MEDICAL MUTUAL®

Drug Policy

Policy:	Saxenda (liraglutide)	Annual Review Date: 01/21/2021 Last Revised Date: 01/21/2021

OVERVIEW

Saxenda is a glucagon like peptide 1 (GLP-1) receptor agonist 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 20 kg/m^2 or greater (obese) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia), and in 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. Saxenda contains liraglutide and should not be co-administered with other liraglutide-containing products or with any other GLP-1 receptor agonist. The safety and effectiveness of Saxenda in pediatric patients with type 2 diabetes mellitus have not been established. The safety and efficacy of Saxenda in combination with other products intended for weight loss have not been established.

POLICY STATEMENT

This policy involves the use of Saxenda. Prior authorization is recommended for pharmacy benefit coverage of Saxenda. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Saxenda is recommended in those who meet the following criteria:

1. <u>Chronic Weight Management, initial therapy</u>
Criteria. *Patient must meet the following criteria*

A. Saxenda will be used as an adjunct to a reduced-calorie diet and increased physical activity; AND
B. The patient has engaged in a trial of behavioral modification and dietary restriction for at least 3 months and has failed to achieve the desired weight loss; AND
C. For adult patients aged 18 years or older, one of the following must be met:
    a. The patient's initial BMI is 30 kg/m^2 or greater; OR

b. The patient's initial BMI is 27 kg/m^2 or greater AND the patient has at least one of the following comorbid conditions:
   i. Hypertension
   ii. Type 2 diabetes mellitus
   iii. Dyslipidemia

D. For pediatric patients younger than 18 years of age, ALL the following must be met:
   a. The patient's body weight is above 60 kg; AND
   b. The patient's initial BMI corresponds to 30 kg/m^2 for adults

2. <u>Chronic Weight Management, continuation of therapy</u>
Criteria. *Patient must meet the following criteria*

A. The patient has been using Saxenda for at least 4 months; AND
B. Saxenda will continue to be used in combination with a reduced-calorie diet and increased physical activity; AND
C. The patient has experienced a reduction in baseline body weight of at least 4%

Initial Approval/ Extended Approval.
A) *Initial Approval:* 4 months
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Saxenda has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Patients with Personal or Family History of Medullary Thyroid Carcinoma (MTC) or with Multiple Endocrine Neoplasia Syndrome type 2 (MEN 2).** Saxenda has a boxed warning for the risk of thyroid C-cell tumors. Liraglutide causes thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. Saxenda is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia type 2 (MEN 2).

2. **Use of Saxenda in Combination with other Liraglutide-Containing Products or other GLP-1 Receptor Agonists.**

3. **Use of Saxenda in Combination with other Products Intended for Weight Loss.**

4. **Use of Saxenda in Pediatric Patients with Type 2 Diabetes Mellitus.**

5. **Use in Pregnant Patients.** Weight loss offers no potential benefit to a pregnant woman and may result in fetal harm. A minimum weight gain is recommended for all pregnant women, including those who are already overweight or obese, due to the necessary weight gain that occurs in maternal tissues during pregnancy. There are no available data with liraglutide in pregnant woman to inform a drug associated risk for major birth defects and miscarriage. Per the

manufacturer's prescribing information, Saxenda should not be used during pregnancy and if a patient wishes to become pregnant or pregnancy occurs, treatment with Saxenda should be discontinued.

6. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Saxenda [prescribing information]. Plainsboro, NJ: Novo Nordisk A/S; December 2020.
2. Liraglutide. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 7 January 2021. Accessed 12 January 2021.