess body weight and maintain weight reduction long term in:
   a. Adults and pediatric patients aged 12 years and older with obesity
   b. Adults with overweight in the presence of at least one weight-related comorbid condition
3. 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

Limitations of Use

- Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended.

Wegovy HD (semaglutide injection)

Wegovy is indicated in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition

Limitations of Use

- Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended.

Wegovy (semaglutide tablet)

Wegovy is indicated in combination with a reduced calorie diet and increased physical activity:

1. 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
2. To reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition

Limitations of Use

- Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended.

Zepbound (tirzepatide injection)
Zepbound is indicated in combination with a reduced calorie diet and increased physical activity:
1. To reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition
2. To treat moderate to severe obstructive sleep apnea in adults with obesity

Limitations of Use
- Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.

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) ≥30 kg/m^2 or ≥27 kg/m^2 in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

POLICY

Required Documentation
Submission of the following information is necessary to initiate the prior authorization review.
- Initial requests and continuation requests:
  - Chart notes or medical record documentation of Body Mass Index (BMI)
  - Chart notes or medical record documentation of weight-related comorbid condition, if applicable.
  - Chart notes, medical record documentation, or claims history supporting established cardiovascular disease (i.e., previous myocardial infarction, previous stroke, or symptomatic peripheral arterial disease), standard of care treatment of cardiovascular disease (i.e., antiplatelet, lipid-lowering, antihypertensive).

  Chart notes or medical records documenting clinical findings supporting the diagnosis of metabolic dysfunction-associated steatohepatitis (MASH), if applicable.

Exclusions
Requests for Wegovy or Zepbound for patients with type 2 diabetes mellitus as a comorbid, weight-related condition are excluded from coverage. Resubmit request for a GLP-1 Receptor Agonists or GIP-GLP-1 Receptor Agonists that is FDA-approved for patients with type 2 diabetes mellitus.

Criteria for Approval
Note: criteria only applies to select plans with specific benefit language to allow coverage of drugs for weight loss management or for weight related comorbidities 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 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 baseline body mass index (BMI) greater than or equal to 30 kg per square meter

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

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

OR

- The patient has a baseline 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 95th 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 baseline body mass index (BMI) greater than or equal to 30 kg per square meter

    OR

  - The patient has a baseline 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 an initial 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 **6 months** for initial approval and **12 months** for requests for continuation.

V. Wegovy (semaglutide injection), Wegovy HD (semaglutide injection), and Wegovy (semaglutide tablet) 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 baseline body mass index (BMI) greater than or equal to 30 kg per square meter

OR

- The patient has a baseline body mass index (BMI) greater than or equal to 27 kg per square meter AND one of the following:
    - The patient has at least one weight related comorbid condition (e.g., hypertension or dyslipidemia)

    OR

    - The patient has established cardiovascular disease as defined by previous myocardial infarction, previous stroke, or symptomatic peripheral arterial disease (i.e., intermittent claudication with ankle-brachial index <0.85 at rest, peripheral arterial revascularization procedure, or amputation due to atherosclerotic cardiovascular disease). Documentation is required for approval.

      AND

      The patient is receiving and will continue standard of care treatment of cardiovascular disease including a drug from each of the following therapeutic classes: antiplatelet (e.g., aspirin, P2Y12 receptor blocker), lipid-lowering (e.g., statin, ezetimibe, PCSK0 inhibitors), antihypertensive (e.g., beta-blocker, angiotensin converting enzyme inhibitors or angiotensin receptor blockers) unless the patient has had an inadequate response, intolerance, documented contraindication, or medically justifiable reason to preclude use of all medications in any or all of the above therapeutic classes.. Documentation is required for approval.

      AND

      The patient does not have a diagnosis of diabetes mellitus or pancreatitis within 180 days prior to the request

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 **6 months** for initial approval for weight loss and cardiovascular risk reduction.
Approval will be for **12 months** for requests for continuation.

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

- The member is 12 to 17 years of age

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

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

OR

- The member 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 member has an initial BMI at the 95th percentile or greater standardized for age and sex

  AND
  - The member 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 **6 months** for initial approval for weight loss.
Approval will be for **12 months** for requests for continuation.

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

- The member has a diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) confirmed by one of the following:
  - Liver biopsy

  OR
  - FAST [(FibroScan-aspartate aminotransferase (AS))

  OR
  - MAST [derived from magnetic resonance imaging-proton density fat fraction, magnetic resonance elastography (MRE), and AST]

  OR
  - MEFIB [MRE combined with fibrosis-4 index (FIB-4)]

AND

- The requested medication is being prescribed by or in consultation with a gastroenterologist, hepatologist, cardiometabolic specialist or primary care physician in consultation with any of the listed specialists.

OR

- Member is requesting the medication for continuation of therapy for MASH and has achieved or maintained a positive clinical response to the requested drug (e.g., improvement in liver function such as reduction in alanine aminotransferase [ALT], reduction of liver fat content by imaging such as magnetic resonance imaging-protein density fat fraction [MRI-PDFF] or FibroScan controlled attenuation parameter [CAP])

AND

- The member does not have evidence of cirrhosis, hepatic decompensation or hepatocellular carcinoma

AND

- The requested medication will be used in conjunction with health lifestyle modifications (e.g. dietary or caloric restriction, exercise, behavioral support, community-based program).

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

VIII. 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 baseline body mass index (BMI) greater than or equal to 30 kg per square meter

  OR
  - The patient has a baseline 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**.

IX. Zepbound (tirzepatide 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 baseline body mass index (BMI) greater than or equal to 30 kg per square meter

OR

- The patient has a baseline 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, dyslipidemia, or cardiovascular disease)

OR

- The patient is requesting the medication for the primary indication of Obstructive Sleep Apnea (OSA) and has a baseline body mass index (BMI) greater than or equal to 27 kg per square meter

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 **6 months** for initial approval and **12 months** for requests for continuation.

Other

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

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

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
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
Saxenda (liraglutide)	18 mg/3 mL soln Pen-Inj	5 pens	30 days
Wegovy (semaglutide injection)	All strengths	4 pens	28 days

Wegovy (semaglutide tablet)	All strengths	30 tabs	30 days
Xenical (orlistat)	120 mg caps	90 caps	30 days
Zepbound (tirzepatide)	All strengths	4 pens	28 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 for those select plans with specific benefit language that allow coverage of drugs for weight loss management or for weight related comorbidities when prior authorization criteria is met. 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^2 or greater than or equal to 27 kg/m^2 if other risk factors are present (e.g., hypertension, 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^2 or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension or 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^2 or greater (obese), or 27 kg/m^2 or greater (overweight) in the presence of at least one weight related comorbid condition (e.g., hypertension 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% 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.

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^2 or greater (obese), or 27 kg/m^2 or greater (overweight) in the presence of at least one weight related comorbidity such as hypertension or dyslipidemia. Qsymia is also indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex. 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% 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% 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% of their baseline body weight on the Qsymia 15 mg/92 mg daily dose or has continued to maintain their initial 5% weight loss. For renewal after 12 weeks of therapy, the patient must have lost at least 3% of their baseline body weight on the Qsymia 7.5 mg/46 mg dose or has continued to maintain their initial 3% 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 adult patients with an initial body mass index (BMI) of 30 kg/m2 or greater (obese), or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension or dyslipidemia). Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients age 12 years and older with a body weight above 60 kg and an initial BMI corresponding to 30 kg/m2 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 5% of baseline body weight or have continued to maintain their initial 5% 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. The duration of approval is 6 months for adult patients new to therapy.

For pediatric renewal after 20 weeks of Saxenda therapy, the patient must have at least 1% reduction in BMI from baseline or the patient has continued to maintain their initial 1% 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. The duration of approval is 6 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/m2 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 to reduce excess body weight and maintain weight reduction long term in adult and pediatric patients age 12 years and older

with obesity and adults with overweight in the presence of at least one weight-related comorbid condition (e.g., hypertension or dyslipidemia) and. Wegovy is indicated as an adjunct to a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (e.g., cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight. The safety and efficacy of coadministration of Wegovy with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended.

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 6 months to allow for dose escalation to the maintenance dosage and 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 6 months of Wegovy therapy, the patient must have lost at least 5% of baseline body weight or has continued to maintain their initial 5% 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.

Zepbound

Zepbound is indicated as an adjunct to a reduced calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, obstructive sleep apnea, or cardiovascular disease). Zepbound is indicated as an adjunct to a reduced calorie diet and increased physical activity to treat moderate to severe obstructive sleep apnea in adults with obesity. The safety and efficacy of coadministration of Zepbound with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.

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.

Zepbound will be approved initially for 6 months to allow for dose escalation and 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 6 months of Zepbound therapy, the patient must have lost at least 5% of baseline body weight or has continued to maintain their initial 5% weight loss. If a patient has not lost at least 5% of baseline body weight, Zepbound 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^2 or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., hypertension, dyslipidemia).

Clinical trials have shown that Xenical improves cardiovascular risk factors and reduces diabetes incidence in high-risk individuals, and therefore may be especially useful in patients at high risk for developing type 2 diabetes, patients with high LDL-cholesterol concentrations, and/or patients 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 was deemed 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% 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.

REFERENCES

- Adipex-P [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; March 2020.
- Benzphetamine [package insert]. East Brunswick, NJ: Avet Pharmaceuticals Inc; December 2019.
- Diethylpropion [package insert]. Philadelphia, PA: Lannett Company, Inc.; December 2019.
- Phendimetrazine [package insert]. Northvale, NJ: Elite Laboratories , Inc.; January 2019.
- Phendimetrazine extended-release [package insert]. Langhorne, PA: Virtus Pharmaceuticals, LLC.; February 2020.
- Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed June 2021.
- Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed June 2021.
- Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 2, 1 February 2015, Pages 342–362. https://academic.oup.com/jcem/article/100/2/342/2813109. Accessed June 28, 2021.

- Jensen MD, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *Circulation.* 2013; 129:S102–S138
- FDA Announces Withdrawal Fenfluramine and Dexfenfluramine (Fen-Phen). July 2005. Available at: https://wayback.archive-it.org/7993/20170723090512/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm179871.htm. Accessed July 2020.
- Qsymia [package insert]. Campbell, CA: Vivus, Inc.; June 2022.
- Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. National Heart, Lung, and Blood Institute. NIH Publication No. 12-7486. October 2012. http://www.nhlbi.nih.gov/guidelines/cvd_ped/peds_guidelines_full.pdf. 141-159. Accessed June 28, 2021.
- Contrave [package insert]. San Diego, CA : Nalpropion Pharmaceuticals, Inc.; March 2021.
- Xenical [package insert]. Montgomery, AL: H2-Pharma, LLC; January 2018.
- National Heart, Lung, and Blood Institute. Goals of Weight Management/Treatment to Prevent Further Weight Gain.https://www.nhlbi.nih.gov/health/educational/wecan/portion/documents/CORESET3. Accessed July 2020.
- Torgerson JS, Boldrin MN, Hauptman J, et al. Xenical in the prevention of diabetes in obese subjects (XENDOS) study. A randomized study of orlistat as an adjunct to lifestyle changes for the prevention of type 2 diabetes in obese patients. *Diabetes Care* 2004; 27:155-161.
- Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc; December 2020.
- Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk, Inc.; March 2026.
- Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed June 7, 2021.
- Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 2, 1 February 2015, Pages 342–362. https://academic.oup.com/jcem/article/100/2/342/2813109. Accessed June 7, 2021.
- Zepbound [package insert]. Indianapolis, IN: Lilly USA, LLC; December 2024.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.04.33
Policy Creation: February 2021
Reviewed: April 2026
Revised: April 2026
Current Effective Date: May 19, 2026