Effective Date: 7/2018
Reviewed: 7/2018, 12/2019, 11/2020, 09/2021, 03/2022, 8/2022, 2/2023, 6/2023, 08/2023, 12/2023 Scope: Medicaid

Weight Loss Management
CONTRAVE (naltrexone and buproprion)
SAXENDA (liraglutide)
WEGOVY (semaglutide)
ZEPBOUND (tirzepatide)

POLICY

I. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests: documentation of baseline weight, body mass index (BMI), and clinical notes documenting current participation in a comprehensive weight management program with monthly follow up (e.g., behavioral modification, nutrition, physical activity) for at least the past six months.
B. Continuation of therapy requests: documentation of baseline & current weight and BMI
    i. Active participation in a comprehensive weight management program (e.g., behavioral modification, nutrition, physical activity) may be indicated if continued pharmacologic benefit is lacking.

II. PRESCRIBER SPECIALTY

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

III. 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 has documentation of current, active participation in a comprehensive weight management program that encourages behavioral modification, reduced calorie diet and increased physical activity with continuing monthly follow-up (at minimum) for at least 6 months prior to using drug therapy.
B. One of the following criteria below:
    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
    ii. 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)
    iii. 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 Saxenda, Wegovy, or Zepbound requests, the patient is not using medication in combination with any other GLP-1 receptor agonist
D. For Contrave or Zepbound requests the patient must be 18 years of age and older

IV. CONTINUATION OF THERAPY

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

A. Clinical notes documenting tolerability of the medication and continued reduced calorie diet with increased physical activity.
B. For Saxenda, Wegovy or Zepbound requests, the patient is not using medication in combination with any other GLP-1 receptor agonist
C. For Wegovy requests (adults and pediatrics), and for Contrave, Saxenda, or Zepbound requests for patients that are 18 years of age and older:
    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, Saxenda or Zepbound with documentation 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]
D. For Saxenda requests for pediatric patients 12 to 17 years of age:
    i. They have completed at least 12 weeks of therapy on maintenance dose of therapy with Saxenda; AND
    ii. The patient had at least a 1 percent reduction in body mass index (BMI) from baseline with documentation provided **AND** meets one of the following criteria:
        1. Patient has continued to display weight loss
        2. Patient has achieved a normal BMI standardized for age and sex (see Appendix)
        3. If the patient has demonstrated no further weight loss, and the BMI is classified as obese when standardized for age and sex, documentation showing active participation in a comprehensive weight loss program is required. [Limit of 1 approval with this criterion]

V. QUANTITY LIMIT AND FDA DOSAGE RECOMMENDATIONS

Saxenda 18mg/3ml: 5 pens per 30 days
Wegovy 0.5mg, 0.25mg, 1.7mg, 1mg, & 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 patient does not tolerate a dose during dosage escalation, consider delaying dosage escalation for 4 weeks
[b]Discontinue 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
Week 4 - Onward	2 tablets	2 tablets

Saxenda Subcutaneous Injection

Week	Daily Dose[a]
1	0.6 mg
2	1.2 mg
3	1.8 mg
4	2.4 mg[b]
5 and onward	3 mg[b]

[a]If patient does not tolerate an increased dose during dose escalation, consider delaying dose escalation for approximately one additional week. Dose escalation for pediatric patients may take up to 8 weeks.
[b]Discontinue Saxenda if adult patient cannot tolerate the 3mg dose or pediatric patient cannot tolerate the 2.4mg dose

Zepbound Subcutaneous Injection

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

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

VI. 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

Adapted from Saxenda PI

VII. REFERENCES

1. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc; May 2023.
2. Contrave [package insert]. Morristown,NJ: Currax Pharmaceuticals LLC; November 2021.
3. Wegovy [package insert]. Plainsboro, NJ: Novo Nordisk, Inc.; July 2023.
4. Zepbound [package insert]. Indianapolis, IN: Eli Lilly and Company LLC; November 2023.
5. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed August 2021.
6. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. National Heart, Lung, and Blood Institute. NIH Publication No. 12-7486. October 2012. http://www.nhlbi.nih.gov/guidelines/cvd_ped/peds_guidelines_full.pdf. 141-159. Accessed August 2021.
7. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. The Journal of Clinical Endocrinology & Metabolism, Volume 100, Issue 2, 1 February 2015, Pages 342–362. https://academic.oup.com/jcem/article/100/2/342/2813109. Accessed August 2021.
8. Jensen MD, 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. *Circulation.* 2013; 129:S102-S138.