Saxenda (liraglutide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	**Adults** Initial: 16 weeks Continuation: 1 year **Adolescents** Initial: 20 weeks Continuation: 1 year

Medications	Quantity Limit
Saxenda (liraglutide)	May be subject to quantity limit

APPROVAL CRITERIA

When member's benefit covers weight loss drugs and requires prior authorization:

I. Initial requests for Saxenda (liraglutide) for adults may be approved if the following criteria are met:

A. Individual is 18 years of age or older and one of the following:
   1. Documentation* is provided that individual has a BMI of 30 kg/m^2 or greater (**documentation of BMI is required within 90 days of the request*); **OR**
   2. Documentation* is provided that 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 (**documentation of BMI is required within 90 days of the request*):
      a. Hypertension defined as treated hypertension or with systolic blood pressure (SBP) ≥130 mmHg or diastolic blood pressure ≥80 mmHg; **OR**
      b. Type II Diabetes Mellitus**; OR**
      c. Dyslipidemia defined as treated dyslipidemia or has low-density lipoprotein (LDL) ≥160 mg/dL (4.1 mmol/L) or triglycerides ≥150 mg/dL (1.7 mmol/L), or high-density lipoprotein (HDL) <40 mg/dL (1.0 mmol/L) for men or HDL <50 mg/dL (1.3 mmol/L) for women; **OR**
      d. Obstructive sleep apnea (as a result of having a BMI of 27 kg/m^2 or greater); **OR**
      e. Cardiovascular disease (example includes ischemic cardiovascular disease, New York Heart Association (NYHA) defined heart failure);

AND

B. Individual has tried but was unsuccessful losing weight through a health care provider supervised comprehensive lifestyle program for at least 6 months, 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; **AND**
2. An exercise goal of completing at least 150 minutes of exercise per week has been achieved for at least 6 months; **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;

OR

C. Individual has a diagnosis of New York Heart Association Class III or IV heart failure;
OR
D. Individual has moderate to severe obstructive sleep apnea with an apnea-hypopnea index (AHI) score of greater than or equal to 15;
OR
E. Individual has a BMI of 40 kg/m2 or greater;

AND

F. 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 (AACE 2016/AGA 2022); **AND**
    2. Completing at least 150 minutes of exercise per week (AACE 2016/AGA 2022); **OR**
        a. Exercise requirements cannot be met due to clinical limitations (including but not limited to cardiovascular conditions, physical limitations, fall risk);

AND

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

AND

H. 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 Saxenda (liraglutide) for adults may be approved if ALL of the following criteria are met:

A. Individual is 18 years of age or older and one of the following:
    1. Documentation is provided that at initiation of therapy, individual had a BMI of 30 kg/m^2 or greater; **OR**

2. Documentation is provided that 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 defined as treated hypertension or with systolic blood pressure (SBP) ≥130 mmHg or diastolic blood pressure ≥80 mmHg; **OR**
    b. Type II Diabetes Mellitus; **OR**
    c. Dyslipidemia defined as treated dyslipidemia or has low-density lipoprotein (LDL) ≥160 mg/dL (4.1 mmol/L) or triglycerides ≥150 mg/dL (1.7 mmol/L), or high-density lipoprotein (HDL) <40 mg/dL (1.0 mmol/L) for men or HDL <50 mg/dL (1.3 mmol/L) for women; **OR**
    d. Obstructive sleep apnea (as a result of having a BMI of 27 kg/m^2 or greater); **OR**
    e. Cardiovascular disease (example includes ischemic cardiovascular disease, New York Heart Association (NYHA) defined heart failure);

AND

B. Documentation^ is provided that individual has achieved/maintained an initial 5% weight loss (^*documentation showing the achieved/maintained 5% weight loss is required within 90 days of each continuation/subsequent request)*; **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 (AACE 2016/AGA 2022); **AND**
    2. Individual is currently maintaining 150 minutes of exercise per week (AACE 2016/AGA 2022); **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 Saxenda (liraglutide) for adolescents may be approved if the following criteria are met:

A. Individual is 12 to 17 years of age; **AND**
B. Documentation* is provided that individual has a body weight above 60 kilograms and has an initial BMI corresponding to 30 kg/m^2 or greater for adults (obese) by

international cut-offs (**documentation of BMI is required within 90 days of the request*); **AND**

C. Individual has tried but was unsuccessful losing weight through intensive health behavior and lifestyle treatment for at least 6 months, prior to request for drug therapy (AAP 2023), 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

D. Individual is currently maintained on their healthy nutrition and behavior counseling; **AND**

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

F. 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 Saxenda (liraglutide) in adolescents (12 to 17 years of age) may be approved if the following criteria are met:

A. Documentation^ is provided that individual has achieved/maintained an initial >4% reduction from baseline BMI (^*documentation showing the achieved/maintained weight loss is required within 90 days of each continuation/subsequent request*) (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 Saxenda (liraglutide) 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 with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) or a personal or family history of medullary thyroid carcinoma (MTC); **OR**

III. Individual is using in combination with another liraglutide-containing agent or GLP-1 agonist [including but not limited to semaglutide (Wegovy, Ozempic, Rybelsus), tirzepatide (Zepbound, Mounjaro), liraglutide (Victoza), orforglipron (Foundayo)].

Key References:

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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

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