I. ALL CLAIMS: HEALTH CARE PROFESSIONALS

Indications and Usage

- 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/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).

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 risk of MTC with use of Saxenda® and inform them of symptoms of thyroid tumors (e.g., 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®.

Contraindications

Saxenda® is contraindicated in the following conditions:

- Personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (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 (e.g., 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 (e.g., anaphylaxis and angioedema) have been reported during postmarketing use of liraglutide. If symptoms of hypersensitivity reactions occur, patients must stop taking Saxenda® and promptly seek medical advice.
- **Suicidal Behavior and Ideation:** In the Saxenda® clinical trials, 6 (0.2%) of 3,384 patients treated with Saxenda® and none 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

- Nursing mothers should either discontinue Saxenda® or discontinue nursing.
- Safety and effectiveness of Saxenda® have not been established in pediatric patients and is not recommended for use in pediatric patients.
- Saxenda® slows gastric emptying. Saxenda® has not been studied in patients with preexisting gastroparesis.

II. ALL CLAIMS: CONSUMERS

Indications and Usage

What is Saxenda®?
Saxenda® is an injectable prescription medicine that may help some adults with excess weight (BMI ≥27) who also have weight-related medical problems or obesity (BMI ≥30), lose weight and keep the weight off. Saxenda® should be used with a reduced-calorie meal plan and increased physical activity.
[Note: spell out BMI acronym at first mention in piece]

- Saxenda® is not for the treatment of type 2 diabetes
- Saxenda® and Victoza® have the same active ingredient, liraglutide, and should not be used together
- Saxenda® should not be used with other GLP-1 receptor agonist medicines
- Saxenda® and insulin should not be used together
- It is not known if Saxenda® is safe and effective when taken with other prescription, over-the-counter, or herbal weight-loss products
- It is not known if Saxenda® changes your risk of heart problems or stroke or of death due to heart problems or stroke
- It is not known if Saxenda® can be used safely in people who have had pancreatitis
- It is not known if Saxenda® is safe and effective in children under 18 years of age. Saxenda® is not recommended for use in children

Important Safety Information

What is the most important information I should know about Saxenda®?
Serious side effects may happen in people who take Saxenda®, including:

1. **Possible thyroid tumors, including cancer.** During the drug testing process, the medicine in Saxenda® caused rats and mice to develop tumors of the thyroid gland. Some of these tumors were cancers. It is not known if Saxenda® will cause thyroid tumors or a type of thyroid cancer called medullary thyroid cancer in people. If medullary thyroid cancer occurs, it may lead to death if not detected and treated early. If you develop tumors or cancer of the thyroid, your thyroid may have to be surgically removed.
   - Before you start taking Saxenda®, tell your health care professional if you or any of your family members have had thyroid cancer, especially medullary thyroid cancer, or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Do not take Saxenda® if you or any of your family members have medullary thyroid cancer, or if you have MEN 2. People with these conditions already have a higher chance of developing medullary thyroid cancer in general and should not take Saxenda®
   - While taking Saxenda®, tell your health care professional if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer
2. **Inflammation of the pancreas (pancreatitis),** which may be severe and lead to death.
   - **Before taking Saxenda®, tell your health care professional if you have had:** pancreatitis, stones in your gallbladder (gallstones), a history of alcoholism, or high blood triglyceride levels. These medical conditions can make you more likely to get pancreatitis in general. It is not known if having these conditions will lead to a higher chance of getting pancreatitis while taking Saxenda®.
   - **While taking Saxenda®:** Stop taking Saxenda® and call your health care professional right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may happen with or without vomiting. The

pain may be felt going from your abdomen through to your back. This type of pain may be a symptom of pancreatitis.

Who should not use Saxenda®?
Do not use Saxenda® if:

- you or any of your family members have a history of medullary thyroid cancer
- you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). This is a disease where people have tumors in more than one gland in their body
- you are allergic to liraglutide or any of the ingredients in Saxenda®. Symptoms of a serious allergic reaction may include: swelling of your face, lips, tongue, or throat, fainting or feeling dizzy, very rapid heartbeat, problems breathing or swallowing, and severe rash or itching. Talk with your health care professional if you are not sure if you have any of these conditions
- are pregnant or planning to become pregnant. Saxenda® may harm your unborn baby

What should I tell my health care professional before using Saxenda®?
Before taking Saxenda®, tell your health care professional if you:

- have any of the conditions listed in the section "What is the most important information I should know about Saxenda®?"
- are taking certain medications called GLP-1 receptor agonists
- are allergic to liraglutide or any of the other ingredients in Saxenda®
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food
- have or have had kidney or liver problems
- have or have had depression or suicidal thoughts
- have any other medical conditions
- are pregnant or plan to become pregnant. Saxenda® may harm your unborn baby. Tell your health care professional if you become pregnant while taking Saxenda®. If you are pregnant you should stop using Saxenda®
- are breastfeeding or plan to breastfeed. It is not known if Saxenda® passes into your breast milk. You and your health care professional should decide if you will take Saxenda® or breastfeed. You should not do both without talking with your health care professional first

Tell your health care professional about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements. Saxenda® slows stomach emptying and can affect medicines that need to pass through the stomach quickly. Saxenda® may affect the way some medicines work and some other medicines may affect the way Saxenda® works. Tell your health care professional if you take diabetes medicines, especially sulfonylurea medicines or insulin.

Know the medicines you take. Keep a list of them with you to show your health care professional and pharmacist each time you get a new medicine.

How should I use Saxenda®?

- Inject your dose of Saxenda® under the skin (subcutaneous injection) in your stomach area (abdomen), upper leg (thigh), or upper arm, as instructed by your health care professional. **Do not inject into a vein or muscle**
- Never share your Saxenda® pen or needles with another person. You may give an infection to them, or get an infection from them

What are the possible side effects of Saxenda®?
Saxenda® may cause serious side effects, including:

- **possible thyroid tumors, including cancer**
- **inflammation of the pancreas (pancreatitis)**
- **gallbladder problems.** Saxenda® may cause gallbladder problems including gallstones. Some gallbladder problems need surgery. Call your health care

professional if you have any of the following symptoms: pain in your upper stomach (abdomen), fever, yellowing of your skin or eyes (jaundice), and clay-colored stools

- **low blood sugar (hypoglycemia) in people with type 2 diabetes who also take medicines to treat type 2 diabetes.** Saxenda® can cause low blood sugar in people with type 2 diabetes who also take medicines used to treat type 2 diabetes (such as sulfonylureas). In some people, the blood sugar may get so low that they need another person to help them. If you take a sulfonylurea medicine, low blood sugar may include: shakiness, sweating, headache, drowsiness, weakness, confusion, irritability, hunger, fast heartbeat, feeling jittery, and dizziness. You should check your blood sugar before you start taking Saxenda® and while you take Saxenda®.
- **increased heart rate.** Saxenda® can increase your heart rate while you are at rest. Your health care professional should check your heart rate while you take Saxenda®. Tell your health care professional if you feel your heart racing or pounding in your chest and it lasts for several minutes when taking Saxenda®
- **kidney problems (kidney failure).** Saxenda® may cause nausea, vomiting, or diarrhea leading to loss of fluids (dehydration). Dehydration may cause kidney failure, which can lead to the need for dialysis. This can happen in people who have never had kidney problems before. Drinking plenty of fluids may reduce your chance of dehydration. Call your health care professional right away if you have nausea, vomiting, or diarrhea that does not go away, or if you cannot drink liquids by mouth.
- **serious allergic reactions.** Serious allergic reactions can happen with Saxenda®. Stop using Saxenda®, and get medical help right away if you have any symptoms of a serious allergic reaction
- **depression or thoughts of suicide.** You should pay attention to any mental changes, especially sudden changes, in your mood, behaviors, thoughts, or feelings. Call your health care professional right away if you have any mental changes that are new, worse, or worry you

Common side effects of Saxenda® include nausea, diarrhea, constipation, low blood sugar (hypoglycemia), vomiting, headache, decreased appetite, upset stomach, tiredness, dizziness, stomach pain, and changes in enzyme (lipase) levels in your blood. Nausea is most common when first starting Saxenda®, but decreases over time in most people as their body gets used to the medicine. Tell your health care professional if you have any side effect that bothers you or that does not go away.