

press release

Québec Becomes First Province to Add Victoza® to the Drug Benefit Formulary* for the Treatment of Type 2 Diabetes

Mississauga, ON – June 4, 2014 – Novo Nordisk today announces that the Québec government has approved the inclusion of Victoza® (liraglutide), the first once-daily human glucagon-like peptide-1 (GLP-1) analogue, to the Lists of Medications, effective June 2, 2014. The reimbursement of Victoza® by the Québec Health Insurance Board (RAMQ) will allow people living with type 2 diabetes to have access to a treatment to help better manage diabetes. Québec is the first province to provide public access to Victoza®.

Effective June 2, 2014, Victoza® is covered for eligible people in Québec, in association with metformin, for the treatment of type 2 diabetes for those whose glycemic control is inadequate and whose body mass index (BMI) is greater than 30 kg/m² when a dipeptidyl peptidase 4 (DPP-4) inhibitor is contraindicated, not tolerated or ineffective. Authorization for an initial request for treatment with Victoza® is granted for a maximum of 12 months. When submitting the first request for continuation of treatment, the physician must provide proof of a beneficial effect defined by a reduction in the glycated hemoglobin (HbA1c) of at least 0.5 per cent or by the attainment of a target value of seven per cent or less.

According to the 2013 Clinical Practice Guidelines from the Canadian Diabetes Association, proper management of type 2 diabetes includes reaching target HbA1c levels within three to six months of initial treatment, reduction in rates of hypoglycemia and weight loss. If these goals are not achieved in the first three to six months, the guidelines suggest incorporating timely adjustments, such as including an anti-hyperglycemic agent.¹

Victoza® is an anti-hyperglycemic agent which improves glycemic control by lowering blood glucose and HbA1C levels, with a low risk of hypoglycemia and the added benefit of weight loss.^{2,3}

Perspectives from Key Authorities on Diabetes in Québec:

“An important point for type 2 diabetes management is to ensure that most patients are reaching their HbA1c goals,” said Dr. Rémi Rabasa-Lhoret, MD, PhD, associate professor, Université de Montréal. “If this is not achieved through diet and exercise and the recommended first-line therapy, metformin, an anti-hyperglycemic treatment like Victoza® should be initiated. The Québec government’s reimbursement of Victoza® should provide some patients with access to a treatment to better manage their diabetes.”

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“Victoza[®] is a leading therapeutic option for an individualized approach to treating type 2 diabetes and preventing hypoglycemia, as numerous studies have confirmed its efficacy in achieving glycemic goals while having a very low risk of hypoglycemia,” said said Dr. Sylvie Bertrand, MD, CSPQ FRCS. “Unlike other treatments traditionally used in type 2 diabetes, Victoza[®] does not cause weight gain and has even promoted weight loss in many patients. The Québec government’s decision to cover Victoza[®] as a treatment of exception will provide these benefits to a larger number of people who live with type 2 diabetes.”

“To ensure blood glucose and HbA1c levels are in the target ranges, it is important to work with type 2 diabetes patients to adjust and refine treatments as required,” said Dr. André Bélanger, MD, CFPC. “The listing of Victoza[®] now presents opportunities for GPs to help their patients reach their targets through an effective non-insulin injectable therapy. Treatment with Victoza[®] allows us to more often reach a composite objective by lowering the blood sugar levels without inducing hypoglycemia, while promoting weight loss for the patient.”

“Promoting the cause of people with diabetes has always been a priority of our organization,” said Serge Langlois, President and CEO of Diabète Québec. “The introduction of new drugs that improve treatment is always a source of hope to help reduce complications associated with diabetes. We applaud the favourable decision of the Prescription Drug Insurance Plan.”

About Victoza[®]:

Victoza[®] is the first once-daily, injectable, GLP-1 for the treatment of adults with type 2 diabetes to improve glycemic control in combination with metformin, when diet and exercise plus maximal tolerated dose of metformin do not achieve adequate glycemic control; metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control; or metformin and a basal insulin, when diet and exercise plus dual therapy with Victoza[®] and metformin do not achieve adequate glycemic control.⁴

Victoza[®] is the leading GLP-1 treatment worldwide for type 2 diabetes, and currently there are more than 800,000 Victoza[®] patients worldwide.⁵ Victoza[®] has a 24-hour duration of action and improves glycemic control by lowering fasting and postprandial blood glucose in patients with type 2 diabetes.⁴ Victoza[®] should not be used in patients with type 1 diabetes.⁴ The safety and efficacy of Victoza[®] has been extensively investigated in studies involving more than 6,000 people⁶ and is currently prescribed in over 69 countries worldwide.

Victoza[®] is administered once daily at any time, independent of meals, by a pre-filled pen injection device in the abdomen, thigh or upper arm. It is not necessary to adjust the dose based on weight. Dosing starts at 0.6 mg and increases to 1.2 mg after one week up to 1.8 mg if needed.⁴

For information about Victoza[®], including important safety information, please visit http://novonordisk.ca/PDF_Files/our_products/Victoza/Victoza_PM_EN.pdf.

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About Diabetes in Canada and Québec:

Diabetes is a life-long, often debilitating and sometimes fatal disease in which the body either cannot produce insulin or cannot properly use the insulin it produces. This leads to high levels of glucose in the blood, which can damage organs, blood vessels and nerves.⁷ Type 2 diabetes occurs when the pancreas does not produce enough insulin to meet the body's needs, or the body is unable to respond properly to the actions of insulin.⁷

Approximately 760,000 people are living with diabetes in Québec.⁸ In Canada, approximately three million people are living with diabetes.⁹ Ten per cent of these live with type 1 diabetes, and 90 per cent live with type 2.⁹ Forty-nine per cent of Canadians living with type 2 diabetes have a BMI of 30 kg/m² or greater.¹⁰

The cost of diabetes to Canada's healthcare system and economy was \$11.7 billion in 2010, which is projected to increase to \$16 billion annually by 2020.¹¹

About Novo Nordisk Canada Inc.

Novo Nordisk is a healthcare company and a world leader in diabetes care and biopharmaceuticals. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society. Novo Nordisk's business is driven by the Triple Bottom Line: a commitment to economic success, environmental soundness, and social responsibility to employees and customers. For more information, visit www.novonordisk.ca.

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* Under special authorization, 'Medicament d'Exception'

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- ¹ Clinical Practice Guidelines. Canadian Diabetes Association, 2013, pg. 76.
- ² Zinman B. et al. Achieving a clinically relevant composite outcome of an HbA1c of <7% without weight gain or hypoglycemia in type 2 diabetes: a meta-analysis of the liraglutide clinical trial programme. *Diabetes, Obesity and Metabolism*, 2011.
- ³ Pratley R. E. et al. Efficacy and Safety of Switching From the DPP-4 Inhibitor Sitagliptin to the Human GLP-1 Analog Liraglutide After 52 Weeks in Metformin-Treated Patients With Type 2 Diabetes. *Diabetes Care* 2012;1-8.
- ⁴ Victoza® Product Monograph, Novo Nordisk, March 14, 2014.
- ⁵ Internal Calculations based on IMS Midas Quantum data, May 2012 (Data on file).
- ⁶ Data on file Novo Nordisk A/S 2012.
- ⁷ "What is Diabetes", Canadian Diabetes Association. Accessed May 27, 2014. Available at <http://www.diabetes.ca/about-diabetes/what-is-diabetes>.
- ⁸ "What is Diabetes", Diabetes Québec. Accessed May 27, 2014. Available at: http://www.diabete.qc.ca/en/html/about_diabetes/whatis.html.
- ⁹ "Diabetes", Canadian Diabetes Association. Accessed May 27, 2014. Available at <http://guidelines.diabetes.ca/CDACPG/media/documents/patient-resources/diabetes.pdf>.
- ¹⁰ GfK 2012 Roper Canadian Diabetes Patient Study, slide 27.

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¹¹ "Diabetes: Canada at the Tipping Point", Diabetes Québec and Canadian Diabetes Association, pg. 2. Accessed May 27, 2014. Available at: http://www.diabete.qc.ca/pdf/rapport/WEB_Eng_CDA_Report.pdf.