### Antiobesity Agents Formulary Exception Program Summary

This program applies to FlexRx Closed and GenRx Closed formularies.

#### FDA APPROVED INDICATIONS AND DOSAGE

<table>
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<tr>
<th>Agent</th>
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</table>
| **Belviq™** (lorcaserin)       | 10 mg               | 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 | Twice daily  
Discontinue at 12 weeks if 5% weight loss is not achieved |
| **Belviq XR™** (lorcaserin ER) | 20 mg               | Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:  
- 30 kg/m² or greater (obese), or  
- 27 kg/m² or greater (overweight) in the presence of at least one weight related comorbidity (e.g., hypertension, dyslipidemia, type 2 diabetes) | 20 mg once daily  
Discontinue if 5% weight loss is not achieved by week 12 |
| **Bontril PDM®, Bontril Slow Release** (phendimetrazine) | 35 mg  105 mg | 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 for patients with an initial body mass index ≥ 30 kg/m² or higher and who have not responded to appropriate weight reducing regimen alone. | • Immediate release (35 mg)  
1 tablet twice or three times daily, 1 hour before meals; dosage should be individualized to lowest effective dosage; maximum dose is 2 tablets three times daily  
• Slow release (105 mg) once daily in the morning, 30 – 60 minutes before morning meal |
| **Contrave®** (naltrexone/bupropion) | 8 mg / 90 mg | 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 or greater (obese)  
- 27 kg/m² or greater (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 |
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<tr>
<td>Didrex®, Regimex® (benzphetamine) tablets</td>
<td>25 mg 50 mg</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 for patients with an initial body mass index ≥ 30 kg/m² or higher and who have not responded to appropriate weight reducing regimen alone.</td>
<td>Discontinue at 12 weeks if 5% weight loss is not achieved</td>
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| Diethylpropion® tablets, capsules ER | 25 mg 75 mg         | 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 for patients with an initial body mass index ≥ 30 kg/m² or higher and who have not responded to appropriate weight reducing regimen alone. | Immediate release (25 mg) three times daily, 1 hour before meals  
Controlled release (75 mg) once daily in midmorning |
| Lomaira (phentermine) tablets | 8 mg                | 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 body mass index greater than or equal to 30 kg/m² or greater than or equal to 27 kg/m² in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). | 1 tablet 3 times daily |
| Phentermine tablets, capsules | 15 mg 30 mg 37.5 mg | Management of exogenous obesity as a short-term adjunct (a few weeks, up to 12 weeks based on agent) in a regimen of weight reduction based on caloric restriction in patients with an initial BMI of 30 kg/m² or higher, or BMI greater than 27 kg/m² in the presence of other risk factors (e.g., hypertension, diabetes mellitus, or dyslipidemia), and who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. | Once or twice daily, depending on agent.  
• 18.75 mg twice daily, one-half hour before meals;  
• 15-37.5 mg once daily before or after breakfast or at least 10-14 hours before bedtime |
| Qsymia™ (phentermine/) | 3.75/23mg 7.5/46mg | Adjunct to a reduced-calorie diet and increased physical activity for | Once daily  
Titration schedule: |
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| topiramate capsules    | 11.25/69mg 15/92mg  | 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 | 3.75mg/23mg once daily for 14 days, then increase to 7.5mg/46mg daily  
|                        |                     |                                                                            | Discontinue or escalate the dose if 3% weight loss is not achieved after 12 weeks on  
|                        |                     |                                                                            | 7.5mg/46mg daily  
|                        |                     |                                                                            | Discontinue if 5% weight loss is not achieved after 12 weeks on maximum daily  
|                        |                     |                                                                            | dose of 15mg/92mg  |
| Saxenda® (liraglutide) | 6 mg/ml, 3 ml/pens  | Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:  
|                        |                     | ≥30 kg/m² or greater (obese) or ≥27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia) | Initiate at 0.6 mg per day for one week. In weekly intervals, increase the dose until a dose of 3 mg per day is reached  
|                        |                     |                                                                            | 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  |
| Suprenza (phentermine) | 15 mg 30 mg 37.5 mg | 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 for patients with an initial body mass index ≥30 kg/m² or ≥27 kg/m² in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia)  
| orally disintegrating tablets |                     | Not for use in pediatric patients <16 years of age  | Once daily  
|                        |                     |                                                                            | Dosage should be individualized to obtain an adequate response with the lowest effective dose.  |
| Xenical (orlistat) capsules | 120 mg | 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)  
|                        |                     | Safety/effectiveness in patients <12 years of age not established | 120 mg three times daily with each main meal containing fat (during or up to 1 hour after the meal)  |
CLINICAL RATIONALE:
The role of drug therapy in treatment of obesity has been questioned due to concerns on efficacy, safety, body weight plateau with continued treatment, and weight gain when drugs are stopped. Many trials have limitations (short duration, high attrition, heterogeneity, inadequate reporting of important clinical outcomes [e.g., cardiovascular outcomes]). There are few head-to-head trials comparing individual therapies and it is uncertain whether people who fail to respond to one therapy will respond to another. Adults with body mass index (BMI) 25-29.9 kg/m² are considered overweight; those with BMI ≥30 kg/m² are considered obese.

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:

- 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 (U.S., 2015) 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.

- 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 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/m² or >27 kg/m² 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.¹³

Safety

**Phentermine, benzphetamine, phendimetrazine, diethylpropion**

Phentermine has the following contraindications:⁶,⁷,¹⁷
- 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: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:¹⁰,¹⁶
- 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:⁸,¹⁵
- 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.

**Lorcaserin**

Contraindications include:

- Pregnancy
- Patients with prior hypersensitivity reactions to lorcaserin or to any of the product components

**Phentermine/topiramate**

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

Black Box Warnings include:

- Qsymia is a federally controlled substance (CIV) because it contains phentermine and can be abused or lead to drug dependence. Keep Qsymia in a safe place, to protect it from theft. Never give your Qsymia to anyone else, because it may cause death or harm them. Selling or giving away this medicine is against the law.

**Naltrexone/bupropion (NB)**

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, and Aplenzin)
- 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

- Serious neuropsychiatric reactions have occurred in patients taking bupropion for smoking cessation. The majority of these reactions occurred during bupropion treatment, but some occurred in the context of discontinuing treatment. In many cases, a causal relationship to bupropion treatment is not certain, because depressed mood may be a symptom of nicotine withdrawal. However, some of the cases occurred in patients taking bupropion who continued to smoke. Although Contrave is not approved for smoking cessation, observe all patients for neuropsychiatric reactions. Instruct the patient to contact a healthcare provider if such reactions occur

**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

**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 Criteria

OBJECTIVE
The criteria defined in the Antiobesity Formulary Exception Criteria will be applied when the included medications are prescribed for any patient. The intent of the criteria is to limit prescribing to those patients whose initial body mass index (BMI) is \( \geq 30 \text{ kg/m}^2 \) or \( \geq 27 \text{ kg/m}^2 \) in the presence of other risk factors (e.g., hypertension, coronary heart disease, type 2 diabetes, dyslipidemia, sleep apnea). Initial criteria also include medical evaluation ruling out organic causes of obesity, determination of obesity-related risk factors, and involvement in a weight loss program including a reduced-calorie diet and/or exercise, and/or behavioral modification. These medications will not be approved for patients receiving monoamine oxidase inhibitors. In addition, the criteria will require use of an orlistat product (prescription Xenical or nonprescription Alli) prior to a stimulant. If the initial criteria are met, Xenical will be approved for 12 months; stimulant medications for 3 months. Clinical literature supports a reasonable and medically significant outcome for many patients is to lose 10% of body weight in the first 6 months of treatment.\(^3\) If the patient loses 5% or more of his/her initial BMI or body weight, the patient will receive an approval for 12 months for Xenical or for 3 months for the stimulants.

TARGET AGENTS
Adipex-P (phentermine)\(^a\)
Belviq (lorcaserin)
Belviq XR™ (lorcaserin ER)
Bontril Slow Release (phendimetrazine)\(^a\)
Bontril PDM (phendimetrazine)\(^a\)
Contrave® (naltrexone/bupropion)
Didrex (benzphetamine)\(^a\)
Diethylpropion
Lomaira (phentermine)
Phentermine\(^a\)
Qsymia™ (phentermine/topiramate)
Regimex™ (benzphetamine)
Saxenda® (liraglutide)
Suprenza™ (phentermine)
Xenical (orlistat)
\(^a\) Indicates generic availability
\(^b\) – brand name product no longer available in U.S. market

FORMULARY EXCEPTION CRITERIA FOR APPROVAL
Initial Evaluation
(Patient new to therapy, new to Prime, or attempting a repeat weight loss course of therapy)
Weight Loss Agents will be approved when ALL the following are met:
1. 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. ALL of the following:
      i. ONE of the following:
         a. The patient has a diagnosis of obesity, confirmed by a
documented BMI≥30 kg/m² OR a BMI of ≥25 kg/m² if the
patient is of South Asian, Southeast Asian, or East Asian descent
OR
         b. 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
      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
OR
   b. BOTH of the following:
      i. The patient has a documented BMI≥27 kg/m² with at least one severe
weight-related comorbidity/risk factor/complication
AND
      ii. 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
AND

4. The patient does not have any FDA labeled contraindication(s) to the requested agent
(see table below)
AND

5. The patient is not taking another weight loss 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. 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 and the pharmacist reviewed information supporting the anticipated
success of repeating therapy
AND

7. ONE of the following:
   a. The requested agent is Xenical, benzphetamine, diethylpropion,
phendimetrazine, or phentermine
OR
   b. The requested agent is Qsymia and ALL of the following:
      i. ONE of the following:
         a. The requested dose is 3.75mg/23mg
         OR
         b. The patient is currently receiving 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 supporting the requested dose for this patient which has been reviewed and approved by the Clinical Review pharmacist  
**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 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 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 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 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 or 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 quantity requested is less than or equal to the program quantity limit
   **OR**
   
   b. The quantity (dose) requested is above the program limit, less than or equal to the maximum dose recommended in FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength
   **OR**
   
   c. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

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

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

**Belviq, Belviq XR, Contrave, Qsymia, Saxenda, Xenical, Phentermine (single agent) only – 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 therapy 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 contraindication(s) 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 demonstrated and maintained a weight loss ≥5% from baseline (prior to the initiation of requested agent)
   OR
b. For Saxenda only, the patient has achieved a weight loss ≥4% from baseline (prior to the initiation of requested agent)
   OR
c. For Qsymia only, the patient has achieved 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
      AND
   ii. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength

7. The patient is not taking another weight loss 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 quantity requested is less than or equal to the program quantity limit,
      OR
   b. The quantity (dose) requested is above the program limit, less than or equal to the maximum dose recommended in FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength,
      OR
   c. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

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
Antiobesity Agents Formulary Exception Criteria

ELECTRONIC EDIT
The overall process for formulary exception will not allow the targeted drugs to adjudicate through the claims system. When a patient requests a targeted drug listed below, the system will reject the claim with the message indicating that formulary exception is necessary. The Formulary Exception Criteria for Approval would then be applied to requests submitted by the patient’s practitioner for evaluation.

FORMULARY EXCEPTION CRITERIA FOR APPROVAL
Initial Evaluation
(New to therapy, new to Prime, or attempt to repeat a weight loss course of therapy)
   1. Is the agent excluded under the patient’s current benefit plan?
      If yes, forward to the health plan for determination of coverage. If no, continue to 2.

   2. Has the patient been previously approved for therapy with a weight loss agent through the Prime Therapeutics prior authorization process?
      a. Yes AND the patient is continuing therapy
      b. Yes AND the patient is attempting a repeated weight loss course of therapy
      c. No (patient is new to therapy or new to Prime)
      If a, refer to renewal evaluation. If b, continue to 3. If c, continue to 5.

   3. Has it been 12 months since the patient’s last approval for weight loss therapy through Prime Therapeutics prior authorization process?
      If yes, continue to 5. If no, continue to 4.

   4. Has the prescriber provided and the pharmacist reviewed information supporting the anticipated success of repeating a weight loss therapy with the requested agent?
      If yes, pharmacist must review and upon approval, continue to 5. If no, deny.

   5. Is the patient the minimum age required for the requested agent?
      Belviq, Belviq XR, Contrave, Qsymia, Saxenda – 18 years of age
      Benzetamine, Diethylpropion, Phendimetrazine, Phentermine – 17 years of age
      Xenical – 12 years of age
      If yes, continue to 6. If no, deny.

   6. Does the patient have a documented BMI of ≥25 kg/m² AND is the patient of South Asian, Southeast Asian, or East Asian descent?
      If yes, continue to 12. If no, continue to 7.

   7. Does the patient have a documented BMI of ≥27 kg/m²?
      If yes, continue to 8. If no, deny.

   8. Does the patient have at least one documented severe weight-related comorbidity/risk factor/complication (e.g. diabetes, dyslipidemia, coronary artery disease)?
      If yes, pharmacist must review and if approved, continue to 9. If no, continue to 10.
9. Will the patient be initiating or is already on and will continue a weight loss regimen of a low calorie diet, increased physical activity, and behavioral modifications along with the requested agent?
   If yes, continue to 17.
   If no, deny.

10. Does the patient have a documented BMI of ≥30 kg/m²?
    If yes, continue to 15.
    If no, continue to 11.

11. Does the patient have at least one weight-related comorbidity/risk/factor/complication (e.g. diabetes, dyslipidemia, coronary artery disease)?
    If yes, continue to 15.
    If no, deny.

12. Does the patient have a documented BMI of ≥27 kg/m²?
    If yes, continue to 13.
    If no, continue to 15.

13. Does the patient have at least one documented severe weight-related comorbidity/risk factor/complication (e.g. diabetes, dyslipidemia, coronary artery disease)?
    If yes, pharmacist must review and if approved, continue to 14.
    If no, continue to 15.

14. Will the patient be initiating or is already on and will continue a weight loss regimen of a low calorie diet, increased physical activity, and behavioral modifications along with the requested agent?
    If yes, continue to 17.
    If no, continue to deny.

15. Has the patient 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?
    If yes, continue to 16.
    If no, deny.

16. Did the patient 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?
    If yes, deny.
    If no, continue to 17.

17. Does the patient have any FDA labeled contraindication(s) to the requested agent (see table below)?
    If yes, deny.
    If no, continue to 18.

18. Is the patient currently on and will continue a weight loss regimen of a low calorie diet, increased physical activity, and behavioral modifications throughout treatment?
    If yes, continue to 19.
    If no, deny.

19. Is the patient currently taking another weight loss agent?
    If yes, continue to 20.
    If no, continue to 21.
20. Will the previous agent be discontinued before starting the requested agent?  
   If yes, continue to 21.  
   If no, deny.

21. Which of the following is the patient requesting?  
   a. Qsymia  
   b. Belviq, Belviq XR, Contrave  
   c. Xenical  
   d. Benzphetamine, diethylpropion, phendimetrazine, phentermine (single agent)  
   e. Saxenda  
   If a, continue to 22.  
   If b, continue to 34.  
   If c or d, continue to 37.  
   If e, continue to 29.

22. Is the dose requested 3.75mg/23mg?  
   If yes, continue to 37.  
   If no, continue to 23.

23. Is the patient currently on Qsymia?  
   If yes, continue to 24.  
   If no, continue to 28.

24. Has the patient received fewer than 14 weeks of Qsymia therapy?  
   If yes, continue to 37.  
   If no, continue to 25.

25. Has the patient demonstrated and maintained a weight loss of ≥5% from baseline 
   (prior to the initiation of requested agent)?  
   \[ \text{% weight loss} = \left(\frac{\text{baseline weight - current weight}}{\text{baseline weight}}\right) \times 100\% \]  
   If yes, continue to 37.  
   If no, continue to 26.

26. Is the patient’s dose being titrated upward?  
   If yes, continue to 37.  
   If no, continue to 27.

27. Has the patient received fewer than 12 weeks of therapy on the 15mg/92mg strength?  
   If yes, continue to 37.  
   If no, deny.

28. Has the prescriber submitted and the pharmacist has reviewed documentation 
   supporting the requested dose for this patient?  
   If yes, pharmacist must review and upon approval, continue to 37.  
   If no, deny.

29. Is the requested agent being used to treat type 2 diabetes?  
   If yes, deny.  
   If no, continue to 30.

30. Is the patient currently taking another GLP-1 receptor agonist agent (e.g. Byetta, 
    Bydureon, Tanzeum, Trulicity, Victoza) (in the past 90 days)?
If yes, continue to 31.
If no, continue to 32.

31. Will the other GLP-1 receptor agonist agent be discontinued before starting the requested agent?
   If yes, continue to 32.
   If no, deny.

32. Is the patient currently taking insulin (in the past 90 days)?
   If yes, continue to 33.
   If no, continue to 34.

33. Will the insulin be discontinued before starting the requested agent?
   If yes, continue to 34.
   If no, deny.

34. Has the patient previously tried the requested therapy?
   a. Yes AND the patient is currently on therapy
   b. Yes. The patient is NOT currently on therapy AND is attempting a repeated course of therapy of the requested agent
   c. No
      If a, continue to 35.
      If b or c, continue to 37.

35. Has the patient received less than 12 weeks of the requested therapy?
   If yes, continue to 37.
   If no, continue to 36.

36. Has the patient achieved and maintained a weight loss of ≥4% for Saxenda or ≥5% for all other agents from baseline (prior to the initiation of requested agent)?
   \[
   \% \text{ weight loss} = \frac{\text{baseline weight} - \text{current weight}}{\text{baseline weight}} \times 100\%
   \]
   If yes, continue to 37.
   If no, deny.

37. Has the patient tried at least three (or as many as available, if fewer than three) formulary alternatives?
   If yes, continue to 39. If no, continue to 38.

38. Has the prescriber indicated that available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient?
   If yes, pharmacist must review, and if approved, continue to 39.
   If no, deny.

39. Is the quantity requested less than or equal to the program quantity limit?
   If yes, approve for 4 months for Saxenda or 3 months for all other agents.
   If no, continue to 40.

40. Can the prescribed dose be achieved with a lower quantity of a higher strength that does not exceed the limit?
   If yes, deny increased quantity requested and approve the PA for the set limit for 4 months for Saxenda and 3 months for all other agents.
   If no, continue to 41.
41. Has the prescriber provided and the pharmacist reviewed documentation supporting therapy with a dose exceeding established program quantity limits?  
If yes, pharmacist must review and may approve Saxenda for 4 months and 3 months for all other agents.  
If no, deny increased quantity requested and approve the PA for the set limit for 4 months for Saxenda and 3 months for all other agents.

Renewal Evaluation (continuation of current weight loss course of therapy)  
Belviq, Belviq XR, Contrave, Qsymia, Saxenda, Xenical, Phentermine (single agent) only – 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

1. Is the agent excluded under the patient’s current benefit plan?  
If yes, forward to the health plan for determination of coverage.  If no, continue to 2.

2. Is the request for benzphetamine, diethylpropion, or phendimetrazine and the patient has been previously approved for therapy through Prime Therapeutics prior authorization process within the past 12 months?  
If yes, deny. (These products are only approved for a maximum of 3 months in a 12 month period.)  
If no, continue to 3.

3. Has the patient been previously approved for therapy through the Prime Therapeutics prior authorization process within the past 12 months?  
   a. Yes AND the patient is continuing therapy  
   b. Yes AND the patient is attempting a repeated weight loss course of therapy  
   c. No  
   If a, continue to 4.  
   If b or c, refer to initial criteria.

4. Is the patient currently on a weight loss regimen of a low calorie diet, increased physical activity and behavioral modifications?  
If yes, continue to 5.  
If no, deny.

5. Does the patient have any FDA labeled contraindication(s) to the requested agent (see table below)?  
If yes, deny.  
If no, continue to 6.

6. Is the request for Saxenda?  
If yes, continue to 7.  
If no, continue to 12.

7. Is the requested agent being used to treat type 2 diabetes?  
If yes, deny.  
If no, continue to 8.

8. Is the patient concurrently using another GLP-1 agonist agent (e.g. Byetta, Bydureon, Tanzeum, Trulicity, Victoza) (in the past 90 days)?  
If yes, continue to 9.
If no, continue to 10.

9. Will the other GLP-1 receptor agonist agent be discontinued before starting the requested agent?
   If yes, continue to 10.
   If no, deny.

10. Is the patient concurrently using insulin (in the past 90 days)?
    If yes, continue to 11.
    If no, continue to 12.

11. Will the insulin be discontinued before starting the requested agent?
    If yes, continue to 12.
    If no, deny.

12. Has the patient demonstrated and maintained a body weight loss from baseline of ≥4% for Saxenda or ≥5% for all other agents (prior to the initiation of requested agent)?
    % weight loss = \frac{\text{current weight} - \text{baseline weight}}{\text{baseline weight}} \times 100%
    If yes, continue to 17.
    If no, continue to 13.

13. Is the patient requesting Qsymia?
    If yes, continue to 14.
    If no, deny.

14. What is the patient’s current dose?
    1. 3.75 mg/23 mg, 7.5 mg/46 mg or 11.25 mg/69 mg
    2. 15 mg/92 mg
    If a, continue to 15.
    If b, continue to 16.

15. Is the patient’s dose being titrated upward?
    If yes, continue to 16.
    If no, deny.

16. Has the patient received less than 12 weeks of therapy on 15mg/92mg strength?
    If yes, continue to 17.
    If no, deny.

17. Is the patient currently taking another weight loss agent?
    If yes, continue to 18.
    If no, continue to 19.

18. Will the previous agent be discontinued before starting the requested agent?
    If yes, continue to 19.
    If no, deny.

19. Has the patient tried at least three (or as many as available, if fewer than three) formulary alternatives?
    If yes, continue to 21. If no, continue to 20.

20. Has the prescriber indicated that available formulary (any formulary tier) alternatives are contraindicated, likely to be less effective, or cause an adverse reaction or other harm for the patient?
If yes, pharmacist must review, and if approved, continue to 21.
If no, deny.

21. Is the quantity requested less than or equal to the program quantity limit?
If yes, approve according to the following:
   - 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
If no, continue to 22.

22. Can the prescribed dose be achieved with a lower quantity of a higher strength that
does not exceed the limit?
If yes, deny for increased quantity requested and approve the PA for the set limit
according to the following:
   - 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.
If no, continue to 23.

23. Has the prescriber provided and the pharmacist reviewed documentation supporting
therapy with a dose exceeding established program summary quantity limit?
If yes, pharmacist must review and may approve according to the following:
   - 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.
If no, deny for increased quantity requested and approve the PA for the set limit
according to the following:
   - 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.

### Contraindications

<table>
<thead>
<tr>
<th>Target Agent</th>
<th>FDA Labeled Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adipex-P/Phentermine/Suprenza</td>
<td>• History of cardiovascular disease (e.g. coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension)</td>
</tr>
<tr>
<td>(phentermine)</td>
<td>• During or within 14 days of taking MAOI</td>
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<tr>
<td></td>
<td>• With other CNS stimulants</td>
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<tr>
<td></td>
<td>• Hyperthyroidism</td>
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<tr>
<td></td>
<td>• Glaucoma</td>
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<tr>
<td></td>
<td>• Agitated states</td>
</tr>
<tr>
<td></td>
<td>• History of drug abuse</td>
</tr>
<tr>
<td></td>
<td>• Pregnancy; Nursing (lactation)</td>
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<tr>
<td>Belviq (lorcaserin)</td>
<td>• Pregnancy</td>
</tr>
<tr>
<td>Belviq (lorcaserin)</td>
<td>• Pregnancy: Weight loss in a pregnant woman offers no benefit and may result in fetal harm</td>
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<tr>
<td></td>
<td>• Hypersensitivity: Belviq XR is contraindicated in patients with prior hypersensitivity reactions to lorcaserin or to any of the product components.</td>
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</tbody>
</table>
Hypersensitivity reactions have been reported

<table>
<thead>
<tr>
<th><strong>Bontril PDM/ Bontril Slow Release</strong></th>
<th><strong>Contrave</strong> (naltrexone/bupropion)</th>
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<tbody>
<tr>
<td>(phendimetrazine)</td>
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<tr>
<td>• Advanced arteriosclerosis</td>
<td>• Uncontrolled hypertension</td>
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<tr>
<td>• Symptomatic cardiovascular disease</td>
<td>• Seizure disorder or a history of seizures</td>
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<tr>
<td>• Moderate/severe hypertension</td>
<td>• Use of other bupropion-containing products</td>
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<tr>
<td>• Hyperthyroidism</td>
<td>• Bulimia or anorexia nervosa, which increase the risk for seizure</td>
</tr>
<tr>
<td>• With other CNS stimulants, including MAOIs</td>
<td>• Chronic opioid or opiate agonist (e.g., methadone) or partial agonists (e.g., buprenorphine) use, or acute opiate withdrawal</td>
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<tr>
<td>• Glaucoma</td>
<td>• Patients undergoing an abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs</td>
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<tr>
<td>• Agitated states</td>
<td>• 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</td>
</tr>
<tr>
<td>• History of drug abuse</td>
<td>• Known allergy to bupropion, naltrexone or any other component of Contrave.</td>
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<tr>
<td></td>
<td>• Anaphylactoid/anaphylactic reactions and Stevens-Johnson syndrome have been reported with bupropion</td>
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<td></td>
<td>• Pregnancy</td>
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<table>
<thead>
<tr>
<th><strong>Didrex/Regimex</strong> (benzphetamine)</th>
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<tbody>
<tr>
<td>• Advanced arteriosclerosis</td>
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<tr>
<td>• Symptomatic cardiovascular disease</td>
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<tr>
<td>• Moderate/severe hypertension</td>
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<td>• Hyperthyroidism</td>
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<tr>
<td>• During or within 14 days of taking MAOI</td>
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<td>• Glaucoma</td>
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<tr>
<td>• Agitated states</td>
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<tr>
<td>• History of drug abuse</td>
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<tr>
<td>• Pregnancy</td>
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<tr>
<th><strong>Diethylpropion</strong></th>
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<tbody>
<tr>
<td>• Pulmonary hypertension</td>
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<tr>
<td>• Advanced arteriosclerosis</td>
</tr>
<tr>
<td>• Severe hypertension</td>
</tr>
<tr>
<td>• Hyperthyroidism</td>
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</tbody>
</table>
| **Lomaira** (phentermine) | • 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 (see PRECAUTIONS)  
• Nursing (see PRECAUTIONS)  
• Known hypersensitivity, or idiosyncrasy to the sympathomimetic amines |
|---|---|
| **Qsymia** (phentermine/topiramate) | • Pregnancy  
• During or within 14 days of taking MAOI  
• Glaucoma  
• Hyperthyroidism |
| **Saxenda** (liraglutide) | • Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2  
• Hypersensitivity to liraglutide or any product components  
• Pregnancy |
| **Xenical** (orlistat) | • Pregnancy  
• Chronic malabsorption syndrome  
• Cholestasis |