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Scope: Medicaid

Weight Loss Management
CONTRAVE (naltrexone and buproprion)
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 member meets one of the following:
   i. For weight reduction, the members meet all of the following:
      a. The member 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 member's performance and efficacy.
      b. The member meets one of the following criteria below (documentation of baseline weight and body mass index (BMI) must be provided):
         i. The member (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 member (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 member (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 member must be 18 years of age and older
      d. The member is not using medication in combination with any other GLP-1 receptor agonist or agents used for weight loss (e.g., phentermine/topiramate)
   ii. For major adverse cardiovascular event (MACE) risk reduction, the member meets all of the following:
      a. The requested drug is Wegovy
      b. The member is 18 years of age and older
      c. Documentation that the member will be treated with Wegovy in combination with a reduced calorie diet and increased physical activity
      d. Documentation that the member has established and has documented cardiovascular disease with a history of ONE of the following:
      e. 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)

f. Documentation the member 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)
g. Documentation the member 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. Members with type 2 diabetes may be treated for risk reduction of cardiovascular events with Ozempic.]
h. Documentation the member 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 member 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 member 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 member experiences a stroke, STEMI, NSTEMI symptomatic PAD or has history of CABG)
i. Documentation the member 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 member meets all of the following:
a. The requested drug is Zepbound
b. The member is 18 years or older
c. Documentation that the member meets all of the following criteria for weight reduction:
i. The member 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 member's performance and efficacy.
ii. The member meets the following criteria below (documentation of baseline weight and body mass index (BMI) must be provided):
a. The member has a body mass index (BMI) greater than or equal to 30 kg per square meter. The member 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 member has moderate to severe OSA evidenced by an apnea-hypopnea index [AHI] of ≥15 measured on polysomnography (PSG)
e. Documentation the member 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 member is not using Zepbound in combination with any other GLP-1 receptor agonist

iv. **For Wegovy for Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis(MASH)**

Authorization of 12 months may be granted when all of the following criteria is met:

a. Member is 18 years of age or older
b. Documentation that Wegovy is being prescribed for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis)
c. The member's moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) at baseline has been confirmed by ONE of the following within the past 6 months: non-invasive liver disease assessment (e.g., ultrasound-based elastography, magnetic resonance elastography [MRE]) OR historical liver biopsy.
d. The requested drug is being used with a reduced-calorie diet AND increased physical activity.

II. CRITERIA FOR CONTINUATION OF THERAPY

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

i. Clinical notes documenting tolerability of the medication and continued reduced calorie diet with increased physical activity
ii. Documentation that the member is not using medication in combination with any other GLP-1 receptor agonist or agents used for weight loss (e.g., phentermine/topiramate)
iii. For Wegovy requests (adults and pediatrics) for weight reduction, and for Contrave or Zepbound requests for members 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 member 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. Member has continued to display weight loss
        2. Member has achieved a normal BMI (18.5-24.9)
        3. If the member 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**
iv. For Wegovy requests for major adverse cardiovascular event (MACE) risk reduction for members that are 18 years of age and older:
    i. Previous documentation indicates that the member has established cardiovascular disease as indicated in initial criteria;
    ii. Documentation that the member will continue to be treated with Wegovy in combination with a reduced calorie diet and increased physical activity;
    iii. Documentation of baseline & current weight and BMI must be provided;
    iv. Documentation that the member 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. Members with type 2 diabetes may be treated for risk reduction of cardiovascular events with Ozempic.];

v. Documentation that the member 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 member 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 member 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 member experiences a stroke, STEMI, NSTEMI symptomatic PAD or has history of CABG);

vi. Documentation that the member is currently being treated with the FDA-recommended maintenance dose (see FDA Dosage Recommendation section below)

v. For Zepbound requests for moderate to severe obstructive sleep apnea (OSA) in members with obesity that are 18 years of age and older:

i. Previous documentation indicates the member has established moderate to severe OSA as indicated in initial criteria;

ii. Documentation the member will continue to be treated with Zepbound in combination with a reduced calorie diet and increased physical activity;

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);
2. The member 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. Member has continued to display weight loss
    2. Member has achieved a normal BMI (18.5-24.9)
    3. If the member 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];

iv. Documentation supporting treatment efficacy by member reporting symptom improvement, such as less daytime sleepiness, fewer sleep arousals, or fewer partner reported snoring episodes or pauses in breathing

vi. **For Wegovy for Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis (MASH)**

Authorization of 12 months may be granted when all of the following criteria is met:

i. The requested drug is being prescribed for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults

ii. The requested drug is being used with a reduced-calorie diet AND increased physical activity

iii. Documentation that the member has achieved or maintained a positive clinical response to the requested drug (e.g., improvement in liver function such as reduction in alanine aminotransferase [ALT], improvement in Enhanced Liver Fibrosis (ELF) score, improvement in liver stiffness measurement [LSM] by ultrasound-based elastography, magnetic resonance elastography [MRE])
iv. The member is being treated with a maintenance dosage of the requested drug which is based on individual treatment response and tolerability
v. Member has not progressed to stage F4 (cirrhosis)

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 members 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.

For Noncirrhotic Metabolic Dysfunction-Associated Steatohepatitis (MASH): The requested drug must be prescribed by or in consultation with a gastroenterologist, or hepatologist.

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]

[a]If member does not tolerate a dose during dosage escalation, consider delaying dosage escalation for 4 weeks
[b]Discontinue Wegovy if the member 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
Week 4 - Onward	2 tablets	2 tablets

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/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

VI. REFERENCES

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