Selected Weight-loss Drugs

Override(s)	Approval Duration
Prior Authorization	Initial: All agents, excluding Qsymia 12 weeks Qsymia* and Saxenda: 16 weeks *approve all strengths to allow for titration Subsequent: 6 months **Note: Agents containing the following ingredients are excluded from ongoing authorization: benzphetamine, diethylpropion, phendimetrazine, phentermine [does not apply to Qsymia]

Medications
**Adipex-P (phentermine)
Belviq (lorcaserin)
Belviq XR (lorcaserin ER)
**Bontril PDM (phendimetrazine)
**Bontril SR (phendimetrazine SR)
Contrave (naltrexone HCl, bupropion HCl extended release)
**Didrex (benzphetamine)
**diethylpropion
**Diethylpropion ER
**Lomaira (phentermine HCL)
**Melfiat (phendimetrazine)
Qsymia (phentermine HCl, topiramate extended release)
**Regimex (benzphetamine)
Plenity (cellulose and citric acid)
Saxenda (liraglutide)
**Suprenza ODT (phentermine ODT)
Wegovy (semaglutide)

APPROVAL CRITERIA

I. If the benefit requires prior authorization, initial requests may be approved if the following criteria are met:

   A. Individual has a BMI of 30 kg/m^2 or greater; **AND**
   B. Individual has attempted to lose weight through a formalized weight management program (hypocaloric diet, exercise, and behavior modification) for at least 6 months prior to requests for drug therapy; **AND**
   C. Individual is currently on a reduced calorie diet and exercise program; **AND**
   D. Individual is NOT receiving two medications for weight loss at the same time.

   *For Saxenda requests, may approve for pediatric patients 12-17 years of age with initial bodyweight above 60 kg **AND** a BMI corresponding to 30 kg/m^2 for adults by international cut-offs.

II. Requests for subsequent authorization for adults taking Saxenda, Wegovy, Qsymia, Contrave, or Plenity (Note: Agents containing the following ingredients are excluded from ongoing authorization: benzphetamine, diethylpropion, phendimetrazine, phentermine [does not apply to Qsymia]) may be approved if the individual meets ALL of the following criteria:

   A. Individual currently has a BMI of 25 kg/m^2 or greater; **AND**
   B. Individual has achieved/maintained an initial 5% weight loss or has continued to lose weight; **AND**
   C. Individual is currently maintained on a reduced calorie diet and exercise program; **AND**
   D. Individual is NOT receiving two medications for weight loss at the same time.

III. Requests for subsequent authorization for pediatric patients aged 12-17 taking Saxenda or may be approved if the individual meets ALL of the following criteria:

   A. Individual currently has a BMI greater than or equal to 85th percentile for age and sex (Styne 2017); **AND**
   B. Individual has achieved/maintained an initial 1% reduction from baseline BMI or has continued to lose weight; **AND**
   C. Individual is currently maintained on a reduced calorie diet and exercise program; **AND**
   D. Individual is NOT receiving two medications for weight loss at the same time.

Requests for naltrexone/bupropion (Contrave) **may not** be approved for any of the following:

I. Individual is currently taking a bupropion product; **OR**
II. Individual is currently undergoing long-term opioid analgesic therapy or is opioid dependent; **OR**
III. Individual has a seizure disorder or history of seizures; **OR**
IV. Individual has bulimia or anorexia nervosa; **OR**
V. Individual is undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, or antiepileptic drugs; **OR**

VI. Individual has uncontrolled hypertension; **OR**
VII. Within 14 days following administration of a MAOI.

Requests for Saxenda (liraglutide) **may not** be approved for any of the following:

I. Individual is using for treatment of type 2 diabetes mellitus; **OR**
II. Individual has a personal or family history of medullary thyroid carcinoma (MTC); **OR**
III. Individual has been diagnosed with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); **OR**
IV. Pediatric Individuals (<18 years of age) with a diagnosis of type 2 diabetes; **OR**
V. Individual is using in combination with another liraglutide agent or any other GLP-1 agonist.

Requests for Wegovy (semaglutide) **may not** be approved for any of the following:

I. Individual is using for treatment of type 2 diabetes mellitus; **OR**
II. Individual has a personal or family history of medullary thyroid carcinoma (MTC); **OR**
III. Individual has been diagnosed with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)**; OR**
IV. Individual has a history of pancreatitis; **OR**
V. Individual is using in combination with another liraglutide agent or any other GLP-1 agonist.

Requests for diethylpropion agents, benzphetamine agents (including Didrex, Regimex), phentermine agents (including Adipex-P,Suprenza, and Lomaira – but does not include Qsymia) and phendimetrazine agents (including Bontril PDM) **may not** be approved for individuals with the following:

I. Advanced arteriosclerosis or history of cardiovascular disease; **OR**
II. Hyperthyroidism; **OR**
III. Known hypersensitivity or idiosyncrasy to sympathetic amines; **OR**
IV. Glaucoma; **OR**
V. Severe hypertension; **OR**
VI. A history of substance abuse; **OR**
VII. Those in an agitated state; **OR**
VIII. Within 14 days following the administration of a MAOI; **OR**
IX. Pregnancy; **OR**
X. Pulmonary hypertension

Requests for phentermine/topiramate (Qsymia) **may not** be approved for individuals with the following:

I. Pregnancy; **OR**
II. Glaucoma; **OR**
III. Hyperthyroidism; **OR**

IV. Within 14 days following the administration of a MAOI; **OR**
V. Known hypersensitivity or idiosyncrasy to sympathetic amines.

Requests for Plenity **may not** be approved for individuals with the following:

I. Pregnancy.

Requests for Belviq and Belviq XR **may not** be approved.

Notes: Black box warnings exist for the following agents:

1. Contrave has a black box warning for suicidality and antidepressant drugs and neuropsychiatric reactions in those taking bupropion for smoking cessation due to the inclusion of bupropion in the combination agent.
2. Saxenda and Wegovy have a black box warning for an increased risk of thyroid c-cell tumors. It is contraindicated in those with a personal or family history of medullary thyroid carcinoma or those with multiple endocrine neoplasia syndrome type 2.

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Key References:

1. Curry S. US Preventative Services Task Force Recommendation Statement. BehavioralWeight Loss Interventions to Prevent Obesity-RelatedMorbidity andMortality in Adults. JAMA 2018; 320(11): 1163-1171.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: April 7, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. Endocr Pract 2016; 22 (Suppl 3):1-203
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
7. Apovian, Caroline M., et al. "Pharmacological management of obesity: an endocrine society clinical practice guideline." J Clin Endocrinol Metab, Feb 2015, 100(2):342-362.
8. Curry S. US Preventative Services Task Force Recommendation Statement. BehavioralWeight Loss Interventions to Prevent Obesity-RelatedMorbidity andMortality in Adults. *JAMA* 2018; 320(11): 1163-1171.
9. Garvey WT, Mechanick JI, Brett EM, et.al. American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. *Endocrine Prac.* July 2016; 22(SUPP 3).
10. Styne DM, Arslanian SA, Connor EL, et al. “Pediatric Obesity- Assesssment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline” J Clin Endocrine Metab, March 2017, 102 (3):709-757.

International Obesity Task Force BMI Cut-offs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (Cole Criteria); *from Saxenda Package Insert (2020)*

Age (years)	Body Mass Index 30 kg/m^2	
	Males	Females

12	26.02	26.67
12.5	26.43	27.24
13	26.84	27.76
13.5	27.25	28.20
14	27.63	28.57
14.5	27.98	28.87
15	28.30	29.11
15.5	28.60	29.29
16	28.88	29.43
6.51	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.