VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Weight Loss – Other Appetite Suppressants and Orlistat Prior Authorization Policy

- Adipex-P® (phentermine hydrochloride capsules and tablets – Teva, generic [brand capsules obsolete 07/12/2023])
- benzphetamine 50 mg tablets (generic only)
- Contrave® (naltrexone HCl/buproprion HCl extended-release tablets – Nalpropion/Currax)
- diethylpropion hydrochloride immediate-release and controlled-release tablets (generic only)
- Lomaira™ (phentermine hydrochloride tablets – KVK-Tech)
- phendimetrazine tartrate tablets and extended-release capsules (generic only)
- phentermine hydrochloride orally disintegrating tablets (generic only)
- benzphetamine 25 mg tablets (generic only)
- Qsymia™ (phentermine and topiramate extended-release capsules – Vivus)
- Xenical® (orlistat 120 mg capsules, authorized generic – Roche, generic)

REVIEW DATE 01/03/2024

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]
- **Qsymia** is indicated as an adjunct to reduced-calorie diet and increased physical activity for chronic weight management in:[7]
  - 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, dyslipidemia, type 2 diabetes).
  - Pediatric patients ≥ 12 years of age with BMI in the 95th percentile or greater standardized for age and sex.
- **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, dyslipidemia, type 2 diabetes).[8]
- **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]

Contrave

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.

Qsymia

The recommended starting dose of Qsymia is 3.75 mg/23 mg once daily for 14 days.[7] After 14 days, increase to 7.5 mg/46 mg once daily. Response to therapy should be evaluated by Week 12 of the 7.5 mg/46 mg dose. If an adult patient has not lost ≥ 3% of baseline body weight or pediatric patient has not lost ≥ 3% BMI, escalate the dose to 11.25 mg/69 mg once daily for 14 days, followed by an increase to 15 mg/92 mg once daily. If an adult patient has not lost ≥ 5% of baseline body weight (or a pediatric patient has not lost ≥ 5% baseline BMI) after an additional 12 weeks of treatment on Qsymia 15 mg/92 mg, discontinue Qsymia as directed as it is unlikely the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

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), Qsymia, 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.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of benzphetamine, diethylpropion, phendimetrazine tartrate, phentermine hydrochloride, Qsymia, 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).

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of benzphetamine, diethylpropion, phendimetrazine tartrate, or phentermine hydrochloride is recommended in those who meet the following:

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, and iv):

i. Patient is ≥ 16 years of age; AND

ii. Patient currently has a body mass index (BMI) ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 for those with comorbidities besides obesity; AND

Note: Examples of comorbidities include diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea.

iii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss; AND

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, criterion (1A) must be met (do not use continuation criteria if the initial 3 months were not completed).

i. Patient is ≥ 16 years of age; AND

ii. Patient had an initial BMI ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 for those with comorbidities besides obesity: AND

Note: Examples of comorbidities include diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea.

iii. Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND

iv. Patient has lost ≥ 5% of baseline body weight.

II. Coverage of Contrave is recommended in those who meet the following:

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 currently has a body mass index (BMI) ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 for those with comorbidities besides obesity; AND

Note: Examples of comorbidities include diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea.

iii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss; AND

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 the following (i, ii, iii, and iv):

Note: For a patient who has not completed 4 months of initial therapy, criterion (1A) must be met (do not use continuation criteria if the initial 4 months were not completed).

i. Patient is ≥ 18 years of age; AND

ii. Patient had an initial BMI ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 for those with comorbidities besides obesity: AND

Note: Examples of comorbidities include diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea.

iii. Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND

iv. Patient has lost ≥ 5% of baseline body weight.

III. Coverage of Qsymia is recommended in those who meet one of the following:

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 the following (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient currently has a BMI ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 for those with comorbidities besides obesity; AND

Note: Examples of comorbidities include diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea.

iii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss; AND

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 the following (i, ii, iii, and iv):

Note: For a patient who has not completed 6 months of initial therapy, criterion (1A) must be met (do not use continuation criteria if the initial 6 months were not completed).

i. Patient is ≥ 18 years of age; AND

ii. Patient had an initial BMI ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 for those with comorbidities besides obesity; AND

Note: Examples of comorbidities include diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea.

iii. Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND

iv. Patient has lost ≥ 5% of baseline body weight.

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 the following (i, ii, iii, and iv):

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

ii. Patient currently has a body mass index (BMI) of ≥ 95th percentile for age and sex; AND

iii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to limit weight gain or to modify comorbidities; AND

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 the following (i, ii, iii, and iv):

Note: For a patient who has not completed 6 months of initial therapy, criterion (2A) must be met (do not use continuation criteria if the initial 6 months were not completed).

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

ii. Patient had an initial BMI of ≥ 95th percentile for age and sex; AND

iii. Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND

iv. Patient has had a reduction in BMI of ≥ 5% from baseline (prior to the initiation of Qsymia).

IV. Coverage of orlistat 120 mg (Xenical, authorized generic) is recommended in those who meet one of the following:

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 meets ONE of the following (a or b):

a) Patient currently has a BMI ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 for those with comorbidities besides obesity; OR

Note: Examples of comorbidities include diabetes, dyslipidemia, hypertension, coronary heart disease, sleep apnea.

b) Patient had 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 a low calorie diet; AND

Note: Examples of comorbidities include diabetes, dyslipidemia, hypertension, coronary heart disease, sleep apnea.

iii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss; AND

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 the following (i, ii, iii, and iv):

Note: For a patient who has not completed 3 months of initial therapy, criterion (1A) must be met (do not use continuation criteria if the initial 3 months were not completed).

i. Patient is ≥ 18 years of age; AND

ii. Patient had an initial BMI ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 for those with comorbidities besides obesity: AND

Note: Examples of comorbidities include diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea.

iii. Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND

iv. Patient has lost ≥ 5% of baseline body weight.

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 the following (i, ii, iii, and iv):

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

ii. Patient currently has a body mass index (BMI) of ≥ 95th percentile for age and sex; AND

iii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to limit weight gain or to modify comorbidities; AND

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 the following (i, ii, iii, and iv):

Note: For a patient who has not completed 3 months of initial therapy, criterion (2A) must be met (do not use continuation criteria if the initial 3 months were not completed).

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

ii. Patient had an initial BMI of ≥ 95th percentile for age and sex; AND

iii. Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND

iv. Patient's current BMI percentile has decreased 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).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of benzphetamine, diethylpropion, phendimetrazine tartrate, phentermine hydrochloride, Qsymia, Contrave, and orlistat 120 mg (Xenical, authorized generic) is not recommended in the following situations:

1. Concomitant Use with Other Weight Loss Medications. Concomitant use with other medications intended for weight loss is not recommended. Of note, examples of medications FDA-approved for weight loss include phentermine, benzphetamine, diethylpropion, phendimetrazine, Contrave, Qsymia, orlistat 120 mg (Xenical, authorized generic), Saxenda (liraglutide subcutaneous injection), and Wegovy (semaglutide subcutaneous injection). Additionally, Alli (orlistat 60 mg capsules) is available over-the-counter.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Benzphetamine hydrochloride tablets [prescribing information]. Newtown, PA: KVK-Tech; March 2022.
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; September 2020.
5. Lomaira™ tablets [prescribing information]. Newtown, PA: KVK-Tech; September 2016.
6. Phentermine ODT [prescribing information]. Pennington, NJ: Zydus; February 2014.
7. Qsymia® capsules [prescribing information]. Mountain View, CA: Vivus; June 2023.
8. Contrave® tablets [prescribing information]. Morristown, NJ: Nalpropion/Currax; November 2023.
9. Xenical® capsules [prescribing information]. Nutley, NJ: Roche; November 2022.
10. Apovian CM, Aronne LJ, Bessesen DH, McDonnell ME, Murad MH, Pagotto U, Ryan DH, Still CD; Endocrine Society. Pharmacological management of obesity: an endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2015 Feb;100(2):342-62.
11. Garvey WT, Mechanick JI, Brett EM, Garber AJ, Hurley DL, Jastreboff AM, Nadolsky K, Pessah-Pollack R, Plodkowski R; Reviewers of the AACE/ACE Obesity Clinical Practice Guidelines. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. *Endocr Pract*. 2016 Jul;22 Suppl 3:1-203.
12. Grunvald E, Shah R, Hernaez R, et al; AGA Clinical Guidelines Committee. AGA Clinical Practice Guideline on Pharmacological Interventions for Adults With Obesity. *Gastroenterology*. 2022 Nov;163(5):1198-1225
13. Styne DM, Arslanian SA, Connor EL, Farooqi IS, Murad MH, Silverstein JH, Yanovski JA. Pediatric Obesity-Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2017 Mar 1;102(3):709-757.
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 Feb 1;151(2):e2022060640.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes. The policy name was changed from "Weight Loss – Other Appetite Suppressants and Xenical" to "Weight Loss – Other Appetite Suppressants and Orlistat". Orlistat 120 mg (authorized generic to Xenical) was added to the policy (already rolled in).	01/04/2023
Selected Revision	Qsymia **Weight Loss, Pediatric:** In the initial therapy criteria, the requirement regarding current body mass index (BMI) was updated such that the patient is required to have a BMI ≥ 95th percentile for age and sex (obesity). Previously, the patient could alternatively have a BMI ≥ 85th percentile and < 95th percentile for age and sex (overweight) if the patient had at least one comorbidity (type 2 diabetes, cardiovascular disease) or a strong family history of type 2 diabetes or premature cardiovascular disease. In continuation criteria, the requirement that the patient currently has a body mass index (BMI) > 85th percentile was removed. Additionally, the requirement regarding baseline body mass index (BMI) was updated such that the patient is required to have had a baseline BMI ≥ 95th percentile for age and sex (obesity). Previously, the patient could alternatively have had a baseline BMI ≥ 85th percentile and < 95th percentile for age and sex (overweight) if the patient had at least one comorbidity (type 2 diabetes, cardiovascular disease) or a strong family history of type 2 diabetes or premature cardiovascular disease. Orlistat **Weight Loss, Pediatric:** In the initial therapy criteria, the requirement regarding current body mass index (BMI) was updated such that the patient is required to have a BMI ≥ 95th percentile for age and sex (obesity). Previously, the patient could alternatively have a BMI ≥ 85th percentile and < 95th percentile for age and sex (overweight) if the patient had at least one comorbidity (type 2 diabetes, cardiovascular disease) or a strong family history of type 2 diabetes or premature cardiovascular disease. In continuation criteria, the requirement that the patient currently has a body mass index (BMI) > 85th percentile was removed. Additionally, the requirement regarding baseline body mass index (BMI) was updated such that the patient is required to have had a baseline BMI ≥ 95th percentile for age and sex (obesity). Previously, the patient could alternatively have had a baseline BMI ≥ 85th percentile and < 95th percentile for age and sex (overweight) if the patient had at least one comorbidity (type 2 diabetes, cardiovascular disease) or a strong family history of type 2 diabetes or premature cardiovascular disease.	01/18/2023
Annual Revision	No criteria changes. Regimax (brand) was removed from the policy (this is obsolete), generics remain. Phendimetrazine tartarate extended-release capsules were added to the header of the document. This product was included, but not previously listed. Criteria for phendimetrazine tartarate continue to be applied to the extended-release capsules and immediate-release tablets.	01/03/2024