Weight Loss Agents Prior Authorization with Quantity Limit

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Adipex-P®, Lomaira™, Phentermine*~ Tablet 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 available ~ 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.	5,6,11
Benzphetamine*~ 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 available ~ 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® (naltrexone/bupropion)~ Tablet ER	Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: • Greater than or equal to 30 kg/m^2 (obese), or • 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) Limitations of Use: • Effect on cardiovascular morbidity and mortality has not been established	~ 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
Diethylpropion*	Short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction in the management of	* Generic available	9

Agent(s)	FDA Indication(s)	Notes	Ref#
Tablet Tablet ER	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. Indicated for use as monotherapy only.		
Phendimetrazine* 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) Indicated for use as monotherapy only.	* Generic available	7
Phendimetrazine* 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). Indicated for use as monotherapy only.	* Generic available	10
Qsymia® (phentermine/topiramate)~ Capsule	Adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in: • Adults with an initial BMI of: o Greater than or equal to 30 kg/m^2 (obese) o 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 • Pediatric patients aged 12 years and older with BMI in the 95th percentile or greater standardized for age and sex Limitations of Use: • Effect on cardiovascular morbidity and mortality has not been established	~ 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
Xenical®, Orlistat Capsule*	Obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet and to reduce the risk for weight regain after prior weight loss. It is indicated for obese patients with an initial body mass index (BMI) 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)	* Generic available	4,21

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Medical records and chart notes must be provided to support patients' height, weight and BMI.

Lifetime maximum allowed of 24 months

Module	Clinical Criteria for Approval
	Initial Evaluation (Patient new to therapy, new to Curative , or attempting a repeat weight loss course of therapy) **Target Agent(s)** will be approved when ALL the following are met: 1. ONE of the following: A. The patient is 17 years of age or over and ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 40 kg/m^2 **OR** B. The patient has a BMI greater than or equal to 30 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., diabetes, dyslipidemia, coronary artery disease) OR C. **AND** 2. The patient has been on a Curative weight loss program or Austin Regional Clinic weight loss program 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** 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** 4. 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. The patient is 12 to 16 years of age and ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 95th percentile for age and gender **OR** B. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 **OR** 2. The patient has been on a weight loss regimen (i.e., HEB's weight loss program) 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** 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** 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** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The patient has not tried a targeted weight loss agent in the past 12 months **OR** 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** 4. ONE of the following: A. The requested agent is, phentermine **OR**

Module	Clinical Criteria for Approval
	B. The requested agent is Qsymia and ONE of the following: 1. The requested dose is 3.75mg/23mg **OR** 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: A. ONE of the following: 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** 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** B. The patient received less than 14 weeks of therapy **OR** C. The patient's dose is being titrated upward **OR** D. The patient has received less than 12 weeks (3 months) of therapy on the 15mg/92mg strength **OR** 3. The prescriber has provided information in support of therapy for the requested dose for this patient **OR** C. The requested agent is Contrave and ONE of the following 1. The patient is newly starting therapy **OR** 2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR** 3. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR** 4. The patient had an inadequate response to trial of Contrave, Qsymia or phentermine and has failed to achieve ≥ 5 % weight loss after completion of treatment (documentation of baseline BMI including height and weight must be provided) Patient has an intolerance to Contrave, Qsymia and phentermine AND 5. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** **Length of Approval:** 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** Patient must be adherent to weight loss program and medication for continued therapy. **Target Agent(s)** will be approved when ALL of the following are met: [Note: patients not previously approved for the requested agent will require initial evaluation review] 1. 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** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication 4. The patient meets ONE of the following: A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR**

Module	Clinical Criteria for Approval
	B. For Qsymia only, ONE of the following: 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 initiation of the requested agent) BMI **OR** 2. The patient has achieved and maintained a weight loss less than 5% from baseline (prior to initiation of requested agent) for adults, or a reduction in BMI less than 5% from baseline (prior to initiation of the requested agent) for pediatric patients aged 12 years or older, AND BOTH of the following: 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** b. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength **OR** **Length of Approval:** • Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): 3 months • Qsymia less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months • All other agents: 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 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** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Length of Approval**: • Initial Approval: o Contrave: up to 4 months o For all other agents: up to 3 months

Module	Clinical Criteria for Approval
	• Renewal Approval: o Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): up to 3 months o Qsymia. less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months o All other agents: up to 3 months