Selected Weight-loss Drugs

Override(s)	Quantity Limit	Approval Duration
Prior Authorization Quantity Limit	May be subject to quantity limit	Initial: All agents, excluding Qsymia: 12 weeks Qsymia: 28 weeks Continuation: 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)
**Lomaira (phentermine)
**benzphetamine
**diethylpropion
**diethylpropion ER
**phendimetrazine
**phendimetrazine ER
Contrave (naltrexone HCl, bupropion HCl extended release)
Qsymia (phentermine HCl, topiramate extended release)
Plenity (cellulose and citric acid)

APPROVAL CRITERIA

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

   A. Individual is 18 years of age or older and one of the following:
      1. Individual has a BMI of 30 kg/m^2 or greater; **OR**

2. Individual has a BMI of greater than or equal to 27 kg/m^2 and at least one of the following weight-related comorbid conditions:
    a. Hypertension
    b. Type II Diabetes Mellitus
    c. Dyslipidemia;

AND

B. Individual has tried but was unsuccessful losing weight through a healthcare provider supervised comprehensive lifestyle program for at least 6 months (AHA/ACC/TOS 2013), prior to request for drug therapy, that included ALL the following:
    1. A calorie deficit of approximately 30% (i.e. 500 kcals relative to their estimated total energy expenditure) in calories per day has been achieved by the individual for at least 6 months (AHA/ACC/TOS 2013); **AND**
    2. An exercise goal of completing at least 150 minutes of exercise per week has been achieved for at least 6 months (AHA/ACC/TOS 2013);
        OR
        a. Exercise requirements cannot be met due to clinical limitations (including but not limited to cardiovascular conditions, physical limitations, fall risk);

    AND

    3. Individual was unable to achieve at least a 5% weight reduction with calorie deficit goals, exercise goals, and behavior therapy (AHA/ACC/TOS 2013);

AND

C. Individual is currently maintained on a healthcare provider supervised lifestyle program that includes all of the following:
    1. An individualized calculated calorie deficit of approximately 30% (or 500 kcals relative to their estimated total energy expenditure) in calories per day (AHA/ACC/TOS 2013); **AND**
    2. Completing at least 150 minutes of exercise per week (AHA/ACC/TOS 2013);
        OR
        a. Exercise requirements cannot be met due to clinical limitations (including but not limited to cardiovascular conditions, physical limitations, fall risk);

AND

D. Individual is NOT receiving two or more medications for weight loss at the same time; **AND**

E. Healthcare provider has consulted with individual regarding risks (including but not limited to adverse drug events), benefits, realistic expectations associated with the requested drug and the need for long-term follow-up and adherence to behavior modifications.

II. Continuation requests for adults taking Qsymia or Contrave (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 is 18 years of age or older and one of the following:
    1. At initiation of therapy, individual had a BMI of 30 kg/m^2 or greater; **OR**

2. At initiation of therapy, individual had a BMI of greater than or equal to 27 kg/m^2 and at least one of the following weight-related comorbid conditions:
    a. Hypertension
    b. Type II Diabetes Mellitus
    c. Dyslipidemia

AND

B. Individual has achieved/maintained an initial 5% weight loss; **AND**
C. Individual continues to be engaged in a comprehensive lifestyle program which includes:
    1. Individual is currently maintained on an individualized calculated calorie deficit of approximately 30% (or 500 kcals relative to their estimated total energy expenditure) in calories per day (AHA/ACC/TOS 2013); **AND**
    2. Individual is currently maintaining 150 minutes of exercise per week (AHA/ACC/TOS 2013);

OR

    a. Exercise requirements cannot be met due to clinical limitations (including but not limited to cardiovascular conditions, physical limitations, fall risk);

AND

D. Individual is NOT receiving two or more medications for weight loss at the same time; **AND**
E. Healthcare provider has consulted with individual regarding risks (including but not limited to adverse drug events), benefits, realistic expectations associated with the requested drug and the need for long-term follow-up and adherence to behavior modifications.

III. Initial requests for adolescents (12 to 17 years of age) taking Qsymia may be approved if the individual meets ALL of following criteria are met:

A. Individual has a BMI in the 95th percentile or greater standardized for age and sex (label); **AND**
B. Individual has tried but was unsuccessful losing weight through intensive health behavior and lifestyle treatment (AAP 2023) for at least 6 months, prior to request for drug therapy, that included ALL the following:
    1. Individual and caregiver have been utilizing healthy nutrition and behavior counseling for at least 6 months; **AND**
    2. Individual was unable to achieve adequate weight reduction with health nutrition and behavior counseling alone; **AND**
C. Individual is currently maintained on their healthy nutrition and behavior counseling: **AND**
D. Individual is NOT receiving two or more medications for weight loss at the same time; **AND**
E. Healthcare provider has consulted with individual regarding risks (including but not limited to adverse drug events), benefits, realistic expectations associated with the requested drug and the need for long-term follow-up and adherence to behavior modifications.

IV. Continuation requests for Qsymia in adolescents (12 to 17 years of age) may be approved if the following criteria are met:

A. Individual has achieved/maintained an initial >4% reduction from baseline BMI while utilizing Qsymia therapy (Styne 2017); **AND**
B. Individual and caregiver are attending healthy nutrition and behavior counseling; **AND**
C. Individual is NOT receiving two or more medications for weight loss at the same time; **AND**
D. Healthcare provider has consulted with individual regarding risks (including but not limited to adverse drug events), benefits, realistic expectations associated with the requested drug and the need for long-term follow-up and adherence to behavior modifications.

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

I. Individual has a BMI of less than 18.5 kg/m^2 (CDC 2024); **OR**
II. Individual is currently taking a bupropion product; **OR**
III. Individual is currently undergoing long-term opioid analgesic therapy or is opioid dependent; **OR**
IV. Individual has a seizure disorder or history of seizures; **OR**
V. Individual has bulimia or anorexia nervosa; **OR**
VI. Individual is undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, or antiepileptic drugs; **OR**
VII. Individual has uncontrolled hypertension; **OR**
VIII. Within 14 days following administration of a MAOI.

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

I. Individual has a BMI of less than 18.5 kg/m^2 (CDC 2024); **OR**
II. Advanced arteriosclerosis or history of cardiovascular disease; **OR**
III. Hyperthyroidism; **OR**
IV. Known hypersensitivity or idiosyncrasy to sympathetic amines; **OR**
V. Glaucoma; **OR**
VI. Severe hypertension; **OR**
VII. A history of substance abuse; **OR**
VIII. Those in an agitated state; **OR**
IX. Within 14 days following the administration of a MAOI; **OR**
X. Pregnancy; **OR**
XI. Pulmonary hypertension.

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

I. Individual has a BMI of less than 18.5 kg/m2 (CDC 2024); **OR**

II. Pregnancy; **OR**
III. Glaucoma; **OR**
IV. Hyperthyroidism; **OR**
V. Within 14 days following the administration of a MAOI; **OR**
VI. Known hypersensitivity or idiosyncrasy to sympathetic amines.

Requests for Plenity **may not** be approved for any diagnosis.

Notes:
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.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. 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.
5. Blonde L, Umpierrez GE, Reddy SS, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan-2022 Update [published correction appears in Endocr Pract. 2023 Jan;29(1):80-81]. *Endocr Pract*. 2022;28(10):923-1049. doi:10.1016/j.eprac.2022.08.002.
6. 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.
7. ElSayed NA, Aleppo G, Aroda VR, et al. 8. Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes: Standards of Care in Diabetes-2023. *Diabetes Care*. 2023;46(Suppl 1):S128-S139. doi:10.2337/dc23-S008.
8. 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.
9. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in Circulation. 2017 Mar 21;135(12):e790]. *Circulation*. 2017;135(12):e686-e725. doi:10.1161/CIR.0000000000000470.
10. Greenway FL, Aronne LJ, Raben A, et al. A randomized, double-blind, placebo-controlled study of Gelesis100: a novel nonsystemic oral hydrogel for weight loss. *Obesity*. 2019;27(2):205–216.
11. Grunvald, E., Shah, R., Hernaez, R., Chandar, A. K., Pickett-Blakely, O., Teigen, L. M., Harindhanavudhi, T., Sultan, S., Singh, S., Davitkov, P., & AGA Clinical Guidelines Committee (2022). AGA Clinical Practice Guideline on Pharmacological Interventions for Adults With Obesity. *Gastroenterology*, *163*(5), 1198–1225. https://doi.org/10.1053/j.gastro.2022.08.045.
12. Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society [published correction appears in Circulation. 2014 Jun 24;129(25 Suppl 2):S139-40]. *Circulation*. 2014;129(25 Suppl 2):S102-S138. doi:10.1161/01.cir.0000437739.71477.ee.
13. 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.
14. Vivus LLC. A Phase IV Safety and Efficacy Study of VI-0521 in Obese Adolescents. Clinical Trials Identifier: NCT03922945. Last update March 3, 2022. Available at https://clinicaltrials.gov/ct2/show/NCT03922945.

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
16.5	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84

BMI Percentiles by Age and Sex for Pediatric Patients Aged 12 years and Older; *from Qsymia Package Insert (2022) and Wegovy Package Insert (2023)*

Age (years)	95th Percentile BMI Value	
	Male	Female
12	24.2	25.3
12.5	24.7	25.8
13	25.2	26.3
13.5	25.6	26.8
14	26.0	27.3
14.5	26.5	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.6	28.9
16.5	27.9	29.3
17	28.3	29.6
17.5	28.6	30.0

BMI Percentiles by Age and Sex for Pediatric Patients Aged 12 years and Older; *from Wegovy Package Insert (2023)*

Age (years)	95th Percentile BMI Value	
	Male	Female
12	24.2	25.2
12.5	24.7	25.7
13	25.1	26.3
13.5	25.6	26.8
14	26.0	27.2
14.5	26.4	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.5	28.9
16.5	27.9	29.3
17	28.2	29.6
17.5	28.6	30.0

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.