Effective Date: 10/1/2023
Reviewed: 8/2023, 12/2023, 5/2024 Scope: Commercial

Weight Loss Management
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:
   i. For weight reduction: documentation of baseline weight, body mass index (BMI), and clinical notes documenting active participation in a comprehensive weight management program, that includes behavioral health counseling, nutritional/dietary counseling, and physical activity, with meetings at least monthly for at least the past six months.
   ii. For major adverse cardiovascular event (MACE) risk reduction: documentation of baseline weight, body mass index (BMI), and clinical notes documenting reduced calorie diet, increased physical activity and established 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). Documentation of guideline-directed medical therapy (GDMT) for cardiovascular disease (e.g., lipid-lowering agent, antiplatelet, beta-blocker, renin-angiotensin inhibitor, etc.) that the patient is currently receiving or the clinical reason the patient is not to be treated with GDMT for cardiovascular disease must be provided.

B. Continuation of therapy requests:
   i. For weight reduction: documentation of baseline & current weight and BMI
      i. Active participation in a comprehensive weight management program that includes behavioral health counseling, nutritional/dietary counseling, and physical activity may be indicated if continued pharmacologic benefit is lacking.
   ii. For major adverse cardiovascular event (MACE) risk reduction: documentation of baseline & current weight and BMI and clinical notes documenting reduced calorie diet, increased physical activity and established 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). Documentation of guideline-directed medical therapy (GDMT) for cardiovascular disease (e.g., lipid-lowering agent, antiplatelet, beta-blocker, renin-angiotensin inhibitor, etc.) that the

patient is currently receiving or the clinical reason the patient is not to be treated with GDMT for cardiovascular disease must be provided

II. 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 behavioral health counseling, nutritional/dietary counseling, and physical activity, with meetings at least monthly for at least 6 months prior to using drug therapy.
   b. One of the following criteria below:
      1. 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
      2. 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)
      3. 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 Zepbound requests, the patient must be 18 years of age and older

ii. For major adverse cardiovascular event (MACE) risk reduction, the patient meets all of the following:
   a. The patient is 18 years of age and older
   b. The patient will be treated with Wegovy in combination with a reduced calorie diet and increased physical activity
   c. The patient has established 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)
   d. The patient has a baseline BMI greater than or equal to 27 kg per square meter
   e. 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.]
   f. 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)

B. The patient is not using medication in combination with any other GLP-1 receptor agonist

III. 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. The patient is not using medication in combination with any other GLP-1 receptor agonist
C. For Wegovy requests (adults and pediatrics) for weight reduction, and Saxenda & 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 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, 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]
E. 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. 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**
    iii. 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**

iv. The patient is currently being treated with the FDA-recommended maintenance dose (see FDA Dosage Recommendation section below)

IV. QUANTITY LIMIT AND FDA DOSAGE RECOMMENDATIONS

Saxenda 18mg/3ml: 5 pens per 30 days
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 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

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.

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

Adapted from Saxenda PI

VI. REFERENCES

1. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc; May 2023.
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5. 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.
6. 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.
7. 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.