Coverage Request for Saxenda®

What you can do to help patients gain access

Anti-obesity medication coverage is different from what you may be used to; an employer decides whether or not to opt-in to add the additional coverage to its base plan. In order to avoid submitting a prior authorization for a patient who does not have coverage, your office can determine whether a patient is covered via the benefits verification tool.

If a patient's insurance plan doesn't include Saxenda®, there are still options. You can help appropriate patients gain access by providing coverage request documentation that your patients can bring to their human resources department. This includes a professional letter affirming that your patient may benefit from Saxenda®. Use the following sample coverage request letter as a guide for what you may write to a patient's HR department. Once the letter is completed, your patient will need to deliver it to his or her employer.

SAMPLE COVERAGE REQUEST LETTER

▶ *The example below is for your reference only. When drafting a coverage request letter, it should be written on your letterhead. This form should **NOT** be used as the coverage request letter.*

To whom it may concern,

I am writing this letter on behalf of my patient, John Doe, to express a concern. My patient is in need of an important medication called Saxenda® that is currently not covered by your insurance plan.

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 comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia), and also for pediatric patients aged 12 years and older with body weight above 60 kg (132 lbs) and initial BMI corresponding to 30 kg/m^2 or greater for adults (obese) by international cut-offs.

It is well recognized that obesity is a chronic illness associated with many related diseases, such as diabetes and hypertension. Obesity deserves the same treatment and attention as any other chronic illness. I believe John Doe is an ideal candidate for Saxenda® and would benefit from treatment. Please contact your health plan or pharmacy benefit manager to pursue coverage for either this individual employee or for the company at large.

Your support may mean employers will cover Saxenda® not only for 1 patient, but for an entire community

For chronic weight management as an adjunct to a reduced-calorie diet and increased physical activity in adults with a BMI ≥30 kg/m^2, or ≥27 kg/m^2 with one or more weight-related comorbidities, and for patients aged 12-17 years with body weight above 60 kg (132 lbs) and initial BMI of ≥30 kg/m^2 for adults. Click for Limitations of Use.

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS
Liraglutide causes dose-dependent and treatment-duration-dependent 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 and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC with use of Saxenda® and inform them of symptoms of thyroid tumors (eg, a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Saxenda®.

Indications and Usage

Saxenda® (liraglutide) injection 3 mg 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 comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia)
- Pediatric patients aged 12 years and older with body weight above 60 kg (132 lbs) and initial BMI corresponding to 30 kg/m^2 or greater for adults (obese) by international cut-offs

Limitations of Use

- Saxenda® contains liraglutide and should not be coadministered 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 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.

Important Safety Information (cont'd)

Contraindications

Saxenda® is contraindicated in:

- Patients with a personal or family history of MTC or patients with MEN 2.
- Patients with a prior serious hypersensitivity reaction to liraglutide or to any of the excipients in Saxenda®.
- Pregnancy.

Warnings and Precautions

- **Risk of Thyroid C-cell Tumors:** If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.
- **Acute Pancreatitis:** Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with liraglutide postmarketing. Observe patients carefully for signs and symptoms of pancreatitis (persistent severe abdominal pain, sometimes radiating to the back with or without vomiting). If pancreatitis is suspected, discontinue Saxenda® promptly and if pancreatitis is confirmed, do not restart.
- **Acute Gallbladder Disease:** Substantial or rapid weight loss can increase the risk of cholelithiasis; however, the incidence of acute gallbladder disease was greater in patients treated with Saxenda® than with placebo even after accounting for the degree of weight loss. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.
- **Hypoglycemia:** Adult patients with type 2 diabetes on an insulin secretagogue (eg, a sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia with use of Saxenda®. The risk may be lowered by a reduction in the dose of insulin secretagogues or insulin. In pediatric patients without type 2 diabetes, hypoglycemia occurred. Inform all patients of the risk of hypoglycemia and educate them on the signs and symptoms.
- **Heart Rate Increase:** Mean increases in resting heart rate of 2 to 3 beats per minute (bpm) were observed in patients treated with Saxenda®. Monitor heart rate at regular intervals and inform patients to report palpitations or feelings of a racing heartbeat while at rest during treatment with Saxenda®. Discontinue Saxenda® in patients who experience a sustained increase in resting heart rate.
- **Renal Impairment:** Acute renal failure and worsening of chronic renal failure, which may sometimes require hemodialysis, have been reported, usually in association with nausea, vomiting, diarrhea, or dehydration. Use caution when initiating or escalating doses of Saxenda® in patients with renal impairment.
- **Hypersensitivity Reactions:** Serious hypersensitivity reactions (eg, anaphylaxis and angioedema) have been reported in patients treated with liraglutide. If a hypersensitivity reaction occurs, patients should stop taking Saxenda® and promptly seek medical advice.
- **Suicidal Behavior and Ideation:** In adult clinical trials, 9 (0.3%) of 3,384 patients treated with Saxenda® and 2 (0.1%) of the 1,941 treated with placebo reported suicidal ideation; one of the Saxenda® treated patients attempted suicide. In a pediatric trial, 1 (0.8%) of the 125 Saxenda® treated patients died by suicide. There was insufficient information to establish a causal relationship to Saxenda®. Monitor patients for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue treatment if patients experience suicidal thoughts or behaviors. Avoid Saxenda® in patients with a history of suicidal attempts or active suicidal ideation.

Adverse Reactions

- The most common adverse reactions, reported in ≥5% are nausea, diarrhea, constipation, vomiting, injection site reactions, headache, hypoglycemia, dyspepsia, fatigue, dizziness, abdominal pain, increased lipase, upper abdominal pain, pyrexia, and gastroenteritis.

Drug Interactions

- Saxenda® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications. Monitor for potential consequences of delayed absorption of oral medications concomitantly administered with Saxenda®.

Use in Specific Populations

- There are no data on the presence of liraglutide in human breast milk; liraglutide was present in the milk of lactating rats.
- Saxenda® has not been studied in patients less than 12 years of age.
- Saxenda® slows gastric emptying. Saxenda® has not been studied in patients with preexisting gastroparesis.

Please see additional Important Safety Information throughout.
Please see Prescribing Information, including Boxed Warning.

Saxenda® liraglutide injection 3mg