Clinical Policy: Liraglutide (Saxenda)

Reference Number: ERX.NPA.97
Effective Date: 12.01.18
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Liraglutide (Saxenda®) is a glucagon-like peptide-1 (GLP-1) receptor agonist.

FDA Approved Indication(s)
Saxenda is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in:

- Adult patients with an initial body mass index (BMI) of:
  - 30 kg/m^2 or greater (obese), or
  - 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia
- Pediatric patients aged 12 years and older with:
  - Body weight above 60 kg and an initial BMI corresponding to 30 kg/m^2 for adults (obese) by international cut-offs

Limitation(s) of use:

- Saxenda is not indicated for the treatment of type 2 diabetes mellitus.
- Saxenda and Victoza® both contain the same active ingredient, liraglutide, and therefore should not be used together. Saxenda should not be used in combination with any other GLP-1 receptor agonists.
- The safety and effectiveness of Saxenda in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Saxenda is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Weight Management (must meet all)**:**

1. Member meets one of the following (a, b, or c):
   a. BMI ≥ 30 kg/m^2;
   b. BMI ≥ 27 kg/m^2 with at least one indicator of increased cardiovascular risk (e.g., coronary artery/heart disease, hypertension, dyslipidemia, diabetes, elevated waist circumference) or other obesity-related medical condition (e.g., sleep apnea);
   c. Member's age is between 12 and 18 years, with body weight > 60 kg and an initial BMI corresponding to 30 kg/m^2 for adults (obese) by international cut-offs (*see Appendix D*);
2. Age ≥ 12 years;
3. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy;
4. Request meets both of the following (a and b):

a. Dose does not exceed 3 mg per day (5 pens per month);
b. After the initial dose escalation period (*see Section V*), one of the following (i or ii):
   i. For age ≥ 18 years: Maintenance dose is 3 mg per day;
   ii. For age < 18 years: Maintenance dose is at least 2.4 mg per day.

Approval duration: 16 weeks

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Weight Management (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. BMI ≥ 25 kg/m^2;
3. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. If this is the first renewal request, member has lost ≥ 4% of baseline body weight;
   b. If this is a second or subsequent renewal request, member has lost weight and/or maintained weight loss on therapy;
4. Documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy;
5. Request meets both of the following (a and b):
   a. If request is for a dose increase, new dose does not exceed 3 mg per day (5 pens per month);
   b. One of the following (i or ii):
      i. For age ≥ 18 years: Maintenance dose is 3 mg per day;
      ii. For age < 18 years: Maintenance dose is at least 2.4 mg per day.

Approval duration:
First reauthorization – 36 weeks
Subsequent reauthorizations – 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BMI: body mass index
FDA: Food and Drug Administration
GLP-1: glucagon-like peptide-1

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): personal or family history of medullary thyroid cancer (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN 2), hypersensitivity to liraglutide or any product components, pregnancy
- Boxed warning(s): risk of thyroid C-cell tumors

Appendix D: General Information

- BMI = 703 x [weight (lbs)/height (inches)^2]
- Examples of coronary artery/heart disease include: coronary artery bypass graft, angina, history of myocardial infarction or stroke.
- Saxenda's prescribing information recommends that change in body weight is evaluated 16 weeks after initiation of therapy. Saxenda should be discontinued if the patient has not lost at least 4% of baseline body weight, since it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.
- International cut-offs for pediatric patients:

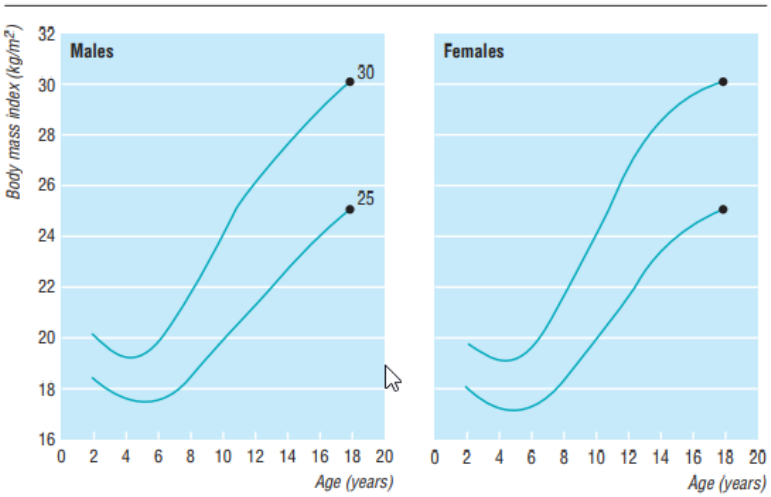

Fig 6 International cut off points for body mass index by sex for overweight and obesity, passing through body mass index 25 and 30 kg/m^2 at age 18 (data from Brazil, Britain, Hong Kong, Netherlands, Singapore, and United States)

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Weight management	**Dose escalation schedule**: • Week 1: 0.6 mg SC QD • Week 2: 1.2 mg SC QD • Week 3: 1.8 mg SC QD • Week 4: 2.4 mg SC QD • Week 5 and onward: 3 mg SC QD **Adult patients**: If patients do not tolerate an increased dose during dose escalation, consider delaying dose escalation for approximately one additional week. Discontinue Saxenda if the patient cannot tolerate the 3 mg dose. **Pediatric patients**: Dose escalation for pediatric patients may take up to 8 weeks. Pediatric patients who do not tolerate 3 mg daily may have their dose reduced to 2.4 mg daily. Discontinue Saxenda if the patient cannot tolerate the 2.4 mg dose.	3 mg/day

VI. Product Availability

Pre-filled, multi-dose pen: 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, or 3 mg (6 mg/mL, 3 mL)

VII. References

1. Saxenda Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc; December 2020. Available at: https://www.saxenda.com. Accessed May 27, 2021.
2. Jensen MD, Ryan DH, Apovian CM, 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. 2014; 129 (suppl 2): S102–S138.
3. Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological management of obesity: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015; 100(2): 42-362.
4. Kelly AS, Auerbach P, Barrientos-Perez M, Gies I, Hale PM, Marcus C, Mastrandrea LD, Prabhu N, Arslanian S, et al. A Randomized, Controlled Trial of Liraglutide for Adolescents with Obesity. N Engl J Med. 2020 May 28;382(22):2117-2128.
5. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: international survey. BMJ 2000;320:1240-1243.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy ERX.NPA.19; added coronary artery/heart disease as an example of cardiovascular risk indicator; modified re-auth approval duration to 36 weeks for first request and 6 months for second/subsequent requests; references reviewed and updated.	08.07.18	11.18
2Q 2019 annual review: no significant changes; removed limitations of use that “Saxenda has not been studied in patients with pancreatitis” and that its “effects on cardiovascular morbidity and mortality have not been established” per updated PI; references reviewed and updated.	03.06.19	05.19
2Q 2020 annual review: no significant changes; removed limitations of use “Saxenda has not been studied in patients taking insulin. Saxenda and insulin should not be used together” per updated labeling; references reviewed and updated.	04.07.20	05.20
Criteria added requiring documentation that member is actively enrolled in a weight loss program that involves a reduced calorie diet and increased physical activity adjunct to therapy as per FDA label.	05.26.20	08.20
2Q 2021 annual review: added pediatric indication for 12 years and older body weight above 60 kg and an initial BMI corresponding to 30 kg/m^2 for adults (obese) by international cut-offs; references reviewed and updated.	02.01.21	05.21
Clarified minimum dosing requirements per PI.	05.27.21	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.