## Antiobesity Agents
Formulary Exception with Quantity Limit Program Summary

This program applies to FlexRx Closed and GenRx Closed formularies.

**FDA APPROVED INDICATIONS AND DOSAGE**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Indication</th>
<th>Dosage</th>
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</thead>
</table>
| **Belviq™, Belviq XR™** (lorcaserin) tablets, tablets ER | Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of:  
- ≥30 kg/m²  
- ≥27 kg/m² in the presence of at least one weight-related comorbid condition | Immediate release: 10 mg twice daily  
Extended release: 20 mg once daily  
Discontinue at 12 weeks if 5% weight loss is not achieved |
| **Bontril PDM** (phendimetrazine) tablets<sup>a</sup> | 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/m² or ≥27 kg/m² in the presence of other risk factors (e.g., hypertension, type 2 diabetes, hyperlipidemia) who have not responded to appropriate weight reducing regimen alone (diet and/or exercise) | 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 |
| **Bontril Slow Release** (phendimetrazine) capsules ER | 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/m² who have not responded to appropriate weight reducing regimen alone (diet and/or exercise)  
Not recommended for patients under 17 years of age | 105 mg once daily in the morning, 30 – 60 minutes before morning meal |
| **Contrave®** (naltrexone/bupropion) tablets 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/m² (obese)  
- ≥27 kg/m² (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia) | 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  
Discontinue at 12 weeks if 5% weight loss is not achieved |
<table>
<thead>
<tr>
<th>Agent</th>
<th>Indication</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Didrex®, Regimex™</strong>&lt;br&gt;(benzphetamine)&lt;br&gt;tablets&lt;sup&gt;a&lt;/sup&gt;</td>
<td>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/m² and who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone.</td>
<td>Max dose: 32mg/360 mg daily</td>
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<tr>
<td><strong>Diethylpropion</strong>&lt;br&gt;tablets&lt;sup&gt;a&lt;/sup&gt;, tablet ER&lt;sup&gt;a&lt;/sup&gt;</td>
<td>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/m² and who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone.</td>
<td>25 mg to 50 mg one to three times daily; dosage should be individualized according to patient response</td>
</tr>
<tr>
<td><strong>Adipex-P®, Lomaira™, Phentermine, Suprenza™</strong>&lt;br&gt;(phentermine)&lt;br&gt;tablets&lt;sup&gt;a&lt;/sup&gt;, capsules&lt;sup&gt;a&lt;/sup&gt;, ODT tablets</td>
<td>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/m² or ≥27 kg/m² in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia).</td>
<td>• Immediate release (25 mg): 1 tablet three times daily, 1 hour before meals, and in midevening if desired to overcome night hunger&lt;br&gt;• Controlled release (75 mg): 1 tablet once daily in midmorning</td>
</tr>
<tr>
<td><strong>Qsymia®</strong>&lt;br&gt;(phentermine/topiramate)</td>
<td>Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in</td>
<td><strong>Titration schedule:</strong> 3.75mg/23mg once daily for 14 days, then increase to 7.5mg/46mg once daily</td>
</tr>
<tr>
<td>Agent</td>
<td>Indication</td>
<td>Dosage</td>
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</tr>
<tr>
<td>capsules</td>
<td>adults with an initial BMI of:</td>
<td>Max dose: 15 mg/92 mg once daily</td>
</tr>
<tr>
<td></td>
<td>• ≥30 kg/m² in the presence of at least one weight-related comorbid condition such as hypertension, type 2 diabetes, or dyslipidemia</td>
<td>Discontinue or escalate the dose if 3% weight loss is not achieved after 12 weeks on 7.5mg/46mg daily</td>
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<tr>
<td></td>
<td>• ≥27 kg/m² in the presence of at least one weight-related comorbid condition such as hypertension, type 2 diabetes, or dyslipidemia</td>
<td>Discontinue if 5% weight loss is not achieved after 12 weeks on daily dose of 15mg/92mg</td>
</tr>
<tr>
<td><strong>Saxenda®</strong> (liraglutide)</td>
<td>Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:</td>
<td>3 mg subcutaneously daily</td>
</tr>
<tr>
<td>injection solution</td>
<td>• ≥30 kg/m² (obese)</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>• ≥27 kg/m² (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)</td>
<td>Evaluate the change in body weight 16 weeks after initiating Saxenda and discontinue Saxenda if the patient has not lost at least 4% of baseline body weight</td>
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<td></td>
<td>Limitations of use:</td>
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<tr>
<td></td>
<td>• Not indicated for the treatment of type 2 diabetes</td>
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<tr>
<td></td>
<td>• Should not be used in combination with any other GLP-1 receptor agonist</td>
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<tr>
<td></td>
<td>• Should not be used in combination with Victoza</td>
<td></td>
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<tr>
<td></td>
<td>• Should not be used with insulin</td>
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<tr>
<td><strong>Xenical®</strong> (orlistat)</td>
<td>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/m² or ≥27 kg/m² in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia)</td>
<td>120 mg three times daily with each main meal containing fat (during or up to 1 hour after the meal)</td>
</tr>
<tr>
<td>capsules</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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/m² are considered overweight; those with BMI ≥30 kg/m² are considered obese. 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.13,17,18
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: 17

- 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/m²) or obese (BMI >30 kg/m²) 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 or 23-24.9 in certain ethnicities* with no complications)
    - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions
  - Obesity Stage 0 (BMI ≥30 or ≥25 in certain ethnicities* with no complications)
    - Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral intervention
    - Weight loss medications - consider if lifestyle intervention fails to prevent progressive weight gain (BMI ≥27 kg/m²)
  - Obesity Stage 1 (BMI ≥25 or ≥23 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/m²)
  - Obesity Stage 2 (BMI ≥25 or ≥23 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/m²)
    - Consider bariatric surgery (BMI ≥35 kg/m²)
  *
  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.\(^\text{13}\)

- Diet, exercise, and behavioral modification should be included in all overweight and obesity management approaches for BMI >25 kg/m\(^2\) and other tools [e.g., pharmacotherapy (if BMI >27 kg/m\(^2\) with comorbidity or BMI >30 kg/m\(^2\)) and bariatric surgery (BMI >35 kg/m\(^2\) with comorbidity or BMI >40 kg/m\(^2\))] 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.

- 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.

- 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.

- 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.

- If a patient's response to a weight loss medication is deemed effective (weight loss ≥ 5% of body weight at 3 mo) and safe, we recommend that the medication be continued. If deemed ineffective (weight loss < 5% at 3 mo) or if there are safety or tolerability issues at any time, we recommend that the medication be discontinued and alternative medications or referral for alternative treatment approaches be considered

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 comorbidity, 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.¹⁸

**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/m², whichever is lower, and overweight as a BMI within 85th to 94th percentile for children and adolescents 2 years of age and older.²⁰

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.²⁰ 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.¹⁹

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:²⁰

- 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.
- An empathetic and empowering counseling style, such as motivational interviewing, should be employed to support patient and family behavior change.
- 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.¹⁹

- 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 medications full dosage.
- Discourages prescribing weigh loss medications off-label to pediatric patients <16 years of age
• Orlistat is the only FDA approved weight loss medication for the treatment of obesity in patients age 12 to 16 years

Safety
Phentermine, benzphetamine, phendimetrazine, diethylpropion

Phentermine has the following contraindications:6,7,8,16
• 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:3,9
• 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:10,15
• Immediate release:
  o Known hypersensitivity or idiosyncratic reactions to sympathomimetics
  o Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate and severe hypertension, hyperthyroidism, and glaucoma
  o Highly nervous or agitated
  o History of drug abuse
  o Use in combination with other CNS stimulants, including monoamine oxidase inhibitors
• Extended release:
  o History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension, pulmonary hypertension)
  o During or within 14 days following the administration of monoamine oxidase inhibitors
  o Hyperthyroidism
  o Glaucoma
  o Agitated states
  o History of drug abuse
  o Pregnancy
  o Nursing
  o Use in combination with other anorectic agents or CNS stimulants
  o Known hypersensitivity or idiosyncratic reactions to sympathomimetics

Diethylpropion has the following contraindications:14
• 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

If tolerance develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued.

Lorcaserin¹
Contraindications include:
• Pregnancy
• Patients with prior hypersensitivity reactions to lorcaserin or to any of the product components

Phentermine/topiramate²
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)⁴
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
• Pregnancy

Black Box 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**
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

Black Box 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**
Contraindications include:
- Pregnancy
- Chronic malabsorption syndrome
- Cholelithiasis
- 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. 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.

For additional clinical information see Prime Therapeutics Formulary Chapter 9.5B: Weight Loss Agents.

**REFERENCES:**
Antiobesity Agents Formulary Exception with Quantity Limit Criteria

TARGET AGENTS
Adipex-P® (phentermine)<sup>a</sup>
Belviq™ (lorcaserin)
Belviq XR™ (lorcaserin ER)
Bontril PDM® (phendimetrazine)<sup>a</sup>
Bontril® Slow Release (phendimetrazine)
Contrave® (naltrexone/bupropion)
Didrex® (benzphetamine)<sup>a</sup>
Diethylpropion<sup>a</sup>
Lomaira™ (phentermine)
Phentermine<sup>a</sup>
Qsymia™ (phentermine/topiramate)
Regimex™ (benzphetamine)<sup>a</sup>
Saxenda® (liraglutide)
Suprenza™ (phentermine)
Xenical® (orlistat)
<sup>a</sup>– generic available

PROGRAM QUANTITY LIMIT

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Multisource Code</th>
<th>Quantity limit per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adipex-P&lt;sup&gt;a&lt;/sup&gt; (phentermine)</td>
<td></td>
<td></td>
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<tr>
<td>37.5 mg capsule</td>
<td>61200070100120</td>
<td>M, N, O, or Y</td>
<td>1 capsule</td>
</tr>
<tr>
<td>37.5 mg tablet</td>
<td>61200070100310</td>
<td>M, N, O, or Y</td>
<td>1 tablet</td>
</tr>
<tr>
<td>Belviq (lorcaserin)</td>
<td></td>
<td></td>
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<tr>
<td>10 mg tablet</td>
<td>61256550100320</td>
<td>M, N, O, or Y</td>
<td>2 tablets</td>
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<tr>
<td>Belviq XR (lorcaserin)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 mg tablet</td>
<td>61256550107520</td>
<td>M, N, O, or Y</td>
<td>1 tablet</td>
</tr>
<tr>
<td>Bontril PDM&lt;sup&gt;a&lt;/sup&gt; (phendimetrazine)</td>
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<tr>
<td>35 mg tablet</td>
<td>61200050100305</td>
<td>M, N, O, or Y</td>
<td>6 tablets</td>
</tr>
<tr>
<td>Bontril Slow Release (phendimetrazine)</td>
<td></td>
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<td></td>
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<tr>
<td>105 mg extended-release capsule</td>
<td>61200050107010</td>
<td>M, N, O, or Y</td>
<td>1 capsules</td>
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<tr>
<td>Contrave (naltrexone/bupropion)</td>
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<td></td>
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<tr>
<td>8 mg / 90 mg tablet</td>
<td>61259902507420</td>
<td>M, N, O, or Y</td>
<td>4 tablets</td>
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<tr>
<td>Didrex&lt;sup&gt;a&lt;/sup&gt; (benzphetamine)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>50 mg tablet</td>
<td>61200010100310</td>
<td>M, N, O, or Y</td>
<td>3 tablets</td>
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<tr>
<td>Diethylpropion&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25 mg tablet</td>
<td>61200020100305</td>
<td>M, N, O, or Y</td>
<td>3 tablets</td>
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<tr>
<td>75 mg extended-release tablet</td>
<td>61200020107510</td>
<td>M, N, O, or Y</td>
<td>1 tablet</td>
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<td>Lomaira (phentermine)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>8 mg tablet</td>
<td>61200070100305</td>
<td>M, N, O, or Y</td>
<td>3 tablets</td>
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<td>Phentermine&lt;sup&gt;a&lt;/sup&gt;</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>15 mg capsule</td>
<td>61200070100110</td>
<td>M, N, O, or Y</td>
<td>1 capsule</td>
</tr>
<tr>
<td>30 mg capsule</td>
<td>61200070100115</td>
<td>M, N, O, or Y</td>
<td>1 capsule</td>
</tr>
<tr>
<td>Qsymia (phentermine/topiramate)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.75mg/23mg capsule</td>
<td>61209902307020</td>
<td>M, N, O, or Y</td>
<td>1 capsule</td>
</tr>
<tr>
<td>7.5mg/46mg capsule</td>
<td>61209902307030</td>
<td>M, N, O, or Y</td>
<td>1 capsule</td>
</tr>
<tr>
<td>11.25mg/69mg capsule</td>
<td>61209902307040</td>
<td>M, N, O, or Y</td>
<td>1 capsule</td>
</tr>
</tbody>
</table>
### 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. The patient is at least the minimum age required for the requested agent:
   a. Belviq, Belviq XR, Contrave, Qsymia, Saxenda – 18 years of age
   b. Benzphetamine, Diethylpropion, Phendimetrazine, Phentermine – 17 years of age
   c. Xenical – 12 years of age
   AND
3. ONE of the following:
   a. The patient is 17 years of age and 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 documented BMI ≥30 kg/m² 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 documented BMI ≥27 kg/m² 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

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### Table: Brand (generic) and Quantity Limit

<table>
<thead>
<tr>
<th>Brand (generic)</th>
<th>GPI</th>
<th>Multisource Code</th>
<th>Quantity limit per day</th>
</tr>
</thead>
<tbody>
<tr>
<td>15mg/92mg capsule</td>
<td>61209902307050</td>
<td>M, N, O, or Y</td>
<td>1 capsule</td>
</tr>
<tr>
<td>Regimex (benzphetamine)</td>
<td>25 mg tablet</td>
<td>M, N, O, or Y</td>
<td>3 tablets</td>
</tr>
<tr>
<td>Saxenda (liraglutide)</td>
<td>6 mg/mL, 3 mL/pen</td>
<td>M, N, O, or Y</td>
<td>0.5 ml</td>
</tr>
<tr>
<td>Suprenza (phentermine)</td>
<td>15 mg disintegrating tablet</td>
<td>M, N, O, or Y</td>
<td>1 tablet</td>
</tr>
<tr>
<td></td>
<td>30 mg disintegrating tablet</td>
<td>M, N, O, or Y</td>
<td>1 tablet</td>
</tr>
<tr>
<td></td>
<td>37.5 mg disintegrating tablet</td>
<td>M, N, O, or Y</td>
<td>1 tablet</td>
</tr>
<tr>
<td>Xenical (orlistat)</td>
<td>120 mg capsule</td>
<td>M, N, O, or Y</td>
<td>3 capsules</td>
</tr>
</tbody>
</table>

*a – generic available and included in quantity limit programs*
ii. BOTH of the following:
   a. The patient has a documented BMI $\geq 27$ 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. The patient has a diagnosis of obesity, confirmed by a documented BMI $\geq 95^{\text{th}}$ percentile for age and gender
   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 (see table below)

AND

5. ONE of the following:
   a. The patient is NOT currently being treated with another weight loss agent
   OR
   b. The patient is currently being treated with another weight loss agent AND will discontinue prior to starting the requested agent

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 documentation 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:
      a. The requested dose is 3.75mg/23mg
      OR
      b. The patient is currently being treated with Qsymia, the requested dose is greater than 3.75 mg/23 mg AND ONE of the following:
1. The patient has demonstrated and maintained a weight loss of ≥5% from baseline (prior to the initiation of requested agent) OR

2. The patient received less than 14 weeks of therapy OR

3. The patient’s dose is being titrated upward OR

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

c. The prescriber has submitted documentation in support of therapy for the requested dose for this patient OR

c. The requested agent is Belviq or Belviq XR 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 12 weeks (3 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 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 12 weeks (3 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

e. 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 year of age and 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

f. The requested agent is Saxenda and ALL of the following
   i. The requested agent is not being used to treat type 2 diabetes AND
ii. The requested agent will not be used concurrently with another GLP-1 receptor agonist agent
   AND
iii. The requested agent will not be used concurrently with insulin
   AND
iv. ONE of the following
   a) The patient is newly starting therapy
   OR
   b) The patient is currently being treated and has received less than 16 weeks (4 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)

   AND
8. ONE of the following:
   a. The patient has tried 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
      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
      AND
      iii. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: For Saxenda: 4 months. For all other agents: 3 months

Renewal Evaluation
(Patient continuing a current weight loss course of therapy)
Renewal criteria will NOT apply to Benzphetamine, Diethylpropion, and Phendimetrazine products which are approved for a maximum of 3 months in a 12 month period.

Belviq, Belviq XR, Contrave, Qsymia, Saxenda, Xenical, Phentermine (single agent) 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 Prime Therapeutics 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 (see table below)

   AND

5. For Saxenda only, ALL of the following:
   a. The requested agent is not being used to treat type 2 diabetes

      AND

   b. The requested agent is not being used concurrently with another GLP-1 receptor agonist agent

      AND

   c. The requested agent is not being used concurrently with insulin

      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, the patient has achieved and maintained a weight loss ≥4% 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 and over AND has achieved and maintained a weight loss ≥5% from baseline (prior to the initiation of requested agent)

      AND

7. ONE of the following:
   a. The patient is NOT currently being treated with another weight loss agent

   OR
b. The patient is currently being treated with another weight loss agent AND will discontinue prior to starting the requested agent

AND

9. ONE of the following:
   a. The patient has tried 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
      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
      AND
      iii. The prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval:
Belviq, Belviq XR, Contrave, Saxenda, Xenical, Phentermine (single agent): 12 months
Qsymia: ≥5% weight loss from baseline: 12 months
Qsymia (<5% weight loss): 3 months