INDICATIONS AND LIMITATIONS OF USE: Victoza® (liraglutide) injection 1.2 mg or 1.8 mg is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, and to reduce the risk of major adverse cardiovascular, CV death, nonfatal myocardial infarction or nonfatal stroke in adults with type 2 diabetes mellitus and established CV disease. Victoza® is not a substitute for insulin and should not be used in patients with type 1 diabetes mellitus or diabetic ketoacidosis. Concurrent use with prandial insulin has not been studied.

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 Victoza® causes thyroid C-cell tumors, including thyroid medullary thyroid carcinoma, MTC, in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined. Victoza® 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 for MTC with the use of Victoza®, and inform them of symptoms of thyroid tumors; for example, 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 Victoza®.

**Dr. Anderson:**
You know, fortunately being a primary care, we get to see our patients all the way through the spectrum, so I can see the pre-diabetes, I can see the weight gain, I can see the failure to change lifestyle, and I can actually watch before my eyes that transition. So, you know, it’s really our job, those of us providers, nurse practitioners, PAs, primary care physicians to try to identify the people at risk and do something.

**Dr. Baron:**
As cardiovascular outcomes trials for type 2 diabetes medications are released, the way we treat these conditions is constantly evolving. What we’re prescribing today may not be the same as what we preferred five years ago.

**Melissa Magwire:**
For some, treating cardiovascular disease and treating type 2 diabetes are two separate endeavors. Some providers can become matrix-driven and just check symptoms off a list. I prefer to view the two conditions truly connected and really look at the patient’s entire cardiometabolic state.

**Dr. Anderson:**
I know some primary care providers like to save injectables as a last resort, often due to the misconception that patients won’t be open to starting this type of therapy, but I don’t feel this should stop us from prescribing the treatment that makes the most sense for the patient. Any provider who tells me their patient won’t do an injection, isn’t a believer in the medication.

**Dr. D’Agostino:**
For me, it’s the data that motivates finding the appropriate treatments for my patients. My goal is to give them the best therapy, and that means staying in tune with the data and considering adjustments when new information is released. That’s why the results from the LEADER cardiovascular outcomes trial and the updated label for Victoza® are both very compelling, and strongly motivate me to consider
Victoza\textsuperscript{\textregistered} for my patients with type 2 diabetes and cardiovascular disease, even if their A1C is under control.

**Melissa Magwire:**
I’ve long found Victoza\textsuperscript{\textregistered} to be an efficacious choice and often bring it up when talking with providers. Now that the label includes reducing the risk of major adverse cardiovascular events, in addition to providing glycemic control, we have another reason to consider prescribing Victoza\textsuperscript{\textregistered}. \textsuperscript{1}

**Dr. Anderson:**
It’s also important to remember that not all GLP-1 receptor agonists are the same. Just because a patient is on a GLP-1 RA, it doesn’t mean that they are getting the cardiovascular risk reduction they may need. Victoza\textsuperscript{\textregistered} is actually the only GLP-1 RA recommended by the ADA to lower CV event rates and mortality in adults with type 2 diabetes and establish cardiovascular disease. \textsuperscript{2} So it’s interesting that Victoza\textsuperscript{\textregistered} can be used for first-line therapy. Do you think that kind of opens up to more patients?

**Melissa Magwire:**
I think it gets rid of a little bit of that inertia that we seem to have. You know, we get that initial diagnosis of diabetes, we start a couple oral medications, and then we kind of linger. For me to be able to suggest someone go on a GLP-1 right out of the gate, hits so many of those targeted defects that we want.

**Dr. Baron:**
I think it’s an exciting time that we’re entering. Where, instead of a stepwise, almost treat-to-failure with oral medications, we can treat-to-goal from the onset.

**Dr. D’Agostino:**
All patients are unique individuals, and the ADA guidelines and the AACE guidelines may not apply to every patient. The guidelines are useful and provide good guidance towards optimal care. And we can consider that guidance to form the best treatment plan for each individual patient.

**Dr. Baron:**
For me, the exciting challenge of diabetes is understanding the disease process. Knowing all of the different treatment options available and not connecting the patient to the treatment until after the chance I’ve had to sit with them and see who they are and what they need.

**Dr. Anderson:**
When I discuss type 2 diabetes with my patients, I stress the importance of changing their lifestyle in addition to taking the appropriate medication. I explain the connection between diabetes and
cardiovascular risk and explain to them that we now have treatments that can address both.¹ I show them that, right there on the label that Victoza® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes and reduce the risk of major adverse cardiovascular events.¹ And here comes Miss. Smith, and her diabetes has been perfectly well controlled and you don’t have to worry about it and she’s fine and you just kept telling her how great her diabetes is, then she has a cardiac event, comes back in, and now you have to say, you know what, we have to change medications. Not only that, we have to do an injectable. And so you have to be prepared to have that conversation and the reasons why this, Victoza®, is a better decision than what you were on previously that has no cardiovascular risk reduction, so it’s a tough conversation to have sometimes with patients in terms of, like you said, changing that whole paradigm that we’re talking about.

Announcer:

IMPORTANT SAFETY INFORMATION CONTINUED:

CONTRAINDICATIONS: Victoza® is contraindicated in patients with a personal or family history of MTC or in patients with MEN-2, and in patients with a prior serious hypersensitivity reaction to Victoza® or any of the product components. Serious hypersensitivity reactions, including anaphylactic reactions and angioedema have been reported with Victoza®.

WARNINGS AND PRECAUTIONS:

Risk of thyroid C-cell tumors: Patients should be referred to an endocrinologist for further evaluation if serum calcitonin is measured and found to be elevated, or thyroid nodules are noted on physical examination or neck imaging.

Pancreatitis: Acute pancreatitis, including fatal and nonfatal hemorrhagic or necrotizing pancreatitis has been observed in patients treated with Victoza® 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 Victoza® promptly. And if pancreatitis is confirmed, do not restart. Victoza® has been studied in a limited number of patients with a history of pancreatitis. It is unknown if patients with a history of pancreatitis are at a higher risk for development of pancreatitis on Victoza®.

Never share a Victoza® pen between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens.
Hypoglycemia: When Victoza® is used with an insulin secretagogue; for example, a sulfonylurea or insulin, serious hypoglycemia can occur. Consider lowering the dose of the insulin secretagogue or insulin to reduce the risk of hypoglycemia.

Renal Impairment: Acute renal failure and worsening of chronic renal failure, which may sometimes require hemodialysis, have been reported postmarketing, usually in association with nausea, vomiting, diarrhea, or dehydration. Use caution when initiating or escalating doses of Victoza® in patients with renal impairment.

Hypersensitivity Reactions: Serious hypersensitivity reactions; for example, anaphylaxis and angioedema, have been reported postmarketing. If symptoms of hypersensitivity reactions occur, patients must stop taking Victoza®. Treat promptly per standard of care and monitor until signs and symptoms resolve. Do not use in patients with a previous hypersensitivity reaction to Victoza®. Anaphylaxis and angioedema have been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of anaphylaxis or angioedema with another GLP receptor agonist because it is unknown whether such patients will be predisposed to these reactions with Victoza®.

Acute Gallbladder Disease: In the LEADER trial, 3.1% of Victoza® versus 1.9% of placebo-treated patients reported an acute event of gallbladder disease, such as cholelithiasis or cholecystitis. The majority of events required hospitalization or cholecystectomy. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

Adverse Reactions: The most common adverse reactions reported in greater than or equal to 5% of patients treated with Victoza®, and more commonly than in patients treated with placebo are nausea, diarrhea, headache, vomiting, decreased appetite, dyspepsia, and constipation. Immunogenicity-related events, including urticaria, were more common among Victoza®-treated patients 0.8% than among comparator-treated patients 0.4% in clinical trials.

Drug Interactions: Victoza® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly-administered oral medications. Caution should be exercised when oral medications are concomitantly administered with Victoza®.

Use in specific populations. Victoza® has not been studied in patients with type 2 diabetes below 18 years of age and is not recommended for use in pediatric patients. Victoza® slows gastric emptying. Victoza® has not been studied in patients with pre-existing gastroparesis. Victoza® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Please click here for full Prescribing Information including Boxed Warning.

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References: