

B.C. PHARMACARE'S PUBLIC INPUT QUESTIONNAIRE
FOR DRUGS BEING REVIEWED UNDER THE B.C. DRUG REVIEW PROCESS

Drug Under Review: lixisenatide (Adlyxine)

Date Submitted: October 20, 2017

Confirmation of Eligibility

1. I am a representative of a patient group that represents patients in British Columbia who have the medical condition or disease which the drug under review would be used for AND the patient group which I represent has registered with PharmaCare to give input.

YES

Contact Information

2. First and last name: Sheila Kern, Diabetes Canada

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Conflict of Interest Declaration

6. Does your patient group have any Conflicts of Interest to declare?

YES

7. Describe any Conflicts of Interest below.

Diabetes Canada solicits and receives unrestricted educational grants from manufacturers/vendors of medications, supplies and devices for diabetes and its complications. These funds help the organization to support community programs and services for people with diabetes and contribute to research and advocacy efforts across Canada. Sponsors were not involved in developing the content of this submission.

Questions on the Drug Under Review

8. Have you read the PharmaCare information sheet for this drug?

YES, I have read the information sheet.

9. Describe how the medical condition or disease which the drug under review would be used for affects the day-to-day life of the patients in your group.

Diabetes is a chronic, progressive disease. Type 2 diabetes occurs when the pancreas does not produce enough insulin or the body does not effectively use the insulin that is produced. Common symptoms of diabetes include extreme fatigue, unusual thirst, frequent urination and weight change (gain or loss).

Diabetes requires considerable self-management, including eating well, engaging in regular physical activity, maintaining a healthy body weight, taking medications (oral and/or injectable) as prescribed, monitoring blood glucose and managing stress. Poor glucose control is serious and problematic. Low blood glucose can result in an acute crisis, such as confusion, coma and/or seizure. High blood glucose over time can cause irreversible damage to blood vessels and nerves resulting in blindness, heart disease, kidney problems and lower limb amputations. The goal of diabetes management is to keep glucose levels within a specified target range to minimize symptoms and avoid or delay complications.

Within the last year, Diabetes Canada conducted two nation-wide online patient input surveys. The purpose of these surveys was to solicit the views of people living with diabetes and their caregivers about the impact of diabetes and their experience with drug therapies. For the majority of survey respondents, diabetes has negatively affected all aspects of their lives and limited activities and opportunities, including travel and career. Some felt that diabetes “dictates” their lives, that they are “held captive by diabetes,” and that diabetes is “overwhelmingly debilitating.” Diabetes management is a “constant struggle” and “a 24 hour, 7 days a week job.” Many expressed frustration and anger at not being able to lead a “normal life” due to diabetes. Some described losing their driver’s privilege, employment, independence and spontaneity in their daily life in general. Several also described challenges managing diabetes alongside other comorbid conditions.

Many respondents indicated they are experiencing complications as a result of diabetes, including neuropathy, foot complications, heart problems, eye problems/loss of vision, kidney problems (that resulted in kidney transplant and dialysis), skin ulcers, erectile dysfunction, amputation and depression. Others disclosed fatigue and lack of energy. There was also a frequent emphasis on the psychological and emotional impact of diabetes on the lives of respondents and their family members. These come as a result of having to adjust to changes in diet and lifestyle, deal with stress and anxiety about hypoglycemia, maintain daily medication and treatment regimens, manage strain on relationships, and cope with financial burden and hardship. For individuals who have to manage diabetes and care for other members of the family, it is particularly difficult.

Below are selected quotes from British Columbians that demonstrate the challenges of living with diabetes:

"I have to remember that I have diabetes every day, as soon as I wake up, and act accordingly. If I want to be healthy and live a long and uncomplicated life, I need to "be" a diabetic 24/7/365."

"I am now experiencing problems due to long term diabetes such as heart issues and kidney problems."

"I can't eat whatever I want anymore. I have to remember to take medication. I have neuropathy in my feet."

"My mood is often flat or down, I am anxious about my health and taking medication while traveling is somewhat challenging."

"Life is very regimented: everything on a schedule to take medication at specific times. Most of the time this is OK but sometimes it can be frustrating to have no flexibility and always be on the same schedule, even on holidays."

"Always a challenge to keep A1C under control. Diabetes choices always on your mind."

"I am always having to keep track of my sugars and my food. Whenever I go out I have to find out what food might be served. I am concerned about my future and worry about complications."

"Constant monitoring of what and when I eat, and what I shop for. Slow healing from any injury, cut or operation. So far, impossibility of losing weight. Impact on lifestyle because of cost of diabetes drugs."

"I have found that family members try to understand but truly do not understand what a diabetic goes through everyday. My husband gets so frustrated with me sometimes. The only one that truly understands is yourself."

"There is no holiday from having diabetes."

The most recent survey conducted in B.C. showed that:

- up to 70 per cent of respondents were experiencing hyperglycemia
- almost half of respondents were experiencing hypoglycemia
- between 20 and 35 per cent of respondents were experiencing high blood pressure, high cholesterol and/or foot problems
- about one in five respondents was experiencing nerve damage

- about one in ten respondents was experiencing kidney problems
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10. What drugs or other treatments have the patients in your group used, either now or in the past, to treat the medical condition or disease which the drug under review would be used for?

Medications being used

Canadians living with diabetes and their caregivers reported broad experience with diabetes medications from Diabetes Canada's surveys. Many people indicated having to take multiple medications as part of prescribed treatment.

The injectable medications that respondents were taking at the time of the most recently administered survey include long-acting, intermediate-acting, short-acting, rapid-acting and premixed insulins, and GLP-1 receptor agonists. Some respondents reported having been on long-acting, intermediate-acting, short-acting and/or premixed insulins in past clinical trials; a few stopped using each of these for a reason unrelated to the clinical trial.

The oral medications that respondents were taking include DPP-4 inhibitors, DPP-4 inhibitors+metformin, SGLT2 inhibitors, TZD+amaryl, sulfonylureas, metformin and/or orlistat. Some respondents reported having been on an SGLT2 inhibitor, SGLT2 inhibitor+metformin, sulfonylurea, metformin and/or acarbose in past clinical trials; a few stopped using a DPP-4 inhibitor, SGLT2 inhibitor, TZD, sulfonylurea and/or acarbose for a reason unrelated to the clinical trial.

Satisfaction with current therapy

As a result of diabetes medications, large percentages of respondents indicated they were better or much better at keeping blood glucose and hemoglobin A1c levels at target.

- 61% were better at meeting target fasting blood glucose levels
- 52% were better at meeting target "upon waking" blood glucose levels
- 41% were better at meeting postprandial blood glucose targets
- 41% were better at avoiding hypoglycemia
- 50% were better at achieving target hemoglobin A1c levels

Surveyed patients were also asked to rate the importance of the following benefits/side effects when choosing diabetes medications, using a five-point scale from "very unimportant" to "very important." The vast majority of respondents indicated "quite important" or "very important" regarding the following benefits of therapy:

- blood glucose kept at satisfactory levels in the morning/after fasting
- blood glucose kept at satisfactory levels during the day/after meals
- avoiding low blood glucose during the day/overnight
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The following aspects were also considered important by the majority of respondents:

- avoiding weight gain
- reducing heart problems and high blood pressure
- avoiding gastrointestinal side effects
- avoiding urinary tract infections or yeast infections

Other aspects deemed important when choosing medications included “ease of use and accuracy”, “minimal side effects” and “cost”.

11. If the patients in your group have tried the drug under review, please tell us about the effects they experienced.

Experience with GLP-1 receptor agonists

Responses were aggregated for all GLP-1 receptor agonists. The majority of people who have experience with this class of drugs noted effectiveness in keeping blood sugar levels at target, achieving target hemoglobin A1c levels, and, in some cases, weight loss.

The majority of respondents indicated:

- fasting blood glucose levels were better
- blood glucose levels upon waking were better
- postprandial blood glucose levels were better
- less hypoglycemia
- improvements to hemoglobin A1c
- better results in weight control

Of respondents with GLP-1 receptor agonist experience, many had switched from another medication as a result of the need to gain better blood glucose control. Most often this medication was added to current therapy to achieve better diabetes management outcomes.

Below are selected quotes on benefits experienced by British Columbians who have taken a GLP-1 receptor agonist:

“...with the [GLP-1 receptor agonist] and other medications I have had much fewer lows and I have been able to lose weight.”

“[GLP-1 receptor agonist] has been a big help in stabilizing blood sugars and in helping with weight loss.”

“My day to day life has improved very much since I started [GLP-1 receptor agonist] about five years ago.”

“[GLP-1 receptor agonist] makes me nauseous a lot, and I have diarrhea and a lot of indigestion,

belching and gas. "

"Got best result of glucose reduction using [GLP-1 receptor agonist] however was extremely ill (vomiting, extreme loss of appetite and constant exhaustion) for 6 month trial period resulting in change to insulin."

While GLP-1 receptor agonists have been associated with many benefits and improved diabetes control, a percentage of respondents reported side effects such as extreme nausea/other gastrointestinal effects and thirst.

12. How do you think the patients in your group could benefit from using the drug under review? (For example: relief of existing symptoms; improvements in quality of life; or improvements to their condition and long-term health and well-being. Please provide details.)

The majority of people who have tried GLP-1 receptor agonists reported improved outcomes, including blood glucose and hemoglobin A1c control, weight loss, and decreased dependence on insulin and other medications. However, a significant number of people also reported side effects. The survey responses reinforce the understanding that different people with diabetes require different medications to help effectively manage their disease. Their clinical profile, preference and tolerance of therapy can direct physicians to the most appropriate drug therapy. Based on reported benefits, lixisenatide (Adlyxine) is an important option for some people with type 2 diabetes to achieve more effective management of diabetes and better health outcomes.

13. Are there any additional factors your organization would like PharmaCare to consider during its review of this drug? (For example: does the drug meet any special patient needs that have not been met by other drugs or treatments; is the drug easier to use than other drugs; does the drug reduce visits to the hospital; does the drug reduce days off work or school; or are the drug's side effects acceptable or intolerable?)

Many respondents commented on the affordability of medications and management of diabetes. Some respondents preferred oral versus injected drugs. An injectable is "not as convenient as a tablet because it requires refrigeration and injection." Many also would like new drugs to help "reduce the dependence on medications". People also expect that new drugs will support good mental health, restore energy, reduce risk of damage to organs, and provide "a feeling of overall wellbeing".

There are clear expectations that new drugs also should offer good blood glucose control to prevent hyperglycemic and hypoglycemic episodes, as well as longer term control, minimal side effects and long term damage to organs, affordable cost, and hope for a healthy and longer life. Given the challenge that many people with type 2 diabetes have with weight loss and the enormous sense of failure associated with weight gain, diabetes medications that do not cause weight gain and/or promote weight loss can be an important part of care.

When asked how they hope new diabetes medications will help people in Canada, respondents made the following comments:

“Stop all the things that happen to diabetics latter[sic] in life.”

“Will help people lose weight.”

“Reduce the price and make it more accessible to any pharmacy/drug stores.”

“Better a1c’s[sic].”

“I hope for less side effects on other body functions, more support and disclosure from pharmaceutical companies, and the ability to control and stabilize blood glucose.”

“That it could cost less and if we have to take medication then[sic] to hopefully only take it once a day.”

Diabetes is a disease that requires intensive self-management. To achieve optimal blood glucose levels, individualization of therapy is essential, including selecting the drug or combination of drugs, route of administration (oral, injection, pen or pump), how frequently the patient monitors blood glucose and adjusts dosage, the benefits and risks that the patient experiences and/or tolerates, and the lifestyle changes the patient is willing or able to make.