PRIOR AUTHORIZATION POLICY

POLICY: Weight Loss Drugs Prior Authorization Policy

- Adipex-P® (phentermine hydrochloride capsules and tablets – Teva, generics)
- benzphetamine hydrochloride tablets (generics only)
- Contrave® (naltrexone HCl/buproprion HCl extended-release tablets – Orexigen Therapeutics)
- diethylpropion hydrochloride immediate-release and controlled-release tablets (generics only)
- Lomaira™ (phentermine hydrochloride tablets – KVK-Tech)
- phendimetrazine tartrate tablets (generics only)
- phentermine hydrochloride orally disintegrating tablets (generics only)
- Regimex (benzphetamine 25 mg tablets – WraSer Pharmaceuticals, generics – obsolete 1/15/2019)
- Saxenda® (liraglutide [rDNA] injection – NovoNordisk)
- Qsymia™ (phentermine and topiramate extended-release capsules – Vivus, Inc.)
- Xenical® (orlistat 120 mg capsules − Roche)

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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.[5-7,31]
- **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).[8-9,30]
- **Qsymia** and **Contrave** are indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients 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).[10,26]
- **Saxenda** is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:
  - Adult patients with an initial BMI ≥ 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 body weight > 60 kg and an initial BMI corresponding to 30 kg/m^2 for adults (obese) by international cutoffs.[27]
- **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/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.[11]

This policy is limited to prescription medications that are indicated to promote weight loss in obese patients. Obesity in adults is defined as a body mass index (BMI) of ≥ 30 kg/m^2; a BMI of 25 to 29.9 kg/m^2 is termed

overweight.[1] The combined prevalence of obesity and overweight is estimated at > 64% of US adults; 4.7% of adults have a BMI ≥ 40 kg/m^2. In the US, an estimated 300,000 adult deaths per year are due to obesity-related causes. With the increase in obesity, treatments for obesity have increased in number and are more commonly used. Diet therapy with a low calorie diet, increased physical activity, and behavioral modification are the mainstays of treatment of overweight and obese adults. Such a regimen should be maintained for at least 6 months before considering pharmacotherapy. The rationale for adding drug therapy to these regimens in selected adults is that a more successful weight loss and maintenance may result.[2-3] Weight loss goals should be individually determined and these goals may include not just weight loss but other parameters, such as improved glucose metabolism, lipid levels, and blood pressure.[1]

Drugs that are indicated for weight loss either: 1) decrease food intake by decreasing appetite or increasing satiety (appetite suppressant, anorectic), or 2) decrease nutrient absorption.[4] The appetite suppressants increase the availability of anorexigenic neurotransmitters (norepinephrine, serotonin, dopamine, or some combination of these) in the central nervous system (CNS). Orlistat acts by inhibiting the absorption of dietary fats and is not an appetite suppressant.[11]

Contrave
The recommended maintenance dose of Contrave is achieved at Week 4.[26] 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
Response to therapy should be evaluated by Week 12.[10] If a patient has not lost ≥ 3% of baseline body weight, discontinue Qsymia or escalate the dose. If a patient has not lost ≥ 5% of baseline body weight after an additional 12 weeks of treatment on the escalated dose, discontinue Qsymia as directed as it is unlikely the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

Saxenda
The change in body weight with Saxenda should be evaluated 16 weeks after initiating Saxenda.[27] If the patient has not lost ≥ 4% of baseline body weight, Saxenda should be discontinued because it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

Guidelines
The Endocrine Society published a clinical practice guideline (2015) for the pharmacological management of obesity.[28] The guidelines recommend that pharmacotherapy be employed for patients with BMI ≥ 27 kg/m^2 with comorbidity or BMI > 30 kg/m^2 as adjuncts to behavioral modification to reduce food intake and increase physical activity when possible. The Society states that patients who have a history of being unable to successfully lose and maintain weight and who meet label indications are candidates for weight-loss medication. Safety and efficacy is recommended to be assessed monthly for the first three months, and then at least every 3 months in all patients prescribed medications for weight loss. If a patient has an adequate response to weight loss medication (weight loss ≥ 5% at 3 months), medication is recommended to be continued. If deemed to be ineffective (weight loss < 5% at 3 months) or if there are safety or tolerability issues at any time, it is recommended that medication be discontinued and alternative medications or referral for alternative treatment approaches be considered.

Although the noradrenergic weight loss medications are only labeled for short-term use, the Endocrine Society (2015) 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.[28] According to prescribing information, safety and efficacy have not been established for

diethylpropion and phentermine (hydrochloride or resin) in children younger than 16 years,[6,8,9,30] and for benzphetamine, phendimetrazine and Xenical in children < 12 years of age.[5,7,11,31] However, the Endocrine Society has established guidelines for use of Xenical in pediatric patients.[16] Benzphetamine, diethylpropion, phendimetrazine and phentermine are not included in these guidelines.

The American Association of Clinical Endocrinology (AACE)/American College of Endocrinology (ACE) guidelines for medical care of patients with obesity (2016) recommend pharmacotherapy for overweight and obese patients only as an adjunct to lifestyle therapy.[29] Pharmacotherapy should be offered to patients who are obese when the potential benefits outweigh the risks, for the chronic treatment of obesity. Short-term (3 to 6 months) use of weight-loss medications has not been demonstrated to produce longer-term health benefits and cannot be generally recommended.

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.[16] 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 antiobesity 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.[16] The Centers for Disease Control (CDC) derived normative percentiles are recommended as the appropriate method for determining the BMI in children.[17-18]

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of benzphetamine (including Regimax 25 mg tablets [generics]), diethylpropion, phendimetrazine tartrate, or phentermine hydrochloride is recommended in those who meet all of the following criteria:

FDA-Approved Indications

1. **Weight Loss in Patients ≥ 16 Years of Age.** Note: For individuals who have not completed the initial 3 months of therapy, criterion (1A) must be met (do not use continuation criteria if the initial 3 months were not completed).

A) Initial Therapy. Approve for 3 months if the patient meets all of the following criteria (i, ii, and iii):
- **i.** 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 (Appendix A contains a BMI chart); AND
  Note: Examples of comorbidities include diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea.
- **ii.** 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
- **iii.** Patient is currently engaged in behavioral modification and on a reduced calorie diet.

B) Patient is Continuing Therapy. Approve for 12 months if the patient meets all of the following criteria (i, ii, and iii):
- **i.** 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.
- **ii.** Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND
- **iii.** Patient has lost ≥ 5% of baseline body weight.

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

FDA-Approved Indications

1. **Weight Loss in Patients ≥ 18 Years of Age.** Note: For individuals who have not completed the initial 4 months of therapy, criterion (1A) must be met (do not use continuation criteria if the initial 4 months were not completed).
   A) Initial Therapy. Approve for 4 months if the patient meets the following criteria (i, ii, and iii):
   - **i.** 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 (Appendix A contains a BMI chart); AND
     Note: Examples of comorbidities include diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea.
   - **ii.** 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
   - **iii.** Patient is currently engaged in behavioral modification and on a reduced calorie diet.

   B) Patient is Continuing Therapy. Approve for 12 months if the patient meets the following criteria (i, ii, and iii):
   - **i.** 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.
   - **ii.** Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND
   - **iii.** Patient has lost ≥ 5% of baseline body weight.

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

FDA-Approved Indications

1. **Weight Loss in Patients ≥ 18 Years of Age.** Note: For individuals who have not completed the initial 6 months of therapy, criterion (1A) must be met (do not use continuation criteria if the initial 6 months were not completed).
   A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, and iii):

i. Patient currently has a BMI ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 for those with comorbidities besides obesity (Appendix A contains a BMI chart); AND
Note: Examples of comorbidities include diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea.
ii. 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
iii. Patient is currently engaged in behavioral modification and on a reduced calorie diet.

B) Patient is Continuing Therapy. Approve for 12 months if the patient meets the following criteria (i, ii, and iii):
i. 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.
ii. Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND
iii. Patient has lost ≥ 5% of baseline body weight.

IV. Coverage of Saxenda is recommended in those who meet all of the following criteria:

1. **Weight Loss in Patients ≥ 18 years of Age.** Note: For individuals who have not completed the initial 4 months of therapy, criterion (1A) must be met (do not use continuation criteria if the initial 4 months were not completed).
   A) Initial Therapy. Approve for 4 months if the patients meets the following criteria (i, ii, and iii):
   i. Patient currently has a BMI ≥ 30 kg/m^2, or a BMI ≥ 27 kg/m^2 for those with comorbidities besides obesity (Appendix A contains a BMI chart); AND
   Note: Examples of comorbidities include diabetes mellitus, impaired glucose tolerance, dyslipidemia, hypertension, coronary heart disease, sleep apnea.
   ii. 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
   iii. Patient is currently engaged in behavioral modification and on a reduced calorie diet.
   B) Patient is Continuing Therapy. Approve for 12 months if the patient meets the following criteria (i, ii, and iii):
   i. 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.
   ii. Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND
   iii. Patient has lost ≥ 4% of baseline body weight.

2. **Weight Loss in Patients Aged ≥ 12 to < 18 Years.** Note: For individuals who have not completed the initial 4 months of therapy, criterion (2A) must be met (do not use continuation criteria if the initial 4 months were not completed).
   A) Initial Therapy. Approve for 4 months if the patient meets the following criteria (i, ii, and iii):
   i. Patient currently has a BMI of ≥ 95th percentile for age and sex, or in ≥ 85th percentile but < 95th percentile for age and sex and has at least one comorbidity (type 2 diabetes mellitus, cardiovascular disease [CVD]) or has a strong family history of type 2 diabetes or premature CVD; 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.
   ii. Patient has engaged in a trial of behavioral modification and dietary restriction for at least 4 months and has failed to limit weight gain or to modify comorbidities; AND
   iii. Patient is currently engaged in behavioral modification and on a reduced calorie diet.

B) Patient is Continuing Therapy. Approve for 12 months if the patient meets the following criteria (i, ii, iii, and iv):
- **i.** Patient had an initial BMI of ≥ 95th percentile for age and sex, or ≥ 85th percentile but < 95th percentile for age and sex and has at least one comorbidity (type 2 diabetes or CVD) or strong family history of type 2 diabetes or premature CVD; 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.
- **ii.** Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND
- **iii.** Patient has had a reduction in BMI of ≥ 1% from baseline; AND
- **iv.** Patient currently has a BMI > 85th percentile.

V. Coverage of Xenical is recommended in those who meet all of the following criteria:

FDA-Approved Indications

1. **Weight Loss in Patients ≥ 18 Years of Age**. Note: For individuals who have not completed the initial 3 months of therapy, criterion (1A) must be met (do not use continuation criteria if the initial 3 months were not completed).
   A) Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, and iii):
   - **i.** 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 (Appendix A contains a BMI chart); 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.
   - **ii.** 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
   - **iii.** Patient is currently engaged in behavioral modification and on a reduced calorie diet.

   B) Patient is Continuing Therapy. Approve for 12 months if the patient meets the following criteria (i, ii, and iii):
   - **i.** 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.
   - **ii.** Patient is currently engaged in behavioral modification and on a reduced calorie diet; AND
   - **iii.** Patient has lost ≥ 5% of baseline body weight.

2. **Weight Loss in Patients Aged ≥ 12 to < 18 Years.** Note: For individuals who have not completed the initial 3 months of therapy, criterion (2A) must be met (do not use continuation criteria if the initial 3 months were not completed).
   A) Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, and iii):
   - **i.** Patient currently has a BMI of ≥ 95th percentile for age and sex, or in ≥ 85th percentile but < 95th percentile for age and sex and has at least one comorbidity (type 2 diabetes mellitus, cardiovascular disease [CVD]) or has a strong family history of type 2 diabetes or premature CVD; 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.

ii. 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

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

B) Patient is Continuing Therapy. Approve for 12 months if the patient meets the following criteria (i, ii, iii, and iv):

i. Patient had an initial BMI of ≥ 95th percentile for age and sex, or ≥ 85th percentile but < 95th percentile for age and sex and has at least one comorbidity (type 2 diabetes or CVD) or strong family history of type 2 diabetes or premature CVD; 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.

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

iii. 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

iv. Patient currently has a BMI > 85th percentile.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of benzphetamine, diethylpropion, phendimetrazine tartrate, phentermine hydrochloride, Qsymia, Contrave, Saxenda, and Xenical is not recommended in the following situations:

1. **Combination Appetite Suppressant Therapy**. Appetite suppressants (benzphetamine, diethylpropion, phendimetrazine tartrate, phentermine hydrochloride or resin, Qsymia, Contrave, Saxenda) are indicated *only* as monotherapy and should not be used in combination with other appetite suppressant drugs.[5-10,26-27,30-31] A 12-week, pilot study assessed the addition of phentermine to Saxenda following 1 year of Saxenda treatment.[33] A total of 45 patients were randomized to Saxenda plus phentermine or Saxenda plus placebo. At 12 weeks, the patients in the Saxenda plus phentermine group had numerically, but not statistically, larger reduction in weight compared with the Saxenda plus placebo group (1.6% vs. 0.1%, respectively, P = 0.073). This study was of inadequate size and duration to assess for long-term safety and efficacy, particularly in regard to cardiovascular outcomes.

2. **Simultaneous Use of Xenical with Any of the Following: benzphetamine, diethylpropion, phendimetrazine tartrate, or phentermine hydrochloride or resin, Contrave, Saxenda or Qsymia.** Limited information from published well-controlled studies is available on the combination use of these drugs. Using weight loss drugs one at a time and starting with the lowest effective doses can decrease the chance of adverse effects.[2] Unproven combination therapy is not recommended.[4]

3. **Treatment of Hyperlipidemia in Non-Obese Patients**. Short-term use of Xenical has slightly decreased total and low density lipoprotein (LDL) cholesterol in patients with increased total and LDL cholesterol levels and normal triglyceride levels who were not obese (BMI 19 to 28.7 kg/m^2).[20] Triglycerides were unchanged and high density lipoprotein (HDL) cholesterol tended to decrease. Although not directly compared with other drugs, Xenical's effects on total and LDL cholesterol were less than those observed with hydroxy-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitors (HMGs) and low dose cholestyramine.

4. **Treatment of Binge-Eating Disorder in Non-Obese Patients (BMI < 30 kg/m^2 or < 27 kg/m^2 for Those with Risk Factors).** In a short term (12 or 24 week) placebo-controlled trial in obese patients (BMI ≥ 30 kg/m^2) with binge eating disorder, Xenical has been effective in producing weight loss.[21-22] In an open-label study, 10 patients with binge eating disorder were treated with Qsymia.[34] Nine of the patients were obesity and one was overweight. After 12 weeks of treatment, the patients on average

lost 4.9 kg of body weight. Patients with binge-eating disorder are usually obese and should be reviewed for weight loss therapy using the criteria in the section above.

5. **Prevention of Diabetes in Patients with BMI < 30 kg/m^2.** In a large (n = 3,305) 4-year study, Xenical, in addition to lifestyle changes, led to a 37% risk reduction in the development of type 2 diabetes in obese (BMI ≥ 30 kg/m^2) patients compared with placebo.[13] However, those most affected had impaired glucose tolerance at baseline and these patients achieved a more pronounced weight reduction. Qsymia in addition to lifestyle modification reduced the progression to type 2 diabetes in overweight/obese patients (BMI 27 to 45 kg/m^2) plus at least two weight-related comorbidities with pre-existing prediabetes and/or metabolic syndrome in a 108-week study compared with placebo (n = 475). However, the magnitude of effect for prevention of type 2 diabetes was related to the degree of weight loss achieved in this sub-analysis. Such patients should be evaluated based on overweight or obesity using the appropriate criteria above.

6. **Nonalcoholic Fatty Liver Disease.** In a single-center trial, 52 patients with nonalcoholic fatty liver disease were randomized to Xenical 120 mg three times daily or placebo.[23] Mean BMI was 33 kg/m^2. All patients were in a behavioral weight loss program. Forty-four patients completed 6 months and their results were analyzed. Patients were not well-matched for baseline characteristics (e.g., BMI, waist circumference, glucose and insulin levels were significantly different between groups at baseline). The authors concluded that Xenical improves serum alanine aminotransferase (ALT) and steatosis on ultrasound in these patients beyond its effect on weight reduction. An additional 24 week study, compared Xenical (n = 68) with conventional treatment (n = 102) in patients with nonalcoholic fatty liver disease and a BMI of ≥ 25 kg/m^2 using magnetic resonance imaging-derived proton density fat fraction.[35] After 24 weeks of treatment, patients treated with Xenical had significantly greater reduction in total liver fat compared with the conventional treatment group (-5.45% vs. -1.96%, P < 0.001). In addition, steatosis improved in more patients treated with Xenical compared with the conventional treatment arm (57.3% vs. 23.5%, p < 0.001). Long-term, well-designed trials in a large number of patients are needed to determine if Xenical has a place in therapy for nonalcoholic fatty liver disease. In a small, randomized trial, Saxenda was compared with lifestyle modification in obese patients with nonalcoholic fatty liver disease.[36] After 26 weeks, similar reductions in weight (-3.3 kg vs. -3.0 kg), liver fat fraction (-8.1% vs. -7.0%), alanine aminotransferase (-39 U/L vs. -26 U/L), and caspase-cleaved cytokeratin-18 (-206 U/L vs. -130 U/L) occurred in the lifestyle modification and Saxenda groups, respectively. However, after discontinuing Saxenda, patients regained weight and liver fat fraction at week 52 while patients in the lifestyle modification group maintained the improvements in weight and liver fat fraction. There is very little good quality evidence to support or refute the use of weight reduction as a treatment for nonalcoholic fatty liver disease.[24]

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

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APPENDIX A

Below is a chart of BMI based on various heights and weights.[2] To use the table, find the appropriate height in the far left column, and move across the row to the given weight; the number at the top of the column is the BMI. For example, a patient who is 5 feet 6 inches in height and weighs 192 pounds has a BMI of 31 kg/m^2.

BMI can also be calculated using the following formula: BMI equals body weight in kilograms divided by height meters squared (m^2), i.e., BMI = kg/m^2.

Body Mass Index

BMI, kg/m^2	25	26	27	28	29	30	31	32	33	34	35	40
Height (feet, inches)	Weight (pounds)											
4’10”	119	124	129	134	138	143	148	153	158	162	167	191
4’11”	124	128	133	138	143	148	153	158	163	168	173	198
5’0”	128	133	138	143	148	153	158	163	168	174	179	204
5’1”	132	137	143	148	153	158	164	169	174	180	185	211
5’2”	136	142	147	153	158	164	169	175	180	186	191	218
5’3”	141	146	152	158	163	169	175	180	186	191	197	225
5’4”	145	151	157	163	169	174	180	186	192	197	204	232
5’5”	150	156	162	168	174	180	186	192	198	204	210	240
5’6”	155	161	167	173	179	186	192	198	204	210	216	247
5’7”	159	166	172	178	185	191	198	204	211	217	223	255
5’8”	164	171	177	184	190	197	203	210	216	223	230	262
5’9”	169	176	182	189	196	203	209	216	223	230	236	270
5’10”	174	181	188	195	202	209	216	222	229	236	243	278
5’11”	179	186	193	200	208	215	222	229	236	243	250	286
6’0”	184	191	199	206	213	221	228	235	242	250	258	294
6’1”	189	197	204	212	219	227	235	242	250	257	265	302
6’2”	194	202	210	218	225	233	241	249	256	264	272	311
6’3”	200	208	216	224	232	240	248	256	264	272	279	319
6”4”	205	213	221	230	238	246	254	263	271	279	287	328