

PRIOR AUTHORIZATION POLICY

- POLICY:** Weight Loss – Other Appetite Suppressants and Xenical Prior Authorization Policy
- Adipex-P® (phentermine hydrochloride capsules and tablets – Teva, generic)
 - benzphetamine 50 mg tablets (generic only)
 - Contrave® (naltrexone HCl/bupropion HCl extended-release tablets – Orexigen)
 - diethylpropion hydrochloride immediate-release and controlled-release tablets (generic only)
 - Lomaira™ (phentermine hydrochloride tablets – KVK-Tech)
 - phendimetrazine tartrate tablets (generic only)
 - phentermine hydrochloride orally disintegrating tablets (generic only)
 - Regimex™ (benzphetamine 25 mg tablets, generic [brand obsolete 01/15/2019] – WraSer, generic)
 - Qsymia™ (phentermine and topiramate extended-release capsules – Vivus)
 - Xenical® (orlistat 120 mg capsules – Roche)

REVIEW DATE 12/15/2021; selected revision 07/20/2022

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/m² 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/m², or a BMI ≥ 27 kg/m² 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/m² (obese), or ≥ 27 kg/m² (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/m² (obese), or ≥ 27 kg/m² (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes).⁸
- **Xenical** 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/m², or ≥ 27 kg/m² 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 $\geq 5\%$ 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 $\geq 3\%$ of baseline body weight or pediatric patient has not lost $\geq 3\%$ 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 $\geq 5\%$ of baseline body weight (or a pediatric patient has not lost $\geq 5\%$ 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 $\geq 30 \text{ kg/m}^2$ or $\geq 27 \text{ kg/m}^2$ 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 $\geq 5\%$ 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.

Guidelines in Pediatric Obesity

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.¹² 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 Xenical. 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 (including Regimax 25 mg tablets [generic]), diethylpropion, phendimetrazine tartrate, or phentermine hydrochloride is recommended in those who meet the following criteria:

FDA-Approved Indication

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

A) Initial Therapy. Approve for 3 months if the patient meets all of the following criteria (i, ii, iii, and iv):

i. Patient is ≥ 16 years of age; AND

ii. Patient currently has a body mass index (BMI) ≥ 30 kg/m², or a BMI ≥ 27 kg/m² 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 criteria (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/m², or a BMI ≥ 27 kg/m² 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 $\geq 5\%$ of baseline body weight.

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

FDA-Approved Indication

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

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

i. Patient is ≥ 18 years of age; AND

ii. Patient currently has a body mass index (BMI) ≥ 30 kg/m², or a BMI ≥ 27 kg/m² 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 criteria (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/m², or a BMI ≥ 27 kg/m² 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 $\geq 5\%$ of baseline body weight.

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

FDA-Approved Indications

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

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

i. Patient is ≥ 18 years of age; AND

ii. Patient currently has a BMI ≥ 30 kg/m², or a BMI ≥ 27 kg/m² 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 criteria (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/m², or a BMI ≥ 27 kg/m² 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 $\geq 5\%$ of baseline body weight.

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

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

- i. Patient is ≥ 12 years of age and < 18 years of age; AND
- ii. Patient meets one of the following (a or b):
 - a) Patient currently has a body mass index (BMI) of $\geq 95^{\text{th}}$ percentile for age and sex; OR
 - b) Patient currently has a BMI $\geq 85^{\text{th}}$ percentile but $< 95^{\text{th}}$ percentile for age and sex and has at least one comorbidity (type 2 diabetes mellitus, cardiovascular disease) or has a strong family history of type 2 diabetes or premature cardiovascular disease; AND
- Note: Premature cardiovascular disease is defined as cardiovascular disease occurring in a male < 55 years of age or in a female < 65 years of age.
- 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 criteria (i, ii, iii, iv, and v):

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 meets one of the following (a or b):
 - a) Patient had an initial BMI of $\geq 95^{\text{th}}$ percentile for age and sex; OR
 - b) Patient had an initial BMI $\geq 85^{\text{th}}$ percentile but $< 95^{\text{th}}$ percentile for age and sex and has at least one comorbidity (type 2 diabetes or cardiovascular disease) or strong family history of type 2 diabetes or premature cardiovascular disease; AND
- Note: Premature cardiovascular disease is defined as cardiovascular disease occurring in a male < 55 years of age or in a female < 65 years of age.
- iii. Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND
- iv. Patient has had a reduction in BMI of $\geq 5\%$ from baseline (prior to the initiation of Qsymia); AND
- v. Patient currently has a BMI $> 85^{\text{th}}$ percentile.

IV. Coverage of Xenical is recommended in those who meet one of the following criteria:

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 criteria (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 $\geq 30 \text{ kg/m}^2$, or a BMI $\geq 27 \text{ kg/m}^2$ 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 $\geq 30 \text{ kg/m}^2$, or a BMI $\geq 27 \text{ kg/m}^2$ 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 criteria (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/m², or a BMI ≥ 27 kg/m² 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 $\geq 5\%$ of baseline body weight.
- 2. Weight Loss, Pediatric.** Approve for the duration noted if the patient meets one of the following criteria (A or B):
- A) Initial Therapy.** Approve for 3 months if the patient meets the following criteria (i, ii, iii, and iv):
 - i. Patient is ≥ 12 years of age and < 18 years of age; AND
 - ii. Patient meets one of the following (a or b):
 - a) Patient currently has a body mass index (BMI) of $\geq 95^{\text{th}}$ percentile for age and sex; OR
 - b) Patient currently has a BMI $\geq 85^{\text{th}}$ percentile but $< 95^{\text{th}}$ percentile for age and sex and has at least one comorbidity (type 2 diabetes mellitus, cardiovascular disease) or has a strong family history of type 2 diabetes or premature cardiovascular disease; AND
Note: Premature cardiovascular disease is defined as cardiovascular disease occurring in a male < 55 years of age or in a female < 65 years of age.
 - 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 criteria (i, ii, iii, iv, and v):
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 meets one of the following (a or b):
 - a) Patient had an initial BMI of $\geq 95^{\text{th}}$ percentile for age and sex; OR
 - b) Patient had an initial BMI $\geq 85^{\text{th}}$ percentile but $< 95^{\text{th}}$ percentile for age and sex and has at least one comorbidity (type 2 diabetes or cardiovascular disease) or strong family history of type 2 diabetes or premature cardiovascular disease; AND
Note: Premature cardiovascular disease is defined as cardiovascular disease occurring in a male < 55 years of age or in a female < 65 years of age.
 - 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 Xenical was started); AND
 - v. Patient currently has a BMI $> 85^{\text{th}}$ percentile.
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CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of benzphetamine, diethylpropion, phendimetrazine tartrate, phentermine hydrochloride, Qsymia, Contrave, and Xenical 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, Xenical, 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

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4. Adipex-P® tablets and capsules [prescribing information]. Horsham, PA: Teva; March 2017.
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6. Phentermine ODT [prescribing information]. Pennington, NJ: Zydus; February 2014.
7. Qsymia® capsules [prescribing information]. Mountain View, CA: Vivus; June 2022.
8. Contrave® tablets [prescribing information]. La Jolla, CA: Orexigen; June 2018.
9. Xenical capsules [prescribing information]. Nutley, NJ: Roche; August 2017.
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11. Garvey WT, Mechanick JL, 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.
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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/18/2020
Update	12/07/2020: Criteria for benzphetamine, diethylpropion, phendimetrazine, phentermine, Contrave, Qsymia, Saxenda, and Xenical in Adults > 18 years of age were revised from: body mass index (BMI) ≥ 27 kg/m ² for those with “risk factors” besides obesity, TO: BMI ≥ 27 kg/m ² for those with “comorbidities” besides obesity. Examples in the Note were changed from “risk factors” to “comorbidities”.	NA
Selected Revision	Saxenda: Added criteria for the use of Saxenda in pediatric patients ≥ 12 and < 18 years of age. Xenical: Criteria for adults was revised by changing risk factors to comorbidities. Criteria for pediatric patients was revised by removing “severe” from criteria – has at least one “severe” comorbidity.	01/20/2021

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	Saxenda, Weight Loss in Patients Aged ≥ 12 to < 18 Years: Removed “premature” from comorbidities in Initial Therapy and Patient is Continuing Therapy criteria. Now reads as follows: $\geq 85^{\text{th}}$ percentile but $< 95^{\text{th}}$ percentile for age and sex and has at least one comorbidity (type 2 diabetes, premature cardiovascular disease). Added Note: Premature cardiovascular disease is defined as cardiovascular disease occurring in males < 55 years of age or in females < 65 years of age. Xenical, Weight Loss in Patients Aged ≥ 12 to < 18 Years: Removed “premature” from comorbidities in Initial Therapy and Patient is Continuing Therapy criteria. Now reads as follows: $\geq 85^{\text{th}}$ percentile but $< 95^{\text{th}}$ percentile for age and sex and has at least one comorbidity (type 2 diabetes, premature cardiovascular disease). Added Note: Premature cardiovascular disease is defined as cardiovascular disease occurring in males < 55 years of age or in females < 65 years of age.	02/10/2021
Update	06/14/2021: The policy was renamed from “Weight Loss Drugs Prior Authorization Policy” to “Weight Loss – Other Appetite Suppressants and Xenical Prior Authorization Policy”. Criteria for Saxenda were removed from the policy. Saxenda criteria are now addressed in the <i>Weight Loss – Glucagon-Like Peptide-1 Agonists Prior Authorization Policy</i>.	NA
Annual Revision	<u>Benzphetamine, diethylpropion, phendimetrazine, phentermine, Contrave, and Qsymia:</u> Weight Loss: The age criterion was moved from the approval condition into criteria. References to a Body Mass Index (BMI) chart were removed. <u>Xenical:</u> Weight Loss, Adult: The condition was reworded as listed, previously this was titled “Weight Loss in Patients ≥ 18 Years of Age”. The age criterion was moved from the approval condition into criteria. References to a BMI chart were removed. Weight Loss, Pediatric: The condition was reworded as listed, previously this was titled “Weight Loss in Patients Aged ≥ 12 to < 18 Years.” The age criterion was moved from the approval condition into criteria. References to a BMI chart were removed. <u>Conditions Not Recommended for Approval:</u> Concomitant Use with Other Weight Loss Medications: The Condition Not Recommended for Approval was reworded to as listed; previously, “Combination Appetite Suppressant Therapy” and “Simultaneous Use of Xenical with any of the Following: benzphetamine, diethylpropion, phendimetrazine tartrate, phentermine hydrochloride or resin, Contrave, Saxenda, or Qsymia” were listed as two separate Conditions Not Recommended for Approval. Treatment of Hyperlipidemia in Non-Obese Patients: The Condition Not Recommended for Approval was removed from the policy. Treatment of Binge-Eating Disorder in Non-Obese Patients (BMI < 30 kg/m² or < 27 kg/m² for Those with Risk Factors): The Condition Not Recommended for Approval was removed from the policy. Prevention of Diabetes in Patients with BMI < 30 kg/m²: The Condition Not Recommended for Approval was removed from the policy. Nonalcoholic Fatty Liver Disease: The Condition Not Recommended for Approval was removed from the policy.	12/15/2021
Selected Revision	<u>Qsymia</u> Weight Loss, Adult: The approval condition was reworded as listed, previously, this was titled “Weight Loss”. Weight Loss, Pediatric: This approval condition and criteria were added to the policy.	07/20/2022

NA – Not applicable.