Drug Coverage Policy

Effective Date.....08/01/2025
Coverage Policy Number.....IP0420
Policy Title.....Appetite Suppressants and Orlistat

Weight Loss –Appetite Suppressants and Orlistat

- Adipex-P® (phentermine hydrochloride capsules and tablets – Teva, generic [brand capsules obsolete 07/12/2023])
- Contrave® (naltrexone HCl/bupropion HCl extended-release tablets –Nalpropion/Currax)
- Lomaira™ (phentermine hydrochloride tablets – KVK-Tech)
- Qsymia™ (phentermine and topiramate extended-release capsules – Vivus, generic)
- Xenical® (orlistat 120 mg capsules, authorized generic – Roche, authorized generic)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used

as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

The appetite suppressant products vary slightly in the wording of their FDA-approved indications.

- **Benzphetamine**, **diethylpropion**, and **phendimetrazine** are indicated for the management of exogenous obesity as a short-term adjunct (a few weeks) to a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of ≥ 30 kg/m^2 who have not responded to a weight reducing regimen (diet and/or exercise) alone.[1-3]

- **Phentermine** hydrochloride is indicated for short-term (a few weeks) adjunctive therapy in a regimen of weight reduction based on exercise, behavioral modification, and caloric restriction in the management of exogenous obesity in those with an initial BMI ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 when other risk factors are present (e.g., controlled hypertension, diabetes mellitus, or dyslipidemia).[4-6]

- **Phentermine/topiramate extended-release** (Qsymia, generic) is indicated as an adjunct to reduced-calorie diet and increased physical activity to reduce excess body weight and maintain weight reduction long term in:[7]
    - Adults and pediatric patients ≥ 12 years of age with obesity; and
    - Adults with overweight in the presence of at least one weight-related comorbid condition.

The recommended starting dose of phentermine/topiramate extended-release (Qsymia, generic) is 3.75 mg/23 mg once daily for 14 days.[7] After 14 days, increase to 7.5 mg/46 mg once daily. After 12 weeks of treatment the 7.5 mg/46 mg dose, evaluate weight loss for adults or BMI reduction for pediatric patients ≥ 12 years of age. If an adult patient has not lost ≥ 3% of baseline body weight or a pediatric patient has not experienced a reduction of ≥ 3% of baseline BMI, increase the dose to 11.25 mg/69 mg once daily for 14 days; followed by an increase to 15 mg/92 mg once daily. After 12 weeks of treatment with 15 mg/92 mg, evaluate weight loss for adults or BMI reduction for pediatric patients ≥ 12 years of age. If an adult patient has not ≥ 5% of baseline body weight or a pediatric patient has not experienced a reduction of ≥ 5% of baseline BMI, discontinue phentermine/topiramate extended-release (Qsymia, generic) as directed as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

- **Contrave** is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of ≥ 30 kg/m^2 (obese), or ≥ 27 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes, dyslipidemia).[8] The recommended maintenance dose of Contrave is achieved at Week 4.[8] Response to therapy should be evaluated after 12 weeks at the maintenance dosage (Week 16, if dosed according to the prescribing information). If a patient has not lost ≥ 5% of baseline body weight, discontinue Contrave, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

- **Orlistat 120 mg** (Xenical, authorized generic) is indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet in patients with an initial body mass index ≥ 30 kg/m^2, or ≥ 27 kg/m^2 in the presence of at least one weight-related comorbidity (e.g., hypertension, diabetes, dyslipidemia), and to reduce the risk for weight gain after prior weight loss.[9]

Guidelines
Guidelines from the Endocrine Society regarding pharmacological management of obesity (2015) recommend pharmacotherapy as adjunct to behavioral modification to reduce food intake and increase physical activity for patients with BMI ≥ 30 kg/m^2 or ≥ 27 kg/m^2 in the presence of at least one comorbidity, such as hypertension, dyslipidemia, type 2 diabetes, or obstructive sleep apnea.[10] If a patient's response to a weight loss medication is deemed effective (weight loss ≥ 5% of body weight at 3 months) and safe, it is recommended that the medication be continued. Although the noradrenergic weight loss medications are only labeled for short-term use, the Endocrine Society notes that off-label, long-term prescribing of phentermine is reasonable for most patients, as long as the patient has been informed that other medications for weight loss are FDA-approved for long-term use.

Per American Association of Clinical Endocrinologists/American College of Endocrinology obesity guidelines (2016), pharmacotherapy for overweight and obesity should be used only as an adjunct to lifestyle therapy and not alone.[11] The addition of pharmacotherapy produces greater weight loss and weight-loss maintenance compared with lifestyle therapy alone. The concurrent initiation of lifestyle therapy and pharmacotherapy should be considered in patients with weight-related complications that can be ameliorated by weight loss. Pharmacotherapy should be offered to patients with obesity, when potential benefits outweigh the risks, for the chronic treatment of the disease. Short-term treatment (3 to 6 months) using weight-loss medications has not been demonstrated to produce longer-term health benefits and cannot be generally recommended based on scientific evidence.

According to the American Gastroenterological Association (AGA) guideline on pharmacological interventions for adults with obesity (2022), in adults with obesity or overweight with weight-related complications who have had an inadequate response to lifestyle interventions, pharmacological agents are recommended to be added to lifestyle rather than continuing lifestyle interventions alone.[12] Wegovy® (semaglutide 2.4 mg subcutaneous injection), Saxenda® (liraglutide 3.0 mg subcutaneous injection), phentermine/topiramate extended-release (Qsymia, generic), Contrave, phentermine, and diethylpropion are all listed among the suggested treatment options. Of note, although the AGA guideline suggests against the use of orlistat, it is noted that for patients who place a high value on the potential small weight loss benefit and low value on gastrointestinal adverse events, orlistat may reasonably be considered. Regarding phentermine and diethylpropion, it is noted that these are only approved as monotherapy for short-term use (12 weeks); however, given the chronic nature of weight management, many practitioners use these agents off-label for longer than 12 weeks.

Guidelines in Pediatric Obesity
Guidelines from the American Academy of Pediatrics on evaluation and treatment of children and adolescents with obesity (2023) note that pediatricians and other primary health care providers should offer adolescents ≥ 12 years of age with obesity (BMI ≥ 95th percentile) weight loss pharmacotherapy, according to medication indications, risks, and benefits, as an adjunct to health behavior and lifestyle treatment.[14]

A 2017 Endocrine Society clinical practice guideline on pediatric obesity recommends pharmacotherapy in combination with lifestyle modification be considered in obese children or adolescents only after failure of a formal program of intensive lifestyle (dietary, physical activity and behavioral) modification to limit weight gain or to ameliorate comorbidities.[13] The Endocrine Society recommends pharmacotherapy in overweight children and adolescents < 16 years only in the context of a clinical trial. Pharmacotherapy should be provided only by clinicians who are experienced in the use of anti-obesity agents and aware of the potential for adverse events. These guidelines recommend limited use of pharmacotherapy because pediatric obesity should be managed preferably as a serious lifestyle condition with important lifelong consequences. The

Endocrine Society defines overweight as BMI in at least the 85th percentile but less than the 95th percentile, and obesity as BMI in at least the 95th percentile for age and sex against routine endocrine studies, unless the height velocity is attenuated or inappropriate for the family background or stage of puberty.

Coverage Policy

Weight loss medications are specifically excluded under many benefit plans [both Employer Groups and Individual and Family Plans]. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

Policy Statement
Prior Authorization is required for prescription benefit coverage of benzphetamine, diethylpropion, phendimetrazine tartrate, phentermine hydrochloride, phentermine/topiramate extended-release **(**Qsymia, generic) Contrave, and orlistat 120 mg (Xenical, authorized generic). All approvals are provided for the durations noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Prior Authorization and prescription benefit coverage is not recommended for Alli® (orlistat 60 mg capsules).

I. Phentermine hydrochloride is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Weight Loss.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, iv and v):
     - **i.** Patient is ≥ 16 years of age; AND
     - **ii.** Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** At baseline, patient had a body mass index (BMI) ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to phentermine hydrochloride.
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)**At baseline, patient had a BMI ≥ 27 kg/m^2; AND
         - **(2)**At baseline, patient had, or patient currently has at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunciton associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
           Note: This refers to baseline prior to phentermine hydrochloride.
     - **iv.** The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.
     - **v.** Preferred product criteria is met for the product(s) as listed in the below table(s)
   - **B)** Patient is Continuing Therapy with phentermine hydrochloride . Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
     Note: For a patient who has not completed 3 months of initial therapy, refer to Initial Therapy criteria above.
     - **i.** Patient is ≥ 16 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):

a) At baseline, patient had a BMI ≥ 30 kg/m^2;OR
Note: This refers to baseline prior to phentermine hydrochloride.

b) Patient meets BOTH of the following [(1) and (2)]:

(1) At baseline, patient had a BMI ≥ 27 kg/m^2: AND

(2) At baseline patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunciton associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
Note: This refers to baseline prior to phentermine hydrochloride.

iii. Patient has lost ≥ 5% of baseline body weight; AND
Note: This refers to baseline prior to phentermine hydrochloride.

iv. The medication will be used concomitantly weigh behavioral modification and a reduced-calorie diet.

Employer Plans:

Product	Criteria
Adipex-P (phentermine hydrochloride 37.5mg tablet)	The patient has tried the bioequivalent generic product, **phentermine 37.5 mg capsule or tablet**, AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction.
Lomaira (phentermine hydrochloride tablet)	The patient meets ONE of the following: 1. The patient has tried generic phentermine 2. There is a significant concern that the patient is unable to use phentermine tablets

II. Contrave is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Weight Loss.** Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 4 months if the patient meets the following (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND

iii. Patient meets ONE of the following (a or b):

a) At baseline, patient had a body mass index (BMI) ≥ 30 kg/m^2: OR
Note: This refers to baseline prior to Contrave.

b) Patient meets BOTH of the following [(1) and (2)]:

(1) At baseline, patient had a BMI ≥ 27 kg/m^2; AND

(2) At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, Type 2 diabetes, dyslipidemia, , obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunciton associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
Note: This refers to baseline prior to Contrave.

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

B) Patient is Continuing Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
Note: For a patient who has not completed 4 months of initial therapy, refer to Initial Therapy.

i. Patient is ≥ 18 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) At baseline, patient had a BMI ≥ 30 kg/m^2; OR
Note: This refers to baseline prior to Contrave

b) Patient meets BOTH of the following [(1) and (2)]:

(1) At baseline, patient had a BMI ≥ 27 kg/m^2; AND

(2) At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, Type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver dsease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
Note: This refers to baseline prior to Contrave.

iii. Patient has lost ≥ 5% of baseline body weight; AND
Note: This refers to baseline prior to Contrave.

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

III. Phentermine/topiramate extended-release (Qsymia, generic) is considered medically necessary when the following criteria are met:

FDA-Approved Indications

1. Weight Loss, Adult. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND

iii. Patient meets ONE of the following (a or b):

a) At baseline, patient had a BMI ≥ 30 kg/m^2; OR
Note: This refers to baseline prior to phentermine/topiramate extended-release (Qsymia, generic).

b) Patient meets BOTH of the following [(1) and (2)]:

(1) At baseline, patient had a BMI ≥ 27 kg/m^2; AND

(2) At baseline, patient had, or patient currently has, at least ONE of the following weigh-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
Note: This refers to baseline prior to phentermine/topiramate extended-release (Qsymia, generic).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

B) Patient is Continuing Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
Note: For a patient who has not completed 6 months of initial therapy, refer to Initial Therapy criteria above.
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** Patient meets ONE of the following (a or b):
  - **a)** At baseline, patient had a BMI ≥ 30 kg/m^2; OR
    Note: This refers to baseline prior to phentermine/topiramate extended-release (Qsymia, generic).
  - **b)** Patient meets BOTH of the following [(1) and (2)]:
    - **(1)** At baseline, patient had a BMI ≥ 27 kg/m^2; AND
    - **(2)** At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease.
      Note: This refers to baseline prior to phentermine/topiramate extended-release (Qsymia, generic).
- **iii.** Patient has lost ≥ 5% of baseline body weight; AND
  Note: This refers to baseline prior to phentermine/topiramate extended-release (Qsymia, generic).
- **iv.** The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

2. Weight Loss, Pediatric. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv):
- **i.** Patient is ≥ 12 years of age and < 18 years of age; AND
- **ii.** Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
- **iii.** At baseline, patient had a body mass index (BMI) ≥ 95th percentile for age and sex; AND
  Note: This refers to baseline prior to phentermine/topiramate extended-release **(**Qsymia, generic).
- **iv.** The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

B) Patient is Continuing Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
Note: For a patient who has not completed 6 months of initial therapy, refer to Initial Therapy criteria above.
- **i.** Patient is ≥ 12 years of age and < 18 years of age; AND
- **ii.** At baseline, patient had a BMI ≥ 95th percentile for age and sex; AND
  Note: This refers to baseline prior to phentermine/topiramate extended-release (Qsymia, generic).
- **iii.** Patient has had a reduction in BMI of ≥ 5% from baseline; AND
  Note: This refers to baseline prior to phentermine/topiramate extended-release (Qsymia, generic).
- **iv.** The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

IV. Orlistat 120 mg (Xenical, authorized generic) is considered medically necessary when the following criteria are met:

FDA-Approved Indications

1. **Weight Loss, Adult**. Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND
     - **iii.** Patient meets ONE of the following (a or b):
       - **a)** At baseline, patient had a BMI ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to orlistat 120 mg (Xenical, authorized generic).
       - **b)** Patient meets BOTH of the following [(1) and (2)]:
         - **(1)** At baseline patient had a BMI ≥ 27 kg/m^2; AND
         - **(2)** At baseline patient had, or patient currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease.
           Note: This refers to baseline prior to orlistat 120 mg (Xenical, authorized generic)
     - **iv.** Patient is currently engaged in behavioral modification and on a reduced-calorie diet.
   - **B)** Patient is Continuing Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
     Note: For a patient who has not completed 3 months of initial therapy, refer to Initial Therapy criteria above.
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** At baseline, patient had a BMI ≥ 30 kg/m^2; OR
         Note: This refers to baseline prior to orlistat 120 mg (Xenical, authorized generic).
       - **b)** Patient meets BOTH of the following [(1) or (2)]:
         - **(1)** At baseline, patient had a BMI ≥ 27 kg/m^2; AND
         - **(2)** At baseline, patient had, or patient currently has, at least ONE of the following weight-related comorbidities:hypertension type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease; AND
           Note: This refers to baseline prior to orlistat 120 mg (Xenical, authorized generic).
     - **iii.** Patient has lost ≥ 5% of baseline body weight; AND
       Note: This refers to baseline prior to orlistat 120 mg (Xenical, authorized generic).
     - **iv.** The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

2. **Weight Loss, Pediatric.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 12 years of age and < 18 years of age; AND

ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months; AND

iii. At baseline, patient had a body mass index (BMI) ≥ 95th percentile for age and sex; AND
Note: This refers to baseline prior to orlistat 120 mg (Xenical, authorized generic).

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

B) Patient is Continuing Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, and iv):
Note: For a patient who has not completed 3 months of initial therapy, refer to INitial Therapy criteria above.

i. Patient is ≥ 12 years of age and < 18 years of age; AND

ii. At baseline, patient had a BMI ≥ 95th percentile for age and sex; AND
Note: This refers to baseline prior to orlistat 120 mg (Xenical, authorized generic).

iii. Patient has had a reduction in BMI percentile for age and weight (taking into account that the patient is increasing in height and will have a different normative BMI from when orlistat 120 mg [Xenical, authorized generic] was started); AND

iv. The medication will be used concomitantly with behavioral modification and a reduced-calorie diet.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Phentermine hydrochloride, phentermine/topiramate extended-release (Qsymia, generic), Contrave, and orlistat 120 mg (Xenical, authorized generic) for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concomitant Use with Other Medications FDA-Approved for Weight Loss.** Concomitant use with other medications intended for weight loss is not recommended.[1-6,15-17] Of note, examples of medications FDA-approved for weight loss include phentermine (Lomaira, generic), benzphetamine, diethylpropion, phendimetrazine, Contrave (naltrexone HCl/bupropion HCl extended-release tablets), phentermine/topiramate extended-release (Qsymia, generic), orlistat 120 mg (Xenical, authorized generic), Saxenda (liraglutide subcutaneous injection), Wegovy (semaglutide subcutaneous injection), and Zepbound (tirzepatide subcutaneous injection). Additionally, Alli (orlistat 60 mg capsules) is available over-the-counter.

References

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2. Diethylpropion immediate release and controlled release tablets [prescribing information]. Philadelphia, PA: Lannett; December 2019.
3. Phendimetrazine tablets and extended-release capsules [prescribing information]. Grover Beach, CA: H.J. Harkins; September 2018.
4. Adipex-P® tablets and capsules [prescribing information]. Horsham, PA: Teva; March 2024.

5. Lomaira™ tablets [prescribing information]. Newtown, PA: KVK-Tech; December 2023.
6. Phentermine ODT [prescribing information]. Pennington, NJ: Zydus; November 2023.
7. Qsymia® capsules [prescribing information]. Mountain View, CA: Vivus; September 2024.
8. Contrave® tablets [prescribing information]. Morristown, NJ: Nalpropion/Currax; May 2024.
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14. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents with Obesity. *Pediatrics*. 2023;151(2):e2022060640.
15. Saxenda® subcutaneous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; November 2024.
16. Zepbound® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; December 2024.
17. Wilding JPH, Batterham RL, Calanna S, et al; STEP 1 Study Group. Once-weekly semaglutide in adults with overweight or obesity. *N Engl J Med*. 2021;384(11):989.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Policy Name Change: Updated** Policy Name from "Weight Loss Medications" to "Weight Loss – Other Appetite Suppressants and Orlistat." **Phentermine hydrochloride (Adipex P):** **Initial therapy: Updated** to 3 months from 4 months. **Patient is Continuing Therapy: Added** note stating that for patients who have not completed 3 months of initial therapy, criterion (1A) must be met. **Updated** weight loss requirement from ≥ 4% to ≥ 5% of baseline body weight. **Contrave:** **Patient is Continuing Therapy: Added** note stating that for patients who have not completed 4 months of initial therapy, criterion (1A) must be	08/15/2024

	met. **Updated** weight loss requirement from ≥ 4% to ≥ 5% of baseline body weight. **Qsymia:** **Weight Loss, Adult.** **Initial therapy: Updated** to 6 months from 4 months. **Patient is Continuing Therapy: Added** note stating that for patients who have not completed 6 months of initial therapy, criterion (1A) must be met. **Updated** weight loss requirement from ≥ 4% to ≥ 5% of baseline body weight. **Weight Loss, Pediatric.** **Initial therapy: Updated** to 6 months from 4 months. **Patient is Continuing Therapy: Added** note stating that for patients who have not completed 6 months of initial therapy, criterion (1A) must be met. **Added** requirement for a BMI reduction of ≥ 5% from baseline (prior to the initiation of Qsymia). **Removed** the requirement for BMI in the 85th percentile for age and sex with comorbidities. **Removed** the requirement for the decrease in BMI percentile for age and weight (taking into account that the individual is increasing in height and will have a different normative BMI from when Qsymia started). **Removed** the requirement of having a BMI greater than 85th percentile. **orlistat 120 mg (Xenical):** **Weight Loss, Adult.** **Initial therapy: Updated** to 3 months from 4 months. **Patient is Continuing Therapy: Added** note stating that for patients who have not completed 3 months of initial therapy, criterion (1A) must be met). **Updated** weight loss criteria from ≥ 4% to ≥ 5% of baseline body weight **Weight Loss, Pediatric.** **Initial therapy: Updated** to 3 months from 4 months. **Patient is Continuing Therapy: Added** note stating that for patients who have not completed 3 months of initial therapy, criterion (1A) must be met. **Removed** the requirement for BMI in the 85th percentile for age and sex with comorbidities. **Removed** the requirement of having a BMI greater than 85th percentile.	

	Conditions Not Covered: Removed treatment of hyperlipidemia in non-obese individuals, binge-eating disorder in non-obese individuals (BMI < 30 kg/m2 or < 27 kg/m2 with risk factors), and prevention of diabetes in individuals with BMI < 30 kg/m2.	
Annual Revision	The policy title was changed to: Weight Loss – Appetite Suppressants and Orlistat (previously Weight Loss – Other Appetite Suppressants and Orlistat). Phentermine hydrochloride and Contrave **Weight Loss.** Initial Therapy. The criterion requiring that the patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months was modified to remove that the patient has failed to achieve the desired weight loss after this intervention. The criterion requiring that the patient currently has a body mass index (BMI) ≥ 30 kg/m^2 or ≥ 27 kg/m^2 for those with comorbidities besides obesity was modified as follows: this criterion was changed to "at baseline, the patient had a BMI ≥ 30 kg/m^2" OR that "at baseline, the patient had a BMI ≥ 27 kg/m^2 AND at baseline, the patient had, or currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease"; previously for a patient with BMI ≥ 27 kg/m^2 examples of comorbidities were hypertension, diabetes mellitus, impaired glucose tolerance, dyslipidemia, and sleep apnea, and coronary heart disease and these items were listed in a Note; a Note was added to clarify that baseline refers to baseline prior to the requested medication for weight loss. The criterion that the patient is currently engaged in behavioral modification and on a reduced calorie diet was modified to state that "the medication will be used concomitantly with behavioral modification and a reduced-calorie diet." Patient is Continuing Therapy. The criterion requiring that the patient currently has a body mass index (BMI) ≥ 30 kg/m^2 or ≥ 27 kg/m^2 for those with comorbidities besides obesity was modified as follows: this criterion was changed to "at baseline, the patient had a BMI ≥ 30 kg/m^2" OR	4/15/2025

	that "at baseline, the patient had a BMI ≥ 27 kg/m^2 AND at baseline, the patient had, or currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease"; previously for a patient with BMI ≥ 27 kg/m^2 examples of comorbidities were hypertension, diabetes mellitus, impaired glucose tolerance, dyslipidemia, and sleep apnea, and coronary heart disease and these items were listed in a Note; a Note was added to clarify that baseline refers to baseline prior to the requested medication for weight loss. The criterion that the patient is currently engaged in behavioral modification and on a reduced calorie diet was modified to state that "the medication will be used concomitantly with behavioral modification and a reduced-calorie diet." A Note was added to the criterion requiring that the patient has lost ≥ 5% of baseline body weight that baseline refers to baseline prior to requested medication for weight loss. <u>Qsymia</u> **<u>Weight Loss, Adult.</u>** <u>Initial Therapy</u>. The criterion requiring that the patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months was modified to remove that the patient has failed to achieve the desired weight loss after this intervention. The criterion requiring that the patient currently has a body mass index (BMI) ≥ 30 kg/m^2 or ≥ 27 kg/m^2 for those with comorbidities besides obesity was modified as follows: this criterion was changed to "at baseline, the patient had a BMI ≥ 30 kg/m^2" OR that "at baseline, the patient had a BMI ≥ 27 kg/m^2 AND at baseline, the patient had, or currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease"; previously for a patient with BMI ≥ 27 kg/m^2 examples of comorbidities were hypertension, diabetes mellitus, impaired glucose tolerance, dyslipidemia, and sleep apnea, and coronary heart disease and these items were	

	listed in a Note; a Note was added to clarify that baseline refers to baseline prior to Qsymia. The criterion that the patient is currently engaged in behavioral modification and on a reduced calorie diet was modified to state that "the medication will be used concomitantly with behavioral modification and a reduced-calorie diet." <u>Patient is Continuing Therapy</u>. The criterion requiring that the patient currently has a body mass index (BMI) ≥ 30 kg/m^2 or ≥ 27 kg/m^2 for those with comorbidities besides obesity was modified as follows: this criterion was changed to "at baseline, the patient had a BMI ≥ 30 kg/m^2" OR that "at baseline, the patient had a BMI ≥ 27 kg/m^2 AND at baseline, the patient had, or currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease"; previously for a patient with BMI ≥ 27 kg/m^2 examples of comorbidities were hypertension, diabetes mellitus, impaired glucose tolerance, dyslipidemia, and sleep apnea, and coronary heart disease and these items were listed in a Note; a Note was added to clarify that baseline refers to baseline prior to Qsymia. The criterion that the patient is currently engaged in behavioral modification and on a reduced calorie diet was modified to state that "the medication will be used concomitantly with behavioral modification and a reduced-calorie diet." A Note was added to the criterion requiring that the patient has lost ≥ 5% of baseline body weight that baseline refers to baseline prior to Qsymia. **<u>Weight Loss, Pediatric.</u>** <u>Initial Therapy</u>. The criterion requiring that the patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months was modified to remove that the patient has failed to limit weight gain or to modify comorbidities after this intervention. The criterion requiring that the patient currently has a body mass index (BMI) of ≥ 95th percentile for age and sex was modified to state that "at baseline", the patient had a BMI ≥ 95th percentile for age and sex and a Note was added to clarify that baseline refers to baseline prior to Qsymia. The criterion that the patient is currently engaged in behavioral modification and on	

	a reduced calorie diet was modified to state that "the medication will be used concomitantly with behavioral modification and a reduced-calorie diet." Patient is Continuing Therapy. The criterion requiring that the patient currently has a body mass index (BMI) of ≥ 95th percentile for age and sex was modified to state that "at baseline", the patient had a BMI ≥ 95th percentile for age and sex and a Note was added to clarify that baseline refers to baseline prior to Qsymia. The criterion that the patient is currently engaged in behavioral modification and on a reduced calorie diet was modified to state that "the medication will be used concomitantly with behavioral modification and a reduced-calorie diet." The requirement that the patient had a reduction in BMI of ≥ 5% from baseline (prior to the initiation of Qsymia) was modified to remove "prior to initiation of Qsymia" and a Note was added that baseline refers to baseline prior to Qsymia. Orlistat 102 mg (Xenical, authorized generic) **Weight Loss, Adult.** Initial Therapy. The criterion requiring that the patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months was modified to remove that the patient has failed to achieve the desired weight loss after this intervention. The criterion requiring that the patient currently has a body mass index (BMI) ≥ 30 kg/m^2 or ≥ 27 kg/m^2 for those with comorbidities besides obesity was modified as follows: this criterion was changed to "at baseline, the patient had a BMI ≥ 30 kg/m^2" OR that "at baseline, the patient had a BMI ≥ 27 kg/m^2 AND at baseline, the patient had, or currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease"; previously for a patient with BMI ≥ 27 kg/m^2 examples of comorbidities were hypertension, diabetes mellitus, dyslipidemia, and sleep apnea, and coronary heart disease and these items were listed in a Note; a Note was added to clarify that baseline refers to baseline prior to orlistat 120 mg (Xenical, authorized generic). The criterion for a patient with an initial BMI ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 for those with comorbidities besides obesity if maintaining	

	weight loss after using allow calorie diet was removed from the policy. The criterion that the patient is currently engaged in behavioral modification and on a reduced calorie diet was modified to state that "the medication will be used concomitantly with behavioral modification and a reduced-calorie diet." Patient is Continuing Therapy. The criterion requiring that the patient currently has a body mass index (BMI) ≥ 30 kg/m^2 or ≥ 27 kg/m^2 for those with comorbidities besides obesity was modified as follows: this criterion was changed to "at baseline, the patient had a BMI ≥ 30 kg/m^2" OR that "at baseline, the patient had a BMI ≥ 27 kg/m^2 AND at baseline, the patient had, or currently has, at least ONE of the following weight-related comorbidities: hypertension, type 2 diabetes, dyslipidemia, obstructive sleep apnea, cardiovascular disease, knee osteoarthritis, asthma, chronic obstructive pulmonary disease, metabolic-dysfunction associated steatotic liver disease/non-alcoholic fatty liver disease, polycystic ovarian syndrome, or coronary artery disease"; previously for a patient with BMI ≥ 27 kg/m^2 examples of comorbidities were hypertension, diabetes mellitus, impaired glucose tolerance, dyslipidemia, and sleep apnea, and coronary heart disease and these items were listed in a Note; a Note was added to clarify that baseline refers to baseline prior to orlistat 120 mg (Xenical, authorized generic). The criterion that the patient is currently engaged in behavioral modification and on a reduced calorie diet was modified to state that "the medication will be used concomitantly with behavioral modification and a reduced-calorie diet." A Note was added to the criterion requiring that the patient has lost ≥ 5% of baseline body weight to clarify that baseline refers to baseline prior to orlistat 120 mg (Xenical, authorized generic). **Weight Loss, Pediatric.** Initial Therapy. The criterion requiring that the patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months was modified to remove that the patient has failed to limit weight gain or to modify comorbidities after this intervention. The criterion requiring that the patient currently has a body mass index (BMI) of ≥ 95th percentile for age and sex was modified to state that "at baseline", the patient had a BMI ≥ 95th percentile for age and sex and a Note was added to clarify that baseline refers to baseline prior a Note was added to clarify that baseline refers to baseline prior to orlistat 120 mg (Xenical,	

	authorized generic). The criterion that the patient is currently engaged in behavioral modification and on a reduced calorie diet was modified to state that "the medication will be used concomitantly with behavioral modification and a reduced-calorie diet." Patient is Continuing Therapy. The criterion requiring that the patient currently has a body mass index (BMI) of ≥ 95th percentile for age and sex was modified to state that "at baseline", the patient had a BMI ≥ 95th percentile for age and sex and a Note was added to clarify that baseline refers to baseline prior a Note was added to clarify that baseline refers to baseline prior to orlistat 120 mg (Xenical, authorized generic). The criterion that the patient is currently engaged in behavioral modification and on a reduced calorie diet was modified to state that "the medication will be used concomitantly with behavioral modification and a reduced-calorie diet." The requirement that the patient had a reduction in BMI of ≥ 5% from baseline (prior to the initiation of Qsymia) was modified to remove "prior to initiation of Qsymia" and a Note was added to the criterion requiring that the patient has lost ≥ 5% of baseline body weight to clarify that baseline refers to baseline prior to orlistat 120 mg (Xenical, authorized generic).	
Selected Revision	**Lomaira** added to the policy. **Phentermine Preferred Product Table** **Added** criteria for Lomaira.	07/01/2025
Selected Revision	Phentermine/topiramate extended-release (generic to Qsymia) was added to the policy. Conditions Not Recommended for Approval: **Concomitant Use with Other Medications FDA-Approved for Weight Loss.** This condition not recommended for approval was clarified to state that concomitant use with other medications FDA-approved for weight loss is not recommended. Previously, the requirement did not specify medications were "FDA-approved" for weight loss. The note with examples of weight loss medications was updated to reflect product availability for medications FDA-approved for weight loss.	08/01/2025

The policy effective date is in force until updated or retired.