# Weight Loss Agents Prior Authorization with Quantity Limit Program Summary

For BCBS KS, this program only applies to groups that have opted into coverage for weight loss

## POLICY REVIEW CYCLE

**Effective Date** 3/1/2023

**Date of Origin**

## FDA APPROVED INDICATIONS AND DOSAGE

| Agent(s) | FDA Indication(s) | Notes | Ref# |
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| Adipex-P®, Lomaira™, Phentermine<br><br>(phentermine)~<br><br>Tablet*<br>Capsule* | 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 greater than or equal to 30 kg/m^2 or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). | * – Generic equivalent available<br><br>~ – The safety and efficacy of coadministration with other weight loss drug products, including prescribed drugs, over-the-counter preparations, and herbal products have not been established. Therefore, coadministration is not recommended. | 11 ; 5 ; 6 |
| Benzphetamine*~<br><br>Tablet | 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 greater than or equal to 30 kg/m^2 who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. | * – Generic equivalent available<br><br>~ – The safety and efficacy of coadministration with other weight loss drug products, including prescribed drugs, over-the-counter preparations, and herbal products have not been established. Therefore, coadministration is not recommended. | 2 |
| Contrave®<br><br>(naltrexone/bupropion)~<br><br>Tablet ER | Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:<br><br>• Greater than or equal to 30 kg/m^2 (obese), or<br>• Greater than or equal to 27 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)<br><br>Limitations of Use: | ~ – The safety and efficacy of coadministration with other weight loss drug products, including prescribed drugs, over-the-counter preparations, and herbal products have not been established. Therefore, coadministration is not recommended. | 3 |

| Agent(s) | FDA Indication(s) | Notes | Ref# |
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| | • Effect on cardiovascular morbidity and mortality has not been established | | |
| Diethylpropion<br><br>Tablet*<br><br>Tablet 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 body mass index (BMI) greater than or equal to 30 kg/m^2 and who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone.<br><br>Indicated for use as monotherapy only. | * – Generic equivalent available | 9 |
| Phendimetrazine*<br><br>Capsule 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 greater than or equal to 30 kg/m^2 or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia) who have not responded to appropriate weight reducing regimen alone (diet and/or exercise)<br><br>Indicated for use as monotherapy only. | * – Generic equivalent available | 7 |
| Phendimetrazine*<br><br>Tablet | 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 greater than or equal to 30 kg/m^2 who have not responded to appropriate weight reducing regimen alone (diet and/or exercise).<br><br>Indicated for use as monotherapy only. | * – Generic equivalent available | 10 |
| Qsymia®<br><br>(phentermine/topiramate)~<br><br>Capsule | Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:<br><br>• Adults with an initial BMI of:<br>○ Greater than or equal to 30 kg/m^2 (obese)<br>○ Greater than or equal to 27 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia<br>• Pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex | ~ – The safety and efficacy of coadministration with other weight loss drug products, including prescribed drugs, over-the-counter preparations, and herbal products have not been established. Therefore, coadministration is not recommended. | 1 |
| Saxenda®<br><br>(liraglutide)~<br><br>Injection solution | Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:<br><br>• Adults with an initial body mass index (BMI) of:<br><br>• Greater than or equal to 30 kg/m^2 (obese), or<br><br>• Greater than or equal to 27 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)<br><br>• Pediatric patients aged 12 years or older with:<br><br>• Body weight greater than 60 kg, and<br><br>• An initial BMI corresponding to greater than 30 kg/m^2 for adults (obese) by international cut-offs (Cole Criteria) | ~ – The safety and efficacy of coadministration with other weight loss drug products, including prescribed drugs, over-the-counter preparations, and herbal products have not been established. Therefore, coadministration is not recommended. | 8 |

| Agent(s) | FDA Indication(s) | Notes | Ref# |
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| | Limitations of use:<br>• Safety and effectiveness in pediatric patients with type 2 diabetes have not been established<br>• Should not be used in combination with any other GLP-1 receptor agonist | | |
| Wegovy™<br><br>(semaglutide) ~<br><br>Subcutaneous injection solution | Adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of<br>• Greater than or equal to 30 kg/m^2 (obese), or<br>• Greater than or equal to 27 kg/m^2 (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)<br><br>Limitations of use:<br>• Should not be coadministered with other semaglutide-containing products or with any other GLP-1 receptor agonist<br>• Wegovy has not been studied in patients with a history of pancreatitis | ~ – The safety and efficacy of coadministration with other weight loss drug products, including prescribed drugs, over-the-counter preparations, and herbal products have not been established. Therefore, coadministration is not recommended. | 20 |
| Xenical® , Orlistat<br><br>Capsule | Obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet and to reduce the risk for weight regain after prior weight loss. It is indicated for obese patients with an initial body mass index (BMI) greater than or equal to 30 kg/m^2 or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia) | | 4 |

*See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm*

## CLINICAL RATIONALE

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| Obesity | Obesity rates have increased sharply over the last 30 years, creating a global public health crisis. The National Health and Nutrition Examination Surveys show that nearly 2 of 3 US adults are overweight or obese, and 1 of 3 adults are obese. Adults with body mass index (BMI) 25-29.9 kg/m^2 are considered overweight; those with BMI greater than or equal to 30 kg/m^2 are considered obese.(14) Weight loss is difficult for most people and weight loss medications help reinforce behavioral strategies to lose weight. Medications for weight loss do not work on their own. Numerous guidelines recommend the addition of weight loss medications only in conjunction with lifestyle and behavioral modifications.(13-15)<br><br>The American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity recommends the following:(14)<br>• 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 |

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| | • For overweight (BMI 25-29.9 kg/m^2) or obese (BMI greater than or equal to 30 kg/m^2) patients, evaluate for adiposity related complications:<br>o Metabolic syndrome<br>o Prediabetes<br>o Type 2 diabetes (T2DM)<br>o Dyslipidemia<br>o Hypertension<br>o Cardiovascular disease<br>o Non-alcoholic fatty liver disease<br>o Polycystic ovary syndrome<br>o Female infertility<br>o Male hypogonadism<br>o Obstructive sleep apnea<br>o Asthma/reactive airway disease<br>o Osteoarthritis<br>o Urinary stress incontinence<br>o Gastroesophageal reflux disease<br>o Depression<br>• Pharmaceutical therapy should only be used as adjunct to lifestyle modifications and depends on the staging of obesity:<br>o Overweight Stage 0 (BMI 25-29.9 kg/m^2 or 23-24.9 kg/m^2 in certain ethnicities* with no complications)<br>▪ Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions<br>o Obesity Stage 0 (BMI greater than or equal to 30 kg/m^2 or greater than or equal to 25 kg/m^2 in certain ethnicities* with no complications)<br>▪ Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral intervention<br>▪ Weight loss medications – consider if lifestyle therapy fails to prevent progressive weight gain (BMI greater than or equal to 27 kg/m^2)<br>o Obesity Stage 1 (BMI greater than or equal to 25 kg/m^2 or greater than or equal to 23 kg/m^2 in certain ethnicities* with greater than or equal to 1 mild/moderate complications)<br>▪ Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions<br>▪ Weight loss medications – consider if lifestyle therapy fails to achieve therapeutic target or initiate concurrently with lifestyle therapy (BMI greater than or equal to 27 kg/m^2)<br>o Obesity Stage 2 (BMI greater than or equal to 25 kg/m^2 or greater than or equal to 23 kg/m^2 in certain ethnicities* with greater than or equal to 1 severe complications):<br>▪ Lifestyle therapy – reduced-calorie healthy meal plan/physical activity/behavioral interventions<br>▪ Weight loss medication – initiate concurrently with lifestyle therapy (BMI greater than or equal to 27 kg/m^2)<br>▪ Consider bariatric surgery (BMI greater than or equal to 35 kg/m^2)<br><br>*Certain ethnicities (A BMI cutoff point value of greater than or equal to 23 kg/m^2 should be used in the screening and confirmation of excess adiposity in South Asian, Southeast Asian, and East Asian adults)<br><br>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 |

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| | assessment and treatment with diet and exercise, as well as bariatric surgery for appropriate candidates.(13)<br><br>• Diet, exercise, and behavioral modification should be included in all overweight and obesity management approaches for BMI greater than or equal to 25 kg/m^2 and other tools [e.g., pharmacotherapy (if BMI greater than or equal to 27 kg/m^2 with comorbidity or BMI greater than 30 kg/m^2) and bariatric surgery (BMI greater than or equal to 35 kg/m^2 with comorbidity or BMI greater than 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. 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.<br>• Assessment of efficacy and safety of prescribed weight loss medications should be performed at least monthly for the first 3 months, then at least every 3 months thereafter.<br>• Clinicians are recommended to perform annual and symptom-based screening for major obesity related chronic conditions in all adult patients with a BMI greater than or equal to 30 kg/m^2, including diabetes, cardiovascular disease, hypertension, hyperlipidemia, obstructive sleep apnea, non-alcoholic fatty liver disease, osteoarthritis, and major depression.<br>• 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.<br>• If a patient's response to a weight loss medication is deemed effective (weight loss greater than or equal to 5% of body weight at 3 months) and safe, it is recommended that the medication be continued. If deemed ineffective (weight loss less than 5% at 3 months) or if there are safety or tolerability issues at any time, the medication should be discontinued and alternative medications or referral for alternative treatment approaches instead considered.<br>• Given the wide clinical prescribing of phentermine for greater than 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.<br><br>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 greater than or equal to 30 kg/m^2 or greater than or equal to 27 kg/m^2 with greater than or equal to 1 obesity-associated comorbid condition(s), adjunctive |

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| | therapy may be considered. The expert panel did not review comprehensive evidence on pharmacotherapy for weight loss. Medications should be FDA approved and clinicians should be knowledgeable about the product label. The provider should weigh potential risks of the medication vs. potential benefits of successful weight loss for the individual patient. If the patient is currently taking an obesity medication but has not lost at least 5% of initial body weight after 12 weeks on a maximal dose of the medication, the provider should reassess the risk-to-benefit ratio of that medication for the patient and consider discontinuation of that drug.(15)<br><br>The Veterans Affairs and Department of Defense (VA/DoD) Clinical Practice Guideline (2020), suggests offering prescribed pharmacotherapy in patients with a BMI greater than or equal to 30 kg/m^2 or greater than or equal to 27 kg/m^2 with greater than or equal to 1 obesity-associated comorbid condition(s), in conjunction with a comprehensive lifestyle intervention.(18)<br><br>Four centrally-acting noradrenergic agents (phentermine, diethylpropion, phendimetrazine, benzphetamine) are FDA-approved for the "short-term" (usually considered less than or equal to 12 weeks) management of obesity. However, the short-term designation was given since all were approved before the necessity of long-term treatment for obesity was established.(12) Since then some of these agents, such as phentermine and diethylpropion, have had literature published in support of long-term use.(13,19) Given the wide clinical prescribing of phentermine for greater than 20 years and lack of evidence of serious side effects, even in the absence of long-term controlled safety and efficacy data, it seems reasonable for clinicians to prescribe phentermine long term. (13) A clinical study found that diethylpropion plus a standard dietary intervention produced sustained and clinically significant weight loss over 1 year, and demonstrated safety under the cardiovascular and psychiatric point of view.(19) |
| Pediatric Obesity | Pediatric obesity has become an epidemic and international problem. In the United States, the prevalence of obesity in children has risen from 5% in 1970 to 17% in 2004. Genetics and environment are the underlying causes of the increase in pediatric obesity. Obese children and adolescents are at risk of developing the same comorbid conditions as obese and overweight adults. Obesity and overweight in children are defined on percentages specific for age and gender defined BMI values. The American Academy of Pediatrics (AAP) define obesity as a BMI greater than or equal to 95$^{th}$ percentile or a BMI greater than or equal to 30 kg/m^2, whichever is lower, and overweight as a BMI within 85$^{th}$ to 94$^{th}$ percentile for children and adolescents 2 years of age and older.(17)<br><br>The AAP recommends that clinicians should assess medical and behavioral risks in any child with a BMI above the 85$^{th}$ percentile before initiating any intervention.(17) The Endocrine Society Pediatric Obesity Treatment Guidelines also recommend that clinicians should evaluate for potential comorbidities in children and adolescents with a BMI greater than or equal to 85$^{th}$ percentile.(16)<br><br>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 greater than or equal to 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 greater than 85$^{th}$ percentile:(17) |

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| | • 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.<br>• 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.<br><br>• 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.<br>• Stage 1: Prevention Plus<br>• Stage 2: Structured Weight Management<br>• Stage 3: Comprehensive Multidisciplinary Intervention<br>• Stage 4: Tertiary Care Intervention<br><br>The 2017 Endocrine Society guidelines only recommend the use of FDA approved pharmacotherapy in pediatric patients as adjunctive therapy to lifestyle modifications of the highest intensity available and only by clinicians that are experienced in the use of anti-obesity agents.(16)<br><br>• Suggest pharmacotherapy in children or adolescents with obesity (greater than or equal to 95$^{th}$ percentile for age and gender) only after a formal program of intense lifestyle modifications has failed to limit weight gain or to ameliorate comorbidities.<br>• Recommend against using obesity agents in children and adolescents less than 16 years of age who are overweight, but not obese, except in the context of clinical trials.<br>• Anti-obesity agents should be discontinued, and patients reevaluated if the patient does not have a greater than 4% BMI reduction after 12 weeks at the medication's full dosage.<br>• Discourages prescribing weigh loss medications off-label to pediatric patients less than 16 years of age. |
| Safety | Phentermine has the following contraindications:(5,6,11)<br><br>• History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension)<br>• During or within 14 days following the administration of monoamine oxidase inhibitors<br>• Hyperthyroidism<br>• Glaucoma<br>• Agitated states<br>• History of drug abuse<br>• Pregnancy<br>• Nursing<br>• Known hypersensitivity, or idiosyncrasy to the sympathomimetic amines<br><br>Benzphetamine has the following contraindications:(2)<br><br>• Patients with advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to sympathomimetic amines, and glaucoma<br>• Benzphetamine should not be given to patients who are in an agitated state or who have a history of drug abuse |

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| | • Hypertensive crises have resulted when sympathomimetic amines have been used concomitantly or within 14 days following use of monoamine oxidase inhibitors<br>• Benzphetamine tablets should not be used concomitantly with other CNS stimulants<br>• Benzphetamine is contraindicated in women who are or may become pregnant<br><br>Phendimetrazine has the following contraindications:(7,10)<br><br>• Immediate release:<br>  ○ Known hypersensitivity or idiosyncratic reactions to sympathomimetics<br>  ○ Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate and severe hypertension, hyperthyroidism, and glaucoma<br>  ○ Highly nervous or agitated<br>  ○ History of drug abuse<br>  ○ Use in combination with other CNS stimulants, including monoamine oxidase inhibitors<br>• Extended release:<br>  ○ History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension, pulmonary hypertension)<br>  ○ During or within 14 days following the administration of monoamine oxidase inhibitors<br>  ○ Hyperthyroidism<br>  ○ Glaucoma<br>  ○ Agitated states<br>  ○ History of drug abuse<br>  ○ Pregnancy<br>  ○ Nursing<br>  ○ Use in combination with other anorectic agents or CNS stimulants<br>  ○ Known hypersensitivity or idiosyncratic reactions to sympathomimetics<br><br>Diethylpropion has the following contraindications:(9)<br><br>• Pulmonary hypertension, advanced arteriosclerosis, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma, severe hypertension<br>• Agitated states<br>• Patients with a history of drug abuse<br>• Use in combination with other anorectic agents is contraindicated<br>• During or within 14 days following the administration of monoamine oxidase inhibitors, hypertensive crises may result<br><br>**Phentermine/topiramate(1)**<br><br>Contraindications include:<br><br>• Pregnancy<br>• Glaucoma<br>• Hyperthyroidism |

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| | • During or within 14 days following the administration of monoamine oxidase inhibitors<br>• Known hypersensitivity or idiosyncrasy to the sympathomimetic amines<br><br>**Naltrexone/bupropion (NB)(3)**<br><br>Contraindications include:<br><br>• Uncontrolled hypertension<br>• Seizure disorder or a history of seizures<br>• Use of other bupropion-containing products (including, but not limited to, Wellbutrin, Wellbutrin SR, Wellbutrin XL, Aplenzin, and Zyban)<br>• Bulimia or anorexia nervosa, which increase the risk for seizure<br>• Chronic opioid or opiate agonist (e.g., methadone) or partial agonists (e.g., buprenorphine) use, or acute opiate withdrawal<br>• Patients undergoing an abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs<br>• 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<br>• Known allergy to bupropion, naltrexone or any other component of Contrave. Anaphylactoid/anaphylactic reactions and Stevens-Johnson syndrome have been reported with bupropion<br><br>Boxed warnings include:<br><br>• 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.<br><br>**Liraglutide(8)**<br><br>Contraindications include:<br><br>• Patients with a personal or family history of medullary thyroid carcinoma (MTC) or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)<br>• Patients with a prior serious hypersensitivity reaction to liraglutide or to any of the product components |

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| | • Pregnancy<br><br>Boxed warnings include:<br><br>• 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.<br>• 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.<br><br>**Orlistat(4)**<br><br>Contraindications include:<br><br>• Pregnancy<br>• Chronic malabsorption syndrome<br>• Cholestasis<br>• Known hypersensitivity to Orlistat or to any component of this product<br><br>**Semaglutide(20)**<br><br>Contraindications include:<br><br>• Personal of family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)<br>• A prior serious hypersensitivity to semaglutide or to any component of this product<br><br>Boxed warnings include:<br><br>• Semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in rodents. It is unknown whether Wegovy causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.<br>• Wegovy is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of Wegovy and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum |

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| | calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Wegovy.<br><br>**Co-Administration**<br><br>None of the FDA approved weight loss agents have approval for co-administration with another weight loss agent. New guidelines do not support the use of co-administration of weight loss pharmacological agents.(13,14,18) Use of non-approved drug combinations for obesity treatment should be limited to clinical trials, and patients should be informed when drugs are being used off label alone or in combination.(12) |

## REFERENCES


| Number | Reference |
|---|---|
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| 2 | Benzphetamine prescribing information. Nivagen Pharmaceuticals. January 2016. |
| 3 | Contrave prescribing information. Nalpropion Pharmaceuticals LLC. March 2021. |
| 4 | Xenical prescribing information. H2-Pharma, LLC. January 2018. |
| 5 | Adipex-P prescribing information. Teva Pharmaceuticals. September 2020. |
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| 7 | Phendimetrazine ER prescribing information. Virtus Pharmaceuticals, LLC. May 2020. |
| 8 | Saxenda prescribing information. Novo Nordisk Inc. December 2021. |
| 9 | Diethylpropion prescribing information. Lannett Company, Inc. December 2019. |
| 10 | Phendimetrazine prescribing information. KVK-Tech, Inc. December 2019. |
| 11 | Lomaira prescribing information. KVK-Tech Inc. December 2018. |
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| 14 | American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. Endocr Pract. 2016 Jul:22(Suppl 3):1-203. |
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| 16 | Styne DM, Arslanian SA, Connor EL, et al. Pediatric Obesity – Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017 Jan;102(3):709–757. |
| 17 | Barlow SE, et al. Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report. Pediatrics. 2007 Dec;120(Suppl 4):S164-S192. |
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| 19 | Cercato C, Roizenblatt VA, Leanca CC, et al. A Randomized Double-Blind Placebo-Controlled Study of the Long-Term Efficacy and Safety of Diethylpropion in the Treatment of Obese Subjects. Int J Obes (Lond). 2009 Aug;33(8):857-865. |
| 20 | Wegovy prescribing information. Novo Nordisk Inc. June 2021. |

 

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

| Target Brand Agent(s) | Target Generic Agent(s) | Strength | Targeted MSC | Available MSC | Preferred Status | Effective Date |
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| | benzphetamine hcl tab | 25 MG ; 50 MG | M ; N ; O ; Y | N ; O ; Y | | |
| | diethylpropion hcl tab ; diethylpropion hcl tab er | 25 MG ; 75 MG | M ; N ; O ; Y | N ; O ; Y | | |
| | phendimetrazine tartrate cap er ; phendimetrazine tartrate tab | 105 MG ; 35 MG | M ; N ; O ; Y | N ; Y | | |
| Adipex-p ; Lomaira | phentermine hcl cap ; phentermine hcl tab | 15 MG ; 30 MG ; 37.5 MG ; 8 MG | M ; N ; O ; Y | N ; O ; Y | | |
| Contrave | naltrexone hcl-bupropion hcl tab er | -90 MG | M ; N ; O ; Y | N | | |
| Qsymia | phentermine hcl-topiramate cap er | 11.25 MG ; 15 MG ; 3.75 MG ; 7.5 MG | M ; N ; O ; Y | N | | |
| Saxenda | liraglutide (weight mngmt) soln pen-inj | 18 MG/3ML | M ; N ; O ; Y | N | | |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector ; semaglutide (weight mngmt) soln auto-injector | 0.25 ; 0.25 MG/0.5ML ; 0.5 MG/0.5ML ; 1 MG/0.5ML ; 1.7 MG/0.75ML ; 2.4 MG/0.75ML | M ; N ; O ; Y | N | | |
| Xenical | Orlistat Cap 120 MG | 120 MG | M ; N ; O ; Y | M ; N | | |
| Xenical | Orlistat Cap 120 MG | 120 MG | M ; N ; O ; Y | M ; N | | |

## POLICY AGENT SUMMARY QUANTITY LIMIT

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| | Benzphetamine HCl Tab 25 MG | 25 MG | 90.0 | TABS | 30 | Days | | | | |
| | Benzphetamine HCl Tab 50 MG | 50 MG | 90.0 | TABS | 30 | Days | | | | |
| | Diethylpropion HCl Tab 25 MG | 25 MG | 90.0 | TABS | 30 | Days | | | | |
| | Diethylpropion HCl Tab ER 24HR 75 MG | 75 MG | 30.0 | TABS | 30 | Days | | | | |
| | Phendimetrazine Tartrate Cap ER 24HR 105 MG | 105 MG | 30.0 | CAPS | 30 | Days | | | | |
| | Phendimetrazine Tartrate Tab 35 MG | 35 MG | 180.0 | TABS | 30 | Days | | | | |
| | Phentermine HCl Cap 15 MG | 15 MG | 30.0 | CAPS | 30 | Days | | | | |
| | Phentermine HCl Cap 30 MG | 30 MG | 30.0 | CAPS | 30 | Days | | | | |
| Adipex-p | Phentermine HCl Cap 37.5 MG | 37.5 MG | 30.0 | CAPS | 30 | Days | | | | |
| Adipex-p | Phentermine HCl Tab 37.5 MG | 37.5 MG | 30.0 | TABS | 30 | Days | | | | |

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | QL Amount | Dose Form | Days Supply | Duration | Addtl QL Info | Allowed Exceptions | Targeted NDCs When Exclusions Exist | Effective Date |
|---|---|---|---|---|---|---|---|---|---|---|
| Contrave | Naltrexone HCl-Bupropion HCl Tab ER 12HR 8-90 MG | -90 MG | 120.0 | TABS | 30 | Days | | | | |
| Lomaira | Phentermine HCl Tab 8 MG | 8 MG | 90.0 | TABS | 30 | Days | | | | |
| Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 11.25-69 MG | 11.25 MG | 30.0 | CAPS | 30 | Days | | | | |
| Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 15-92 MG | 15 MG | 30.0 | CAPS | 30 | Days | | | | |
| Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 3.75-23 MG | 3.75 MG | 30.0 | CAPS | 30 | Days | | | | |
| Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 7.5-46 MG | 7.5 MG | 30.0 | CAPS | 30 | Days | | | | |
| Saxenda | Liraglutide (Weight Mngmt) Soln Pen-Inj 18 MG/3ML (6 MG/ML) | 18 MG/3ML | 15.0 | MLS | 30 | Days | | | | |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 1.7 MG/0.75 ML | 8.0 | PENS | 180 | Days | * - These strengths are not approvable for maintenance dosing | | | |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 0.25 ; 0.25 MG/0.5 ML | 8.0 | PENS | 180 | Days | * - These strengths are not approvable for maintenance dosing | | | |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 2.4 MG/0.75 ML | 4.0 | PENS | 28 | Days | | | | |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 1 MG/0.5 ML | 8.0 | PENS | 180 | Days | * - These strengths are not approvable for maintenance dosing | | | |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 0.5 MG/0.5 ML | 8.0 | PENS | 180 | Days | * - These strengths are not approvable for maintenance dosing | | | |
| Xenical | Orlistat Cap 120 MG | 120 MG | 90.0 | CAPS | 30 | Days | | | | |
| Xenical | Orlistat Cap 120 MG | 120 MG | 90.0 | CAPS | 30 | Days | | | | |

## CLIENT SUMMARY – PRIOR AUTHORIZATION

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|---|---|---|---|
| Adipex-p ; Lomaira | phentermine hcl cap ; phentermine hcl tab | 15 MG ; 30 MG ; 37.5 MG ; 8 MG | Commercial ; ResultsRx |
| | benzphetamine hcl tab | 25 MG ; 50 MG | Commercial ; ResultsRx |
| Contrave | naltrexone hcl-bupropion hcl tab er | -90 MG | Commercial ; ResultsRx |

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|---|---|---|---|
| | diethylpropion hcl tab ; diethylpropion hcl tab er | 25 MG ; 75 MG | Commercial ; ResultsRx |
| Xenical | Orlistat Cap 120 MG | 120 MG | Commercial ; ResultsRx |
| | phendimetrazine tartrate cap er ; phendimetrazine tartrate tab | 105 MG ; 35 MG | Commercial ; ResultsRx |
| Qsymia | phentermine hcl-topiramate cap er | 11.25 MG ; 15 MG ; 3.75 MG ; 7.5 MG | Commercial ; ResultsRx |
| Saxenda | liraglutide (weight mngmt) soln pen-inj | 18 MG/3ML | Commercial ; ResultsRx |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector ; semaglutide (weight mngmt) soln auto-injector | 0.25 ; 0.25 MG/0.5ML ; 0.5 MG/0.5ML ; 1 MG/0.5ML ; 1.7 MG/0.75ML ; 2.4 MG/0.75ML | Commercial ; ResultsRx |
| Xenical | Orlistat Cap 120 MG | 120 MG | Commercial ; ResultsRx |

## CLIENT SUMMARY – QUANTITY LIMITS

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|---|---|---|---|
| Adipex-p | Phentermine HCl Cap 37.5 MG | 37.5 MG | Commercial ; ResultsRx |
| Adipex-p | Phentermine HCl Tab 37.5 MG | 37.5 MG | Commercial ; ResultsRx |
| | Benzphetamine HCl Tab 25 MG | 25 MG | Commercial ; ResultsRx |
| | Benzphetamine HCl Tab 50 MG | 50 MG | Commercial ; ResultsRx |
| Contrave | Naltrexone HCl-Bupropion HCl Tab ER 12HR 8-90 MG | -90 MG | Commercial ; ResultsRx |
| | Diethylpropion HCl Tab ER 24HR 75 MG | 75 MG | Commercial ; ResultsRx |
| | Diethylpropion HCl Tab 25 MG | 25 MG | Commercial ; ResultsRx |
| Lomaira | Phentermine HCl Tab 8 MG | 8 MG | Commercial ; ResultsRx |
| Xenical | Orlistat Cap 120 MG | 120 MG | Commercial ; ResultsRx |
| | Phendimetrazine Tartrate Cap ER 24HR 105 MG | 105 MG | Commercial ; ResultsRx |
| | Phendimetrazine Tartrate Tab 35 MG | 35 MG | Commercial ; ResultsRx |
| | Phentermine HCl Cap 15 MG | 15 MG | Commercial ; ResultsRx |
| | Phentermine HCl Cap 30 MG | 30 MG | Commercial ; ResultsRx |
| Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 11.25-69 MG | 11.25 MG | Commercial ; ResultsRx |
| Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 15-92 MG | 15 MG | Commercial ; ResultsRx |
| Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 3.75-23 MG | 3.75 MG | Commercial ; ResultsRx |
| Qsymia | Phentermine HCl-Topiramate Cap ER 24HR 7.5-46 MG | 7.5 MG | Commercial ; ResultsRx |
| Saxenda | Liraglutide (Weight Mngmt) Soln Pen-Inj 18 MG/3ML (6 MG/ML) | 18 MG/3ML | Commercial ; ResultsRx |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 0.25 ; 0.25 MG/0.5ML | Commercial ; ResultsRx |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 0.5 MG/0.5ML | Commercial ; ResultsRx |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 1 MG/0.5ML | Commercial ; ResultsRx |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 1.7 MG/0.75ML | Commercial ; ResultsRx |
| Wegovy | Semaglutide (Weight Mngmt) Soln Auto-Injector | 2.4 MG/0.75ML | Commercial ; ResultsRx |
| Xenical | Orlistat Cap 120 MG | 120 MG | Commercial ; ResultsRx |

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|---|---|
| | **Initial Evaluation**<br><br>(Patient new to therapy, new to Prime, or attempting a repeat weight loss course of therapy)<br><br>**Target Agent(s)** will be approved when ALL the following are met:<br><br>1. ONE of the following:<br>A. The patient is 17 years of age or over and ONE of the following:<br>1. ALL of the following:<br>A. ONE of the following:<br>1. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 OR a BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **OR**<br>2. The patient has a BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., diabetes, dyslipidemia, coronary artery disease) **AND**<br>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**<br>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**<br>D. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **OR**<br>2. BOTH of the following:<br>A. The patient has a BMI greater than or equal to 27 kg/m^2 with at least one severe weight-related comorbidity/risk factor/complication **AND**<br>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**<br>B. The patient is 12 to 16 years of age and ALL of the following:<br>1. ONE of the following:<br>A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 95th percentile for age and gender **OR**<br>B. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 **OR**<br>C. The patient has a BMI greater than or equal to 85th percentile for age and gender AND at least one severe weight-related comorbidity/risk factor/complication **AND**<br>2. 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**<br>3. 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**<br>4. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND**<br>2. ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>4. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication **AND**<br>5. ONE of the following:<br>A. The patient has not tried a targeted weight loss agent in the past 12 months **OR**<br>B. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months AND the prescriber anticipates success with repeating therapy **AND**<br>6. ONE of the following:<br>A. The requested agent is benzphetamine, diethylpropion, phendimetrazine, or phentermine **OR**<br>B. The requested agent is Qsymia and ONE of the following:<br>1. The requested dose is 3.75 mg/23 mg **OR**<br>2. The patient is currently being treated with Qsymia, the requested dose is greater than 3.75 mg/23 mg AND ONE of the following:<br>A. ONE of the following:<br>1. For adults, the patient has demonstrated and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of the requested agent) **OR**<br>2. For pediatric patients aged 12 years and older, the patient has experienced a reduction of at least 5% of baseline BMI (prior to initiation of the requested agent) **OR**<br>B. The patient received less than 14 weeks of therapy **OR**<br>C. The patient's dose is being titrated upward **OR**<br>D. The patient has received less than 12 weeks (3 months) of therapy on the 15 mg/92 mg strength **OR**<br>3. The prescriber has provided information in support of therapy for the requested dose for this patient **OR**<br>C. The requested agent is Contrave and ONE of the following<br>1. The patient is newly starting therapy **OR**<br>2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR**<br>3. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to the initiation of requested agent) **OR**<br>D. The requested agent is Xenical or Orlistat and ONE of the following:<br>1. The patient is 12 to 16 years of age and ONE of the following:<br>A. The patient is newly starting therapy **OR**<br>B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR**<br>C. The patient has achieved and maintained a weight loss of greater than 4% from baseline (prior to the initiation of requested agent) **OR**<br>2. The patient is 17 years of age or over and ONE of the following:<br>A. The patient is newly starting therapy **OR**<br>B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR**<br>C. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to the initiation of requested agent) **OR**<br>E. The requested agent is Saxenda and ALL of the following:<br>1. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**<br>2. ONE of the following:<br>A. The patient is 18 years of age or over and ONE of the following:<br>1. The patient is newly starting therapy **OR**<br>2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR**<br>3. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to the initiation of requested agent) **OR** |

| Module | Clinical Criteria for Approval |
|---|---|
| | B. The patient is pediatric (12 to less than 18 years of age) and BOTH of the following:<br>1. The requested agent is NOT being used to treat type 2 diabetes **AND**<br>2. ONE of the following:<br>A. The patient is newly starting therapy **OR**<br>B. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR**<br>C. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to the initiation of requested agent) **OR**<br>F. The requested agent is Wegovy and ALL of the following:<br>1. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**<br>2. The patient does NOT have a history of pancreatitis **AND**<br>3. ONE of the following:<br>A. The patient is newly starting therapy **OR**<br>B. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR**<br>C. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to the initiation of the requested agent)<br><br>**Length of Approval:**<br><br>• For Wegovy: 12 months<br>• For Saxenda pediatric patients (age 12 to less than 18): 5 months.<br>• For Saxenda (adults) and Contrave: 4 months.<br>• For all other agents: 3 months<br><br>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria section below.<br><br>**Renewal Evaluation**<br><br>(Patient continuing a current weight loss course of therapy)<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br><br>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND**<br>2. 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**<br>3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**<br>4. For Saxenda only, BOTH of the following:<br>A. The requested agent is NOT being used to treat type 2 diabetes in pediatric patients (12 to less than 18 years of age) **AND**<br>B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**<br>5. For Wegovy only, ALL of the following:<br>A. The requested dose is 2.4 mg **AND**<br>B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**<br>C. The patient does NOT have a history of pancreatitis **AND**<br>6. The patient meets ONE of the following: |

| Module | Clinical Criteria for Approval |
|---|---|
| | A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to the initiation of requested agent) **OR**<br>B. For Saxenda only, ONE of the following:<br>1. If the patient is 18 years of age or over, the patient has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to the initiation of requested agent) **OR**<br>2. If the patient is pediatric (12 to less than 18 years of age), the patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to the initiation of requested agent) **OR**<br>C. For Qsymia only, ONE of the following:<br>1. For pediatric patients aged 12 years and older, the patient has achieved and maintained a reduction of at least 5% of baseline (prior to the initiation of the requested agent) BMI **OR**<br>2. The patient has achieved and maintained a weight loss less than 5% from baseline (prior to the initiation of requested agent) for adults, or a reduction in BMI less than 5% from baseline (prior to the initiation of the requested agent) for pediatric patients aged 12 years or older, AND BOTH of the following:<br>A. 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**<br>B. The patient has received less than 12 weeks of therapy on the 15 mg/92 mg strength **OR**<br>D. For Xenical or Orlistat only, ONE of the following:<br>1. The patient 12 to 16 years of age AND has achieved and maintained a weight loss greater than 4% from baseline (prior to the initiation of requested agent) **OR**<br>2. The patient is 17 years of age or over AND has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to the initiation of requested agent) **OR**<br>E. For Wegovy only, the patient has received less than 52 weeks of therapy on the 2.4 mg dose **AND**<br>7. If the patient is 12 to less than 18 years of age, the current BMI is greater than 85th percentile for age and gender **AND**<br>8. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication<br><br>**Length of Approval:**<br><br>• Qsymia: greater than or equal to 5% weight loss from baseline: 12 months<br>• Qsymia (less than 5% weight loss): 3 months<br>• All other agents: 12 months<br><br>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria section below. |

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|---|---|
| | **Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR**<br>3. ALL of the following:<br>A. The requested quantity (dose) is greater than the program quantity limit **AND**<br>B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** |

| Module | Clinical Criteria for Approval |
|---|---|
| | C. The prescriber has provided information in support of therapy with a higher dose for the requested indication<br><br>**Length of Approval**:<br><br>• Initial Approval:<br>o For Wegovy: 12 months<br>o For Saxenda pediatric patients (age 12 to less than 18): 5 months.<br>o For Saxenda (adults) and Contrave: 4 months.<br>o For all other agents: 3 months<br>• Renewal Approval:<br>o Qsymia: greater than or equal to 5% weight loss from baseline: 12 months<br>o Qsymia (less than 5% weight loss): 3 months<br>o All other agents: 12 months |