Anti-obesity Agents Formulary Exception with Quantity Limit Program Summary

This program applies to FlexRx Closed and GenRx Closed formularies.

FDA APPROVED INDICATIONS AND DOSAGE[1-11]

Agent(s)	Indication(s)	Dosage
Adipex-P®, Lomaira™, Phentermine (phentermine) Tablet[a] Capsule[a]	Short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity in patients with an initial BMI ≥30 kg/m^2 or ≥27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia).[b]	Lomaira tablets: 1 (8 mg) tablet three times daily, 30 minutes before meals Tablets/capsules (15 mg, 30 mg, 37.5 mg): 1 tablet/capsule daily
Benzphetamine Tablet[a]	Short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction in the management of exogenous obesity for patients with an initial body mass index ≥30 kg/m^2 who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone.[b]	25 mg to 50 mg one to three times daily; dosage should be individualized according to patient response
Contrave® (naltrexone/bupropion) Tablet ER	Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • ≥30 kg/m^2 (obese), or • ≥27 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) Limitations of Use:[b] - Effect on cardiovascular morbidity and mortality has not been established	Dose escalation schedule: • Week 1 – 1 tablet in the morning • Week 2 – 1 tablet in the morning and 1 tablet in the evening • Week 3 – 2 tablets in the morning and 1 tablet in the evening • Week 4 and onward – 2 tablets in the morning and 2 tablets in the evening Evaluate after 12 weeks at the maintenance dosage (4 tablets/day). Discontinue if a patient has not lost ≥5% baseline body weight. Max dose: 32mg/360 mg daily

Agent(s)	Indication(s)	Dosage
Diethylpropion Tablet[a] Tablet ER[a]	Short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction in the management of exogenous obesity for patients with an initial body mass index (BMI) ≥30 kg/m^2 and who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. Indicated for use as monotherapy only.	• Immediate release (25 mg): 1 tablet three times daily, 1 hour before meals, and in midevening if desired to overcome night hunger • Controlled release (75 mg): 1 tablet once daily in midmorning
Phendimetrazine Tablet[a]	Short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction in the management of exogenous obesity for patients with an initial BMI ≥30 kg/m^2 who have not responded to appropriate weight reducing regimen alone (diet and/or exercise). Indicated for use as monotherapy only.	1 tablet (35 mg) two to three times daily, 1 hour before meals Dosage should be individualized to lowest effective dosage Maximum dose is 2 tablets three times daily
Phendimetrazine Capsule ER[a]	Short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction in the management of exogenous obesity for patients with an initial BMI ≥30 kg/m^2 or ≥27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia) who have not responded to appropriate weight reducing regimen alone (diet and/or exercise) Indicated for use as monotherapy only.	1 capsule (105 mg) once daily in the morning, 30 – 60 minutes before morning meal

Agent(s)	Indication(s)	Dosage
Qsymia® (phentermine/ topiramate) Capsule	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) • ≥27 kg/m^2 (overweight) in the presence of at least one weight-related comorbid condition such as hypertension, type 2 diabetes, or dyslipidemia[b]	3.75mg/23mg once daily for 14 days, then increase to 7.5mg/46mg once daily. Evaluate weight loss after 12 weeks of treatment at 7.5mg/46mg. If a patient has not lost at least 3% of baseline body weight, discontinue OR escalate the dose to 11.25mg/69mg. After 14 days, increase to 15mg/92mg once daily. Evaluate weight loss after an additional 12 weeks of treatment at 15mg/92mg. If the patient has not lost at least 5% of baseline body weight, discontinue as directed in labeling.

Saxenda® (liraglutide)
 	
Injection solution
	Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:
	• Adults with an initial body mass index (BMI) of:
	  • ≥30 kg/m^2 (obese), or
	  • ≥27 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)
	
	• Pediatric patients aged 12 years or older with:
	  • Body weight >60 kg, and
	  • an initial BMI corresponding to ≥30 kg/m^2 for adults (obese) by international cut-offs (Cole Criteria)
	
	Limitations of use:[b]
	• Safety and effectiveness in pediatric patients with type 2 diabetes have not been established
	• Should not be used in combination with any other GLP-1 receptor agonist
		Adults and pediatric patients aged 12 years and older:
		
		Initiate at 0.6 mg per day for one week. Increase dose by 0.6 mg weekly until a dose of 3 mg per day is reached. Dose escalation for pediatric patients may take up to 8 weeks.
		
		Recommended maintenance dosage for adults and pediatric patients is 3 mg daily. Pediatric patients who do not tolerate 3 mg daily may reduce their maintenance dose to 2.4 mg daily.
		
		Discontinue in adults who cannot tolerate 3 mg dose, and pediatric patients who cannot tolerate the 2.4 mg dose.
		
		Adults: Evaluate the change in body weight 16 weeks after initiating, and discontinue if the patient has not lost at least 4% of baseline body weight.
		
		Pediatric patients: Evaluate the change in BMI after 12 weeks on the maintenance dose, and discontinue if the patient has not had a reduction in BMI of at least 1% from baseline.

Agent(s)	Indication(s)	Dosage
Xenical® (orlistat) Capsule	Obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet and to reduce the risk for weight regain after prior weight loss. It is indicated for obese patients with an initial body mass index (BMI) ≥30 kg/m^2 or ≥27 kg/m^2 in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia)	One capsule (120 mg) three times daily with each main meal containing fat (during or up to 1 hour after the meal)

a – Generic equivalent available
b – The safety and efficacy of coadministration with other weight loss drug products, including prescribed drugs, over-the-counter preparations, and herbal products have not been established. Therefore, coadministration is not recommended.

CLINICAL RATIONALE

Obesity rates have increased sharply over the last 30 years, creating a global public health crisis. The National Health and Nutrition Examination Surveys show that nearly 2 of 3 US adults are overweight or obese, and 1 of 3 adults are obese. Adults with body mass index (BMI) 25-29.9 kg/m^2 are considered overweight; those with BMI ≥30 kg/m^2 are considered obese.[14] Weight loss is difficult for most people and weight loss medications help reinforce behavioral strategies to lose weight. Medications for weight loss do not work on their own. Numerous guidelines recommend the addition of weight loss medications only in conjunction with lifestyle and behavioral modifications.[13-15]

The American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity recommends the following:[14]

- The principal outcome and therapeutic target in the treatment of obesity should be to improve the health of the patient by preventing or treating weight related complications using weight loss, not the loss of body weight per se
- For overweight (BMI 25-29.9 kg/m^2) or obese (BMI ≥30 kg/m^2) patients, evaluate for adiposity related complications:
    - Metabolic syndrome
    - Prediabetes
    - Type 2 diabetes (T2DM)
    - Dyslipidemia
    - Hypertension
    - Cardiovascular disease
    - Non-alcoholic fatty liver disease
    - Polycystic ovary syndrome
    - Female infertility
    - Male hypogonadism
    - Obstructive sleep apnea
    - Asthma/reactive airway disease
    - Osteoarthritis
    - Urinary stress incontinence
    - Gastroesophageal reflux disease
    - Depression

- Pharmaceutical therapy should only be used as adjunct to lifestyle modifications and depends on the staging of obesity:
    - Overweight Stage 0 (BMI 25-29.9 kg/m^2 or 23-24.9 kg/m^2 in certain ethnicities* with no complications)
        - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions
    - Obesity Stage 0 (BMI ≥30 kg/m^2 or ≥25 kg/m^2 in certain ethnicities* with no complications)
        - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral intervention
        - Weight loss medications - consider if lifestyle therapy fails to prevent progressive weight gain (BMI ≥27 kg/m^2)
    - Obesity Stage 1 (BMI ≥25 kg/m^2 or ≥23 kg/m^2 in certain ethnicities* with ≥1 mild/moderate complications)
        - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions
        - Weight loss medications – consider if lifestyle therapy fails to achieve therapeutic target or initiate concurrently with lifestyle therapy (BMI ≥27 kg/m^2)
    - Obesity Stage 2 (BMI ≥25 kg/m^2 or ≥23 kg/m^2 in certain ethnicities* with ≥1 severe complications):
        - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions
        - Weight loss medication – initiate concurrently with lifestyle therapy (BMI ≥27 kg/m^2)
        - Consider bariatric surgery (BMI ≥35 kg/m^2)

      *Certain ethnicities (A BMI cutoff point value of ≥23 kg/m2 should be used in the screening and confirmation of excess adiposity in South Asian, Southeast Asian, and East Asian adults)

The Endocrine Society clinical practice guidelines suggests medications approved for chronic weight management can be useful adjuncts to lifestyle change for patients who have been unsuccessful with diet and exercise alone. They recommend adherence to American Heart Association Guidelines (2013) [see below] which include advice for assessment and treatment with diet and exercise, as well as bariatric surgery for appropriate candidates.[13]

- Diet, exercise, and behavioral modification should be included in all overweight and obesity management approaches for BMI ≥25 kg/m2 and other tools [e.g., pharmacotherapy (if BMI ≥27 kg/m2 with comorbidity or BMI >30 kg/m2) and bariatric surgery (BMI ≥35 kg/m2 with comorbidity or BMI >40 kg/m2)] should be used as adjuncts to behavioral modification to reduce food intake and increase physical activity when possible. Drugs may amplify adherence to behavior change and may improve physical functioning such that increased physical activity is easier in those who cannot exercise initially. Patients who have a history of being unable to successfully lose and maintain weight and who meet label indications are candidates for weight loss medications.
- Assessment of efficacy and safety of prescribed weight loss medications should be performed at least monthly for the first 3 months, then at least every 3 months thereafter.
- Clinicians are recommended to perform annual and symptom-based screening for major obesity related chronic conditions in all adult patients with a BMI ≥30 kg/m^2, including diabetes, cardiovascular disease, hypertension, hyperlipidemia, obstructive sleep apnea, non-alcoholic fatty liver disease, osteoarthritis, and major depression.

- Prescribers should identify chronic medications, for concomitant medical conditions, that contribute to weight gain, and prescribe drugs that are weight neutral or that will promote weight loss when possible.
- 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. If deemed ineffective (weight loss <5% at 3 months) or if there are safety or tolerability issues at any time, the medication should be discontinued and alternative medications or referral for alternative treatment approaches instead considered.
- Given the wide clinical prescribing of phentermine for >20 years and lack of evidence of serious side effects, even in the absence of long-term controlled safety and efficacy data, it seems reasonable for clinicians to prescribe phentermine long term as long as the patient: 1) has no evidence of serious cardiovascular disease; 2) does not have serious psychiatric disease or a history of substance abuse; 3) has been informed about weight loss medications that are FDA approved for long-term use and told that these have been documented to be safe and effective whereas phentermine has not; 4) does not demonstrate a clinically significant increase in pulse or BP when taking phentermine; and 5) demonstrates a significant weight loss while using the medication. These aspects of care should be documented in the patient's medical record, and the off-label nature of the prescribing should be documented at each visit. Medication should be started at 7.5 or 15 mg/day initially and only increased if the patient is not achieving clinically significant weight loss. Patients should be followed at least monthly during dose escalation and then at least every 3 months when on a stable dose.

The American Heart Association/American College of Cardiology/Obesity Society Guideline (2013) suggests if weight and lifestyle history indicates the patient has never participated in a comprehensive lifestyle intervention program as defined in the guidelines (i.e., trained interventionist or nutritional professional supervision of diet, exercise, and behavior therapy), it is recommended that the patient undertake such a program before addition of adjunctive therapies (e.g., pharmacotherapy), since a substantial proportion of patients will lose sufficient weight to improve health with comprehensive lifestyle management alone. If a patient has been unable to lose weight or sustain weight loss with comprehensive lifestyle intervention and has BMI ≥30 kg/m^2 or ≥27 kg/m^2 with ≥1 obesity-associated comorbid condition(s), adjunctive therapy may be considered. The expert panel did not review comprehensive evidence on pharmacotherapy for weight loss. Medications should be FDA approved and clinicians should be knowledgeable about the product label. The provider should weigh potential risks of the medication vs. potential benefits of successful weight loss for the individual patient. If the patient is currently taking an obesity medication but has not lost at least 5% of initial body weight after 12 weeks on a maximal dose of the medication, the provider should reassess the risk-to-benefit ratio of that medication for the patient and consider discontinuation of that drug.[15]

The Veterans Affairs and Department of Defense (VA/DoD) Clinical Practice Guideline (2020), suggests offering prescribed pharmacotherapy in patients with a BMI ≥30 kg/m^2 or ≥27 kg/m^2 with ≥1 obesity-associated comorbid condition(s), in conjunction with a comprehensive lifestyle intervention.[18]

Four centrally-acting noradrenergic agents (phentermine, diethylpropion, phendimetrazine, benzphetamine) are FDA-approved for the "short-term" (usually considered ≤12 weeks) management of obesity. However, the short-term designation was given since all were approved before the necessity of long-term treatment for obesity was established.[12] Since then some of these agents, such as phentermine and diethylpropion, have had literature published in support of long-term use.[13,19] Given the wide clinical prescribing of phentermine for >20 years and lack of evidence of serious side effects, even in the absence of long-term

controlled safety and efficacy data, it seems reasonable for clinicians to prescribe phentermine long term.[13] A clinical study found that diethylpropion plus a standard dietary intervention produced sustained and clinically significant weight loss over 1 year, and demonstrated safety under the cardiovascular and psychiatric point of view.[19]

Pediatric Obesity

Pediatric obesity has become an epidemic and international problem. In the United States, the prevalence of obesity in children has risen from 5% in 1970 to 17% in 2004. Genetics and environment are the underlying causes of the increase in pediatric obesity. Obese children and adolescents are at risk of developing the same comorbid conditions as obese and overweight adults. Obesity and overweight in children are defined on percentages specific for age and gender defined BMI values. The American Academy of Pediatrics (AAP) define obesity as a BMI ≥95th percentile or a BMI ≥30 kg/m^2, whichever is lower, and overweight as a BMI within 85th to 94th percentile for children and adolescents 2 years of age and older.[17]

The AAP recommends that clinicians should assess medical and behavioral risks in any child with a BMI above the 85th percentile before initiating any intervention.[17] The Endocrine Society Pediatric Obesity Treatment Guidelines also recommend that clinicians should evaluate for potential comorbidities in children and adolescents with a BMI ≥85th percentile.[16]

The 2007 AAP guidelines recommend the use of weight loss agents in conjunction with lifestyle and behavioral changes. The AAP noted that orlistat is the only FDA approved medication, with limited use in pediatric patients ≥12 years of age. The AAP treatment guidelines have the following recommendations following a 4-stage approach to treat obesity for children between 2 to 19 years of age whose BMI is >85th percentile:[17]

- Patients should start at the least intensive stage and advance through the stages based upon the response to treatment, age, BMI, health risks and motivation.
- Children age 2–5 who have obesity should not lose more than 1 pound/month; older children and adolescents with obesity should not lose more than an average of 2 pounds/week.
- Weight loss through lifestyle changes is optimal, but medications may be used as adjunctive therapy when clear health risks are present and lifestyle changes alone have not been effective.
- Stage 1: Prevention Plus
- Stage 2: Structured Weight Management
- Stage 3: Comprehensive Multidisciplinary Intervention
- Stage 4: Tertiary Care Intervention

The 2017 Endocrine Society guidelines only recommend the use of FDA approved pharmacotherapy in pediatric patients as adjunctive therapy to lifestyle modifications of the highest intensity available and only by clinicians that are experienced in the use of anti-obesity agents.[16]

- Suggest pharmacotherapy in children or adolescents with obesity (≥95th percentile for age and gender) only after a formal program of intense lifestyle modifications has failed to limit weight gain or to ameliorate comorbidities.
- Recommend against using obesity agents in children and adolescents <16 years of age who are overweight, but not obese, except in the context of clinical trials.
- Anti-obesity agents should be discontinued, and patients reevaluated if the patient does not have a >4% BMI reduction after 12 weeks at the medication's full dosage.
- Discourages prescribing weigh loss medications off-label to pediatric patients <16 years of age.

Safety

Phentermine has the following contraindications:[5,6,11]

- History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension)
- During or within 14 days following the administration of monoamine oxidase inhibitors
- Hyperthyroidism
- Glaucoma
- Agitated states
- History of drug abuse
- Pregnancy
- Nursing
- Known hypersensitivity, or idiosyncrasy to the sympathomimetic amines

Benzphetamine has the following contraindications:[2]

- Patients with advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to sympathomimetic amines, and glaucoma
- Benzphetamine should not be given to patients who are in an agitated state or who have a history of drug abuse
- Hypertensive crises have resulted when sympathomimetic amines have been used concomitantly or within 14 days following use of monoamine oxidase inhibitors
- Benzphetamine tablets should not be used concomitantly with other CNS stimulants
- Benzphetamine is contraindicated in women who are or may become pregnant

Phendimetrazine has the following contraindications:[7,10]

- Immediate release:
    - Known hypersensitivity or idiosyncratic reactions to sympathomimetics
    - Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate and severe hypertension, hyperthyroidism, and glaucoma
    - Highly nervous or agitated
    - History of drug abuse
    - Use in combination with other CNS stimulants, including monoamine oxidase inhibitors
- Extended release:
    - History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension, pulmonary hypertension)
    - During or within 14 days following the administration of monoamine oxidase inhibitors
    - Hyperthyroidism
    - Glaucoma
    - Agitated states
    - History of drug abuse
    - Pregnancy
    - Nursing
    - Use in combination with other anorectic agents or CNS stimulants
    - Known hypersensitivity or idiosyncratic reactions to sympathomimetics

Diethylpropion has the following contraindications:[9]

- Pulmonary hypertension, advanced arteriosclerosis, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma, severe hypertension
- Agitated states
- Patients with a history of drug abuse
- Use in combination with other anorectic agents is contraindicated
- During or within 14 days following the administration of monoamine oxidase inhibitors, hypertensive crises may result

Phentermine/topiramate[1]
Contraindications include:
- Pregnancy
- Glaucoma
- Hyperthyroidism
- During or within 14 days following the administration of monoamine oxidase inhibitors
- Known hypersensitivity or idiosyncrasy to the sympathomimetic amines

Naltrexone/bupropion (NB)[3]
Contraindications include:
- Uncontrolled hypertension
- Seizure disorder or a history of seizures
- Use of other bupropion-containing products (including, but not limited to, Wellbutrin, Wellbutrin SR, Wellbutrin XL, Aplenzin, and Zyban)
- Bulimia or anorexia nervosa, which increase the risk for seizure
- Chronic opioid or opiate agonist (e.g., methadone) or partial agonists (e.g., buprenorphine) use, or acute opiate withdrawal
- Patients undergoing an abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs
- Concomitant administration of monoamine oxidase inhibitors (MAOI). At least 14 days should elapse between discontinuation of MAOI and initiation of treatment with Contrave. There is an increased risk of hypertensive reactions when Contrave is used concomitantly with MAOIs. Starting Contrave in a patient treated with reversible MAOIs such as linezolid or intravenous methylene blue is also contraindicated
- Known allergy to bupropion, naltrexone or any other component of Contrave. Anaphylactoid/anaphylactic reactions and Stevens-Johnson syndrome have been reported with bupropion

Boxed warnings include:
- Contrave is not approved for use in the treatment of major depressive disorder or other psychiatric disorders. Contrave contains bupropion, the same active ingredient as some other antidepressant medications (including, but not limited to, Wellbutrin, Wellbutrin SR, Wellbutrin XL, and Aplenzin). Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term trials. These trials did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in subjects over age 24; there was a reduction in risk with antidepressant use in subjects aged 65 and older. In patients of all ages who are started on Contrave, monitor closely for worsening, and for the emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber. Contrave is not approved for use in pediatric patients.

Liraglutide[8]

Contraindications include:

- Patients with a personal or family history of medullary thyroid carcinoma (MTC) or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- Patients with a prior serious hypersensitivity reaction to liraglutide or to any of the product components
- Pregnancy

Boxed warnings include:

- Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Saxenda causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined.
- Saxenda is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of Saxenda and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Saxenda.

Orlistat[4]

Contraindications include:

- Pregnancy
- Chronic malabsorption syndrome
- Cholestasis
- Known hypersensitivity to Orlistat or to any component of this product

Co-Administration

None of the FDA approved weight loss agents have approval for co-administration with another weight loss agent. New guidelines do not support the use of co-administration of weight loss pharmacological agents.[13,14,18] Use of non-approved drug combinations for obesity treatment should be limited to clinical trials, and patients should be informed when drugs are being used off label alone or in combination.[12]

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Antiobesity Agents Formulary Exception with Quantity Limit Criteria

TARGET AGENT(S)
Adipex-P® (phentermine)[a]
Benzphetamine[a]
Contrave® (naltrexone/bupropion)
Diethylpropion[a]
Lomaira™ (phentermine)
Phendimetrazine[a]
Phentermine[a]
Qsymia® (phentermine/topiramate)
Saxenda® (liraglutide)
Xenical® (orlistat)
a – Generic equivalent available

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Adipex-P (phentermine)[a]			
37.5 mg capsule	61200070100120	M, N, O, or Y	1 capsule
37.5 mg tablet	61200070100310	M, N, O, or Y	1 tablet
Benzphetamine[a]			
25 mg tablet	61200010100305	M, N, O, or Y	3 tablets
50 mg tablet	61200010100310	M, N, O, or Y	3 tablets
Contrave (naltrexone/bupropion)			
8 mg / 90 mg tablet	61259902507420	M, N, O, or Y	4 tablets
Diethylpropion[a]			
25 mg tablet	61200020100305	M, N, O, or Y	3 tablets
75 mg extended-release tablet	61200020107510	M, N, O, or Y	1 tablet
Lomaira (phentermine)			
8 mg tablet	61200070100305	M, N, O, or Y	3 tablets
Phendimetrazine[a]			
35 mg tablet	61200050100305	M, N, O, or Y	6 tablets
105 mg extended-release capsule	61200050107010	M, N, O, or Y	1 capsule
Phentermine[a]			
15 mg capsule	61200070100110	M, N, O, or Y	1 capsule
30 mg capsule	61200070100115	M, N, O, or Y	1 capsule
Qsymia (phentermine/topiramate)			
3.75mg/23mg capsule	61209902307020	M, N, O, or Y	1 capsule
7.5mg/46mg capsule	61209902307030	M, N, O, or Y	1 capsule
11.25mg/69mg capsule	61209902307040	M, N, O, or Y	1 capsule
15mg/92mg capsule	61209902307050	M, N, O, or Y	1 capsule
Saxenda (liraglutide)			
6 mg/mL, 3 mL/pen	6125205000D220	M, N, O, or Y	0.5 mL
Xenical (orlistat)			
120 mg capsule	61253560000120	M, N, O, or Y	3 capsules

a – Generic equivalent available

FORMULARY EXCEPTION CRITERIA FOR APPROVAL

Initial Evaluation

(Patient new to therapy, new to Prime, or attempting a repeat weight loss course of therapy)

Target Agents will be approved when ALL the following are met:

1. The requested agent is not excluded under the patient's current benefit plan
   AND
2. ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent
      OR
   B. The prescriber has provided information in support of using the requested agent for the patient's age
   AND
3. ONE of the following:
   A. The patient is 17 years of age or over and ONE of the following:
      i. ALL of the following:
         a. ONE of the following:
            1. The patient has a diagnosis of obesity, confirmed by a BMI ≥30 kg/m^2 OR a BMI ≥25 kg/m2 if the patient is of South Asian, Southeast Asian, or East Asian descent
               OR
            2. The patient has a BMI ≥27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., diabetes, dyslipidemia, coronary artery disease)
         AND
         b. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent
            AND
         c. The patient did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent
            AND
         d. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications
      OR
      ii. BOTH of the following:
         a. The patient has a BMI ≥27 kg/m^2 with at least one severe weight-related comorbidity/risk factor/complication
            AND
         b. The patient will initiate or is currently on and will continue a weight loss regimen of a low-calorie diet, increased, physical activity, and behavioral modifications along with the requested agent
   OR
   B. The patient is 12 to 16 years of age and ALL of the following:
      i. ONE of the following:

a. The patient has a diagnosis of obesity, confirmed by a BMI ≥95th percentile for age and gender
OR
b. The patient has a diagnosis of obesity, confirmed by a BMI ≥30 kg/m^2
OR
c. The patient has a BMI ≥85th percentile for age and gender AND at least one severe weight-related comorbidity/risk factor/complication

AND

ii. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent
AND
iii. The patient did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent
AND
iv. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications

AND

4. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
5. The patient will NOT be using the requested agent in combination with another weight loss agent for the requested indication
AND
6. ONE of the following:
   A. The patient has no evidence of a prior authorization for a weight loss agent in the past 12 months of claims history
   OR
   B. The patient has evidence of a prior authorization for a weight loss agent for a previous course of therapy in the past 12 months of claims history AND the prescriber has provided information supporting the anticipated success of repeating therapy

AND

7. ONE of the following:
   A. The requested agent is benzphetamine, diethylpropion, phendimetrazine, or phentermine
   OR
   B. The requested agent is Qsymia and ONE of the following:
      i. The requested dose is 3.75mg/23mg
      OR
      ii. The patient is currently being treated with Qsymia, the requested dose is greater than 3.75 mg/23 mg AND ONE of the following:
         a. The patient has demonstrated and maintained a weight loss of ≥5% from baseline (prior to the initiation of requested agent)
         OR
         b. The patient received less than 14 weeks of therapy
         OR
         c. The patient's dose is being titrated upward
         OR

d. The patient has received less than 12 weeks (3 months) of therapy on the 15mg/92mg strength

OR

iii. The prescriber has provided information in support of therapy for the requested dose for this patient

OR

C. The requested agent is Contrave and ONE of the following:
   i. The patient is newly starting therapy
   OR
   ii. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy
   OR
   iii. The patient has achieved and maintained a weight loss of ≥5% from baseline (prior to the initiation of requested agent)

OR

D. The requested agent is Xenical and ONE of the following:
   i. The patient is 12 to 16 years of age and ONE of the following:
      a. The patient is newly starting therapy
      OR
      b. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy
      OR
      c. The patient has achieved and maintained a weight loss of >4% from baseline (prior to the initiation of requested agent)

   OR

   ii. The patient is 17 years of age or over and ONE of the following:
      a. The patient is newly starting therapy
      OR
      b. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy
      OR
      c. The patient has achieved and maintained a weight loss of ≥5% from baseline (prior to the initiation of requested agent)

OR

E. The requested agent is Saxenda and ALL of the following:
   i. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent
   AND
   ii. ONE of the following:
      a. The patient is 18 years of age or over and ONE of the following:
         1. The patient is newly starting therapy
         OR
         2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy
         OR
         3. The patient has achieved and maintained a weight loss of ≥4% from baseline (prior to the initiation of requested agent)

      OR

      b. The patient is pediatric (12 to <18 years of age) and BOTH of the following:
         1. The requested agent is NOT being used to treat type 2 diabetes

AND

2. ONE of the following:
    A. The patient is newly starting therapy
    OR
    B. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy
    OR
    C. The patient has achieved and maintained a reduction in BMI of ≥1% from baseline (prior to the initiation of requested agent)

AND

8. ONE of the following:
    A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives
    OR
    B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or other harm

AND

9. ONE of the following:
    A. The requested quantity (dose) does NOT exceed the program quantity limit
    OR
    B. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
        AND
        iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
    OR
    C. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
        AND
        iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: For Saxenda pediatric patients (age 12 to <18): 5 months
For Saxenda (adults) and Contrave: 4 months
For all other agents: 3 months

Renewal Evaluation
(Patient continuing a current weight loss course of therapy)

Target Agent(s) will be approved when ALL of the following are met:

1. Requested agent is not excluded under the patient's current benefit plan
   AND
2. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
   AND
3. The patient is currently on and will continue to be on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications
   AND
4. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
5. For Saxenda only, BOTH of the following:
   A. The requested agent is NOT being used to treat type 2 diabetes in pediatric patients (12 to <18 years of age)
      AND
   B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent

   AND
6. The patient meets ONE of the following:
   A. The patient has achieved and maintained a weight loss ≥5% from baseline (prior to the initiation of requested agent)
      OR
   B. For Saxenda only, ONE of the following:
      i. If the patient is 18 years of age or over, the patient has achieved and maintained a weight loss ≥4% from baseline (prior to the initiation of requested agent)
         OR
      ii. If the patient is pediatric (12 to <18 years of age), the patient has achieved and maintained a reduction in BMI of ≥1% from baseline (prior to the initiation of requested agent)

      OR
   C. For Qsymia only, the patient has achieved and maintained a weight loss <5% from baseline (prior to the initiation of requested agent) and BOTH of the following:
      i. The patient's dose is being titrated upward (for the 3.75 mg/23 mg, 7.5 mg/46 mg or 11.25 mg/69 mg strengths only)
         AND
      ii. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength

      OR
   D. For Xenical only, ONE of the following:
      i. The patient 12 to 16 years of age AND has achieved and maintained a weight loss >4% from baseline (prior to the initiation of requested agent)
         OR
      ii. The patient is 17 years of age or over AND has achieved and maintained a weight loss ≥5% from baseline (prior to the initiation of requested agent)

   AND
7. If the patient is 12 to <18 years of age, the current BMI is >85th percentile for age and gender
   AND
8. The patient will NOT be using the requested agent in combination with another weight loss agent

AND

9. ONE of the following:
    A. The patient has tried and failed at least three (or as many as available, if fewer than three) formulary alternatives
    OR
    B. The prescriber has indicated that available formulary alternatives are contraindicated, likely to be less effective, or likely to cause an adverse reaction or other harm

AND

10. ONE of the following:
    A. The requested quantity (dose) does NOT exceed the program quantity limit
    OR
    B. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
        AND
        iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
    OR
    C. ALL of the following:
        i. The requested quantity (dose) is greater than the program quantity limit
        AND
        ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
        AND
        iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: Qsymia: ≥5% weight loss from baseline: 12 months
Qsymia (<5% weight loss): 3 months
All other agents: 12 months

