

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® was approved by the FDA on December 23, 2014, 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 (obesity), or in adults with a BMI of 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia).

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

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/m² or greater (obesity) or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia)

Limitations of Use

- Saxenda® is not indicated for the treatment of type 2 diabetes
- 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 agonist
- Saxenda® has not been studied in patients taking insulin. Saxenda® and insulin should not be used together
- The effects of Saxenda® on cardiovascular morbidity and mortality have not been established
- The safety and efficacy of Saxenda® in combination with other products for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established
- Saxenda® has not been studied in patients with a history of pancreatitis

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®.



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

Saxenda®
liraglutide injection 3mg

Important Safety Information (cont'd)

Contraindications

Saxenda® is contraindicated in:

- Patients with a personal or family history of MTC or MEN 2
- Patients with a prior serious hypersensitivity reaction to liraglutide or to any of the product components
- 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:** Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with liraglutide. After initiation of Saxenda® observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, Saxenda® should promptly be discontinued and appropriate management should be initiated. If pancreatitis is confirmed, Saxenda® should not be restarted
- **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
- **Risk of Hypoglycemia with Concomitant Use of Anti-Diabetic Therapy:** When Saxenda® is used with an insulin secretagogue (eg, a sulfonylurea) serious hypoglycemia can occur. Consider lowering the dose of the insulin secretagogue to reduce the risk of hypoglycemia. Monitor blood glucose parameters prior to starting Saxenda® and during Saxenda® treatment in patients with type 2 diabetes mellitus
- **Heart Rate Increase:** Mean increases in resting heart rate of 2 to 3 beats per minute (bpm) were observed with routine clinical monitoring in patients treated with Saxenda® compared to placebo in clinical trials. Heart rate should be monitored at regular intervals consistent with usual clinical practice. Patients should inform healthcare providers of palpitations or feelings of a racing heartbeat while at rest during Saxenda® treatment. For patients who experience a sustained increase in resting heart rate while taking Saxenda®, Saxenda® should be discontinued

- **Renal Impairment:** In patients treated with GLP-1 receptor agonists, including Saxenda®, there have been reports of acute renal failure and worsening of chronic renal failure, 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:** Serious hypersensitivity reactions (eg, anaphylaxis and angioedema) have been reported during postmarketing use of liraglutide. If a hypersensitivity reaction occurs, patients should stop taking Saxenda® and promptly seek medical advice
- **Suicidal Behavior and Ideation:** In the Saxenda® clinical trials, 9 (0.3%) of 3,384 patients treated with Saxenda® and 2 (0.1%) of the 1,941 with placebo reported suicidal ideation; one of the patients treated with Saxenda® attempted suicide. Patients treated with Saxenda® should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue Saxenda® in patients who experience suicidal thoughts or behaviors. Avoid Saxenda® in patients with a history of suicidal attempts or active suicidal ideation

Adverse Events

- The most common adverse reactions, reported in ≥5% are: nausea, hypoglycemia, diarrhea, constipation, vomiting, headache, decreased appetite, dyspepsia, fatigue, dizziness, abdominal pain, and increased lipase

Drug Interactions

- **Oral Medications:** Saxenda® causes a delay of gastric emptying, and thereby 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
- Safety and effectiveness of Saxenda® have not been established in pediatric patients. Saxenda® is not recommended for use in pediatric patients
- 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.



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Saxenda®
liraglutide injection **3mg**