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Scope: Medicaid

Weight Loss Management
CONTRAVE (naltrexone and bupropion)
WEGOVY (semaglutide)
ZEPBOUND (tirzepatide)

POLICY

I. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for the requested drug when all the following criteria are met:

A. The patient meets one of the following:

- i. For weight reduction, the patient meets all of the following:
 - a. The patient has documentation of current, active participation in a comprehensive weight management program that includes a Behavioral Health Counseling component, a Dietary/Nutritional education/counseling component, and reinforcement of and advocacy for an exercise regimen. A comprehensive weight loss program meets at least monthly for 6 months prior to using drug therapy and tracks a patient's performance and efficacy.
 - b. The patient meets one of the following criteria below (documentation of baseline weight and body mass index (BMI) must be provided):
 - i. The patient (adult or pediatric 12 years of age and older) has a body mass index (BMI) greater than or equal to 30 kg per square meter. The patient (adult) has a body mass index (BMI) greater than or equal to 27 kg per square meter and has at least one additional risk factor present (e.g., coronary heart disease, type 2 diabetes, dyslipidemia, hypertension, sleep apnea)
 - ii. The patient (pediatric 12 years of age and older ONLY) has a BMI that is classified as obese when standardized for age and sex
 - c. For Contrave or Zepbound requests, the patient must be 18 years of age and older
 - d. For Wegovy or Zepbound requests, the patient is not using medication in combination with any other GLP-1 receptor agonist
- ii. For major adverse cardiovascular event (MACE) risk reduction, the patient meets all of the following:
 - a. The requested drug is Wegovy
 - b. The patient is 18 years of age and older
 - c. Documentation that the patient will be treated with Wegovy in combination with a reduced calorie diet and increased physical activity
 - d. Documentation that the patient has established and has documented cardiovascular disease with a history of ONE of the following: A) previous myocardial infarction (MI), B) previous stroke, C) symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease, D) prior history of revascularization (coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), or angioplasty)

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- e. Documentation the patient has a baseline BMI greater than or equal to 27 kg per square meter (documentation of baseline weight and body mass index (BMI) must be provided)
- f. Documentation the patient does NOT have type 2 diabetes [NOTE: Ozempic is indicated to reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. Patients with type 2 diabetes may be treated for risk reduction of cardiovascular events with Ozempic.]
- g. Documentation the patient is currently receiving guideline-directed medical therapy (GDMT) for cardiovascular disease (e.g., lipid-lowering agent, antiplatelet, beta-blocker, renin-angiotensin inhibitor, etc.) with documentation provided OR the patient has a documented clinical reason not to be treated with GDMT for cardiovascular disease (*Note:* Clinical guidelines recommend bisoprolol, carvedilol or metoprolol succinate specifically after a patient experiences a ST-elevation myocardial infarction (STEMI), non-ST-elevation myocardial infarction (NSTEMI) or has history of revascularization and a high-intensity statin, specifically atorvastatin 40-80mg or rosuvastatin 20-40mg, after a patient experiences a stroke, STEMI, NSTEMI symptomatic PAD or has history of CABG)
- h. Documentation the patient is not using medication in combination with any other GLP-1 receptor agonist
- iii. For the treatment of moderate to severe obstructive sleep apnea (OSA) in adults with obesity, the patient meets all of the following:
 - a. The requested drug is Zepbound
 - b. The patient is 18 years or older
 - c. Documentation that the patient meets all of the following criteria for weight reduction:
 - i. The patient has documentation of current, active participation in a comprehensive weight management program that includes a Behavioral Health Counseling component, a Dietary/Nutritional education/counseling component, and reinforcement of and advocacy for an exercise regimen. A comprehensive weight loss program meets at least monthly and tracks a patient's performance and efficacy.
 - ii. The patient meets the following criteria below (documentation of baseline weight and body mass index (BMI) must be provided):
 - a. The patient has a body mass index (BMI) greater than or equal to 30 kg per square meter. The patient has a body mass index (BMI) greater than or equal to 27 kg per square meter and has at least one additional risk factor present (e.g., coronary heart disease, type 2 diabetes, dyslipidemia, hypertension, sleep apnea)
 - d. Documentation the patient has moderate to severe OSA evidenced by an apnea-hypopnea index [AHI] of ≥ 15 measured on polysomnography (PSG)
 - e. Documentation the patient has been receiving treatment for the underlying airway obstruction [e.g., continuous positive airway pressure (CPAP)] for at least one month, and has documented evidence of residual sleepiness despite compliance.
 - f. Documentation the patient is not using Zepbound in combination with any other GLP-1 receptor agonist

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II. CRITERIA FOR CONTINUATION OF THERAPY

Authorization of 6 months may be granted for the requested drug when the following criteria are met:

- A. Clinical notes documenting tolerability of the medication and continued reduced calorie diet with increased physical activity; **AND**
- B. For Wegovy or Zepbound requests, documentation that the patient is not using medication in combination with any other GLP-1 receptor agonist; **AND**
- C. For Wegovy requests (adults and pediatrics) for weight reduction, and for Contrave or Zepbound requests for patients that are 18 years of age and older, documentation of BOTH of the following:
 - i. They have completed at least 20 weeks of therapy with Wegovy or Zepbound or 16 weeks of therapy of Contrave or Saxenda and are currently being treated with the FDA-recommended maintenance dose (see FDA Dosage Recommendation section below); **AND**
 - ii. The patient lost at least 5 percent of baseline body weight while taking Wegovy, Contrave or Zepbound (documentation of baseline & current weight and BMI must be provided) **AND** meets one of the following criteria:
 1. Patient has continued to display weight loss
 2. Patient has achieved a normal BMI (18.5-24.9)
 3. If the patient has demonstrated no further weight loss, and the BMI is 25 or greater, documentation showing active participation in a comprehensive weight loss program is required. [Limit of 1 approval with this criterion] **OR**
- D. For Wegovy requests for major adverse cardiovascular event (MACE) risk reduction for patients that are 18 years of age and older:
 - i. Previous documentation indicates that the patient has established cardiovascular disease as indicated in initial criteria; **AND**
 - ii. Documentation that the patient will continue to be treated with Wegovy in combination with a reduced calorie diet and increased physical activity; **AND**
 - iii. Documentation of baseline & current weight and BMI must be provided; **AND**
 - iv. Documentation that the patient does NOT have type 2 diabetes [NOTE: Ozempic is indicated to reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. Patients with type 2 diabetes may be treated for risk reduction of cardiovascular events with Ozempic.]; **AND**
 - v. Documentation that the patient is currently receiving guideline-directed medical therapy (GDMT) for cardiovascular disease (e.g., lipid-lowering agent, antiplatelet, beta-blocker, renin-angiotensin inhibitor, etc.) with documentation provided **OR** the patient has a documented clinical reason not to be treated with GDMT for cardiovascular disease (*Note: Clinical guidelines recommend bisoprolol, carvedilol or metoprolol succinate specifically after a patient experiences a ST-elevation myocardial infarction (STEMI), non-ST-elevation myocardial infarction (NSTEMI) or has history of revascularization and a high-intensity statin, specifically atorvastatin 40-80mg or rosuvastatin 20-40mg, after a patient experiences a stroke, STEMI, NSTEMI symptomatic PAD or has history of CABG*); **AND**
 - vi. Documentation that the patient is currently being treated with the FDA-recommended maintenance dose (see FDA Dosage Recommendation section below)
- E. For Zepbound requests for moderate to severe obstructive sleep apnea (OSA) in patients with obesity that are 18 years of age and older:
 - i. Previous documentation indicates the patient has established moderate to severe OSA as indicated in initial criteria; **AND**

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- ii. Documentation the patient will continue to be treated with Zepbound in combination with a reduced calorie diet and increased physical activity; **AND**
- iii. Documentation of BOTH of the following:
 - 1. They have completed at least 20 weeks of therapy with Zepbound are currently being treated with the FDA-recommended maintenance dose for OSA (see FDA Dosage Recommendation section below); **AND**
 - 2. The patient lost at least 5 percent of baseline body weight while taking Zepbound (documentation of baseline & current weight and BMI must be provided) **AND** meets one of the following criteria:
 - 1. Patient has continued to display weight loss
 - 2. Patient has achieved a normal BMI (18.5-24.9)
 - 3. If the patient has demonstrated no further weight loss, and the BMI is 25 or greater, documentation showing active participation in a comprehensive weight loss program is required. [Limit of 1 approval with this criterion]; **AND**
- iv. Documentation supporting treatment efficacy by patient reporting symptom improvement, such as less daytime sleepiness, fewer sleep arousals, or fewer partner reported snoring episodes or pauses in breathing

III. PRESCRIBER SPECIALTY

For weight reduction: The requested drug must be prescribed by, or in consultation, with a weight loss clinic or a dietician/nutritionist.

For OSA in patients with obesity: The requested drug must be prescribed by, or in consultation, with a weight loss clinic or a dietician/nutritionist with documentation from a sleep specialist.

IV. QUANTITY LIMIT AND FDA DOSAGE RECOMMENDATIONS

Wegovy 0.25mg, 0.5mg, 1mg, 1.7mg & 2.4mg: 4 pens per 28 days

Zepbound 2.5mg/0.5ml, 5mg/0.5ml, 7.5mg/0.5ml, 10mg/0.5ml, 12.5mg/0.5ml, 15mg/0.5ml: 4 pens per 28 days

Wegovy Subcutaneous Injection

Treatment	Weeks	Once Weekly Dose ^a
Initiation	1 through 4	0.25 mg
Escalation	5 through 8	0.5 mg
	9 through 12	1 mg
	13 through 16	1.7 mg
Maintenance	17 and onward	1.7 mg or 2.4 mg ^b

^aIf patient does not tolerate a dose during dosage escalation, consider delaying dosage escalation for 4 weeks

^bDiscontinue Wegovy if the patient cannot tolerate 1.7mg once weekly dosage

Contrave (8 mg naltrexone/90 mg bupropion) ER tablets

Week 1	1 tablet	None
Week 2	1 tablet	1 tablet
Week 3	2 tablets	1 tablet

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Week 4 - Onward	2 tablets	2 tablets
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Zepbound Subcutaneous Injection

Treatment	Weeks	Once Weekly Dose
Initiation	1 through 4	2.5 mg
Maintenance	5 and onward*	5 mg, 10mg or 15mg
Maintenance for OSA only	5 and onward*	10mg or 15mg

*The dosage may be increased in 2.5 mg increments, after at least 4 weeks on the current dose.

V. APPENDIX

Table 2: International Obesity Task Force BMI Cut-offs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (Cole Criteria)

Age (years)	Body mass index 30 kg/m²	
	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

VI. REFERENCES

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