**LIRAGLUTIDE [rDNA origin] INJECTION (Saxenda®)**

**UTILIZATION MANAGEMENT CRITERIA**

<table>
<thead>
<tr>
<th><strong>DRUG CLASS:</strong></th>
<th>Obesity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BRAND (generic) NAMES:</strong></td>
<td>Saxenda (liraglutide [rDNA origin] injection)</td>
</tr>
<tr>
<td>- Solution for subcutaneous injection, pre-filled, multi-dose pen that delivers doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3 mg (6 mg/mL, 3 mL)</td>
<td></td>
</tr>
</tbody>
</table>

**FDA-APPROVED INDICATIONS:**

Saxenda (liraglutide [rDNA origin] injection) 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/m² or greater (obese) or
- 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).

**COVERAGE AUTHORIZATION CRITERIA:**

**INITIAL COVERAGE** (*If approved, initial coverage will be for 18 weeks*)

Liraglutide (Saxenda) may be eligible for coverage when the following criteria are met:

1. Patient is 18 years of age or older; **AND**
2. The patient has a body mass index (BMI) ≥30 kg/m²; **OR**
3. The patient has a BMI ≥27 kg/m² and at least ONE of the following:
   a. Patient has two or more cardiovascular risk factors:
      i. LDL > 160 mg/dl;
      ii. HDL < 40 mg/dl;
      iii. Hypertension;
      iv. Smoking;
      v. Impaired fasting glucose;
      vi. Family history of premature coronary heart disease (CHD): CHD in male first degree relative < 55 years; CHD in female first degree relative < 65 years;
      vii. Age (male > 45 years or female > 55 years or postmenopausal);
   **OR**
   b. Waist circumference > 40 inches in men or > 35 inches in women; **OR**
   c. Patient has one or more obesity-related co-morbidities (established CHD, other atherosclerotic diseases, type 2 diabetes, obstructive sleep apnea).
CONTINUATION COVERAGE (after 18 weeks of initial therapy)

Liraglutide (Saxenda) may be eligible for coverage when the following criteria are met:

1. After initial approval, patient has lost at least 4% of their initial body weight (body weight immediately prior to starting therapy).

*After each year of therapy, an additional 12 months of therapy will be approved if the member has maintained a weight loss of at least 4% of their initial body weight.

CONTRAINDICATIONS:

- Personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2
- Hypersensitivity to liraglutide or any product components
- Pregnancy

BLACK BOX WARNING:

- Liraglutide causes thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Saxenda causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined.
- Saxenda is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the risk of MTC and the symptoms of thyroid tumors.

WARNINGS AND PRECAUTIONS:

- Thyroid C-cell Tumors: Counsel patients regarding the risk of medullary thyroid carcinoma and the symptoms of thyroid tumors
- Acute Pancreatitis: Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed
- Acute Gallbladder Disease: If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated
- Serious Hypoglycemia: Can occur when Saxenda is used with an insulin secretagogue (e.g., a sulfonylurea). Consider lowering the dose of anti-diabetic drugs to reduce the risk of hypoglycemia
- Heart Rate Increase: Monitor heart rate at regular intervals
- Renal Impairment: Has been reported postmarketing, usually in association with nausea, vomiting, diarrhea, or dehydration which may sometimes require hemodialysis. Use caution when initiating or escalating doses of Saxenda in patients with renal impairment
- Hypersensitivity Reactions: Postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema). Discontinue Saxenda and other suspect medications and promptly seek medical advice
- Suicidal Behavior and Ideation: Monitor for depression or suicidal thoughts. Discontinue Saxenda if symptoms develop.
DOSAGE AND ADMINISTRATION:

The recommended dosage of Saxenda is 3 mg daily. The dose escalation schedule in Table 1 should be used to reduce the likelihood of gastrointestinal symptoms. If patients do not tolerate an increased dose during dose escalation, consider delaying dose escalation for approximately one additional week. Saxenda should be discontinued, however, if a patient cannot tolerate the 3 mg dose, as efficacy has not been established at lower doses (0.6, 1.2, 1.8, and 2.4 mg).

Dose Escalation Schedule

<table>
<thead>
<tr>
<th>Week</th>
<th>Daily Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.6 mg</td>
</tr>
<tr>
<td>2</td>
<td>1.2 mg</td>
</tr>
<tr>
<td>3</td>
<td>1.8 mg</td>
</tr>
<tr>
<td>4</td>
<td>2.4 mg</td>
</tr>
<tr>
<td>5 and onward</td>
<td>3 mg</td>
</tr>
</tbody>
</table>

Saxenda should be taken once daily at any time of day, without regard to the timing of meals. Saxenda can be injected subcutaneously in the abdomen, thigh, or upper arm. The injection site and timing can be changed without dose adjustment. Saxenda must not be administered intravenously or intramuscularly.

Evaluate the change in body weight 16 weeks after initiating Saxenda and discontinue Saxenda 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.

REFERENCES: