Clinical Policy: Liraglutide for Weight Loss (Saxenda)

Reference Number: HNCA.CP.CPA.332
Effective Date: 03.25
Last Review Date: 02.25
Line of Business: Commercial

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 contains liraglutide and should not be coadministered with other liraglutide-containing products or with any other GLP-1 receptor agonists.
- The safety and effectiveness of Saxenda in pediatric patients with type 2 diabetes have not been established.
- 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, including active participation in an approved weight loss program for at least 6 months prior to use of GLP-1 agonist, which includes a reduced calorie diet, increased physical activity, and behavioral modification.

It is the policy of Health Net of California 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. If age is between 12 and 17 years, both of the following (i and ii):
      i. Body weight > 60 kg;
      ii. Initial BMI corresponding to 30 kg/m^2 for adults (obese) by international cut-offs (*see Appendix D*);
2. Age ≥ 12 years;
3. Saxenda is not prescribed concurrently with other liraglutide-containing products or any other GLP-1 receptor agonist(s);
4. For members with concurrent type 2 diabetes mellitus, both of the following (a and b):
   a. Failure of ≥ 3 consecutive months of Ozempic®, Trulicity®, and Liraglutide, unless clinically significant adverse effects are experienced or all are contraindicated;*
      **Prior authorization may be required*
   b. If member is currently receiving a GLP-1 receptor agonist and is requesting to switching to Saxenda, medical justification* supports necessity for Saxenda;

   **Intolerance due to common adverse effects of the GLP-1 receptor agonists class such as gastrointestinal symptoms is not considered acceptable medical justification*
5. Documentation supports member's participation in a Health Net approved weight loss program (e.g., Weight Watchers, Active&Fit) or other weight loss program recommended by the prescriber that involves a reduced calorie diet, increased physical activity, and behavioral modification that meets both of the following (a and b):
   a. Been actively enrolled in a Health Net approved weight loss program or other weight loss programs recommended by the prescriber for at least 6 months prior to use of GLP-1 agonist;
   b. Will continue to be actively enrolled in a weight loss program while concomitantly prescribed Saxenda;
6. Documentation of member's baseline and current height and body weight within the last 30 days;
7. Follow-up visits are planned to assess adherence and response to the treatment plan;
8. 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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

II. Continued Therapy

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

Note: For a patient who has not completed 4 months of initial therapy, refer to Initial Therapy criteria above.

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. If this is the first renewal request, one of the following (i or ii):
      i. For age $\geq$ 18 years: Member has lost $\geq$ 4% of baseline body weight;
      ii. For age < 18 years: Member has lost $\geq$ 1% of baseline BMI;
   b. If this is a second or subsequent renewal request, member has lost weight and/or maintained weight loss on therapy;
3. Documentation of member's current height and body weight within the last 30 days;
4. Follow-up visits are planned every 4 months to assess adherence and response to the treatment plan;
5. Saxenda is not prescribed concurrently with other liraglutide-containing products or any other GLP-1 receptor agonist(s);
6. Documentation that member is actively enrolled in a Health Net approved weight loss program (e.g., Weight Watchers, Active&Fit) or other weight loss program recommended by the prescriber that involves a reduced calorie diet, increased physical activity, and behavioral modification adjunct to therapy;
7. 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: 16 weeks

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

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 – CP.CPA.09 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 carcinoma (MTC) or with multiple endocrine neoplasia syndrome type 2 (MEN 2), pregnancy, patients with a prior hypersensitivity reaction to liraglutide or to any of the excipients in Saxenda.
- 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 aged 12 years and older

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

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.	3 mg/day

Indication	Dosing Regimen	Maximum 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.	

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.; April 2023. Available at: www.saxenda.com. Accessed January 16, 2024.
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.
6. Barlow SE and the Expert Committee. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. Pediatrics 2007; 120 Supplement December 2007:S164-S192.
7. Styne, DM, Arslanian SA, Connor EL, et al. Pediatric obesity - assessment, treatment, and prevention: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. March 2017; 102(3):709-757.
8. Grunvald E, Shah R, Hernaez R et al. AGA clinical practice guidelines on pharmacological interventions for adults with obesity. Gastroenterology 2022;163:1198-1225.
9. Hampl SE, Hassink SG, Skinner AC, et al. Clinical practice guideline for the evaluation and treatment of children and adolescents with obesity [published online ahead of print, 2023 Jan 9]. Pediatrics. 2023;e2022060640.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2020 annual review: removed limitations of use "Saxenda has not been studied in patients taking insulin. Saxenda and insulin should not be used together"; 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 for adults (obese) by international cut-offs; references reviewed and updated.	01.29.21	05.21
Clarified minimum dosing requirements per PI.	05.27.21	
2Q 2022 annual review: added "For age < 18 years: Member has lost > 1% of baseline body weight" to criteria defining positive response to therapy for age < 18 years per PI; updated limitations of use per PI; updated international cut-offs for pediatric patients in Appendix D per PI; references reviewed and updated.	01.20.22	05.22
Template changes applied to other diagnoses/indications and continued therapy section.	11.23.22	
2Q 2023 annual review: revised "age < 18 years: member has lost > 1% of baseline body weight" to baseline BMI per PI; removed continued therapy criterion of BMI ≥ 25 kg/m^2; references reviewed and updated.	01.11.23	05.23
For documentation of weight loss program, added members has been actively enrolled for at least 6 months, added a weight loss program that also involves behavioral modification, clarified weight loss program to be either a Health Net approved weight loss program or a weight loss program recommended by the prescriber.	12.12.23	02.24
2Q 2024 annual review: no significant changes; references reviewed and updated.	01.26.24	05.24
New CA policy - Added documentation is required that shows member has been enrolled in a weight loss program for at least 6 months prior to use of GLP-1. - Documentation of baseline and current height and weight within the last 30 days. - Documentation that member will have f/u visit every 4 months to assess adherence and response to therapy. - Approval durations shortened to 16 weeks.	07.10.24	08.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added Active&Fit as additional example of HN approved weight loss program. Removed every 4 months f/u visit requirement from initial criteria.	11.08.24	12.24
Added concurrent diabetes criteria with redirection to preferred GLP-1 agonists	02.14.25	03.25

Important Reminders

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions. Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.