

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

Drug Under Review: insulin glargine-lixisenatide (Soliqua)

Date Submitted: October 17, 2018

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

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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 receives unrestricted educational grants from, among others, 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. No sponsor was involved in soliciting input for or 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 illness with no known cure. A combination of genetic, lifestyle and environmental factors contribute to its development. Type 2 diabetes occurs when the pancreas does not produce enough insulin or the body does not properly 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 medication (oral and/or injectable) as prescribed, monitoring blood glucose and managing stress. Poor glucose control is serious and problematic. Low blood glucose can precipitate an acute crisis, such as confusion, coma, and/or seizures that, in addition to being dangerous themselves, may contribute to a motor vehicle, workplace or other type of accident causing harm. High blood glucose over time can irreversibly damage blood vessels and nerves, resulting in complications such as blindness, heart disease, kidney problems and lower limb amputations. The goal of diabetes management is to keep glucose levels within a target range to minimize symptoms and avoid or delay secondary disease.

This submission contains patient input from online surveys conducted in October 2016 and April 2018. Each survey was open for two weeks to people across Canada and consisted of a self-administered questionnaire. The surveys were directed at people living with type 2 diabetes and caregivers of people with type 2 diabetes and inquired about respondents' lived experience with diabetes and diabetes medications, and expectations for new drug therapies in Canada. The more recent of the two surveys posed a number of questions specifically about the drug under review, insulin glargine-lixisenatide (Soliqua).

A total of 847 people participated in the October 2016 survey, with 86 reporting residence in British Columbia. Every respondent from British Columbia was over the age of 40, with the majority (67%, n=58) having lived with type 2 diabetes for over 10 years. Fewer people participated in the April 2018 survey; responses were collected from a total of 12 respondents (11 with type two diabetes and one caregiver). Two respondents in total disclosed their age and time since diagnosis. Both were between 25 and 55 years, with one having lived with diabetes for less than a year, and the other for 6 to 10 years. One survey participant reported living in British Columbia.

Most people surveyed talked about the negative impact diabetes has had on their lives. They reported constantly thinking about and planning around their disease, and talked about the stress this causes. They spoke about the ways that diabetes interferes with every aspect of life, from eating and exercising to working and socializing. People commented

that diabetes makes it difficult to be flexible and spontaneous. Daily medication, constant monitoring of blood sugar levels and frequent visits to health care providers were described as burdensome. People attested to the fact that diabetes is even more difficult to treat when someone is also dealing with comorbidity or disability.

Several respondents spoke about the blame they inflict upon themselves for their disease, the shame and guilt they feel, and the stigma they experience. Some talked about how tough it is to interact with people who know very little about diabetes or who offer unsolicited advice about its management. People shared that diabetes has adversely affected relationships and decreased independence. They also mentioned the significant and overwhelming financial burden the disease inflicts on individuals and families.

Many people mentioned dealing with, and being apprehensive about, disease symptoms, medication side effects and diabetes complications. Respondents described being chronically in pain and exhausted. They cited problems ranging from weight management issues, neuropathy and nephropathy, to amputations, changes to circulation, vision problems, and sexual difficulties, including erectile dysfunction. They also reported living with depression and anxiety.

Of the total responses from people living in British Columbia to questions about symptoms and disease complications in the October 2016 survey (n=86), the following were said to have been experienced “sometimes” (“moderately”), “often” (“severely”) or “very often” (“very severely”):

- hyperglycemia (74%)
- hypoglycemia (33%)
- high blood pressure (57%)
- high cholesterol (39%)
- heart problems (12%)
- mental health problems (22%)
- kidney symptoms or disease (13%)
- foot problems (54%)
- eye problems (41%)
- nerve damage (47%)
- damage to blood vessels, heart or brain (7%)
- liver disease (11%)

Of the total number who responded to this question in the April 2018 survey (n=4), people experienced hyperglycemia, hypoglycemia, high blood pressure, high cholesterol, mental health problems and eye problems “sometimes”, “often” or “very often”. Additionally, bladder issues, infection control and general muscle/joint pain were reported.

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

“Life is very regimented...sometimes it can be frustrating to have no flexibility and always be on the same schedule, even on holidays.”

“I love to cook but it restricts the things I eat.”

"I am always having to keep track of my sugars and my food...I am concerned about my future and worry about complications."

"Taking medication is a part of my daily routine and if I for any reason miss taking it can suffer low blood sugars which is very unpleasant. Diabetes also has an impact on my vision, and...if my blood sugars are high or uncontrolled for any reason my vision is not clear and my eyes feel very tired."

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

"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 fear is that I will not be able to afford [a particular antihyperglycemic agent] when I retire and no longer have medical coverage."

"I am concerned about further loss of health and possible complications in the future...I often get weary of the daily discipline required to manage diabetes daily in order to prevent or delay these possible future outcomes...I am concerned about possible financial hardships in the future. I currently have extended medical coverage for my medications but given how expensive some are...I may use up my lifetime maximum before I die and will have to cover much of the costs through my pension and savings."

"I have had type 2 diabetes for over 20 years. I think it has taken me that long to actually get it under control...I have found that family members try to understand but truly do not understand what a diabetic goes through everyday [sic]...The only one that truly understands is yourself."

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?

Past and present medication use

Many respondents reported antihyperglycemic agents being part of their past or present treatment history (or the history of the person for whom they provide care) in both surveys. A number of people mentioned having to take multiple medications as part of their prescribed regimen.

In the study conducted in October 2016, the following medications were reported as being currently in use by respondents from British Columbia: insulin, metformin, GLP-1 receptor

agonists, SGLT2 inhibitors, a combination of SGLT2 inhibitors and metformin, DPP-4 inhibitors, a combination of DPP-4 inhibitors and metformin, sulfonylureas, acarbose, meglitinides and a combination of TZDs and metformin. Some respondents indicated that they had experience with certain medications in the past as part of a clinical trial (but are now no longer taking them). A small number reported stopping certain medications due to reasons other than the end of a clinical trial. The most commonly cited medications were GLP-1 receptor agonists, TZDs, sulfonylureas, DPP-4 inhibitors, SGLT2 inhibitors and metformin.

In the more recent study conducted in April 2018, the following medications were reported being currently in use by respondents (n=3): insulin, metformin, GLP-1 receptor agonists, SGLT2 inhibitors, DPP-4 inhibitors and sulfonylureas. No respondent had used a medication in a past clinical trial or reported stopping a medication for any reason.

Satisfaction with current therapy

Of those living in British Columbia who responded to this survey question in October 2016, over 67% said they were “better” or “much better” able to meet their fasting blood glucose target, as well as their morning and post-prandial targets on their current antihyperglycemic therapy than before (without treatment). Close to 80% also stated that their current medication(s) helped them achieve hemoglobin A1c targets “better” or “much better” than previously. Between 13% and 27% of respondents reported the following as “somewhat worse” or “much worse” on their current regimen: ability to maintain or lose weight, thirst/dehydration and incidence of yeast infection/urinary tract infection.

When asked what factors were “quite important” or “very important” in choosing diabetes medications, over 70% of respondents reported the following: keeping blood glucose at satisfactory level during the day or after meals and upon waking or after fasting, avoiding low blood sugar during the day and overnight, avoiding weight gain/facilitating weight loss, reducing risk of heart problems, and avoiding gastrointestinal issues (nausea, vomiting, diarrhea, pain).

Of the total number who participated in the April 2018 survey, all who responded to the question (n=3) said they were “better” or “much better” able to meet blood glucose targets in general, upon waking, and post-prandially on their current antihyperglycemic therapy. They all also stated that their medication(s) helped them achieve hemoglobin A1c targets and maintain or lose weight “better” or “much better” than their previous regimen. When asked what factors were important in choosing between diabetes medications, 100% of respondents (n=3) said the following were “quite important” or “very important”: keeping blood glucose at satisfactory level during the day or after meals and upon waking or after fasting, avoiding low blood sugar during the day and overnight, avoiding weight gain/facilitating weight loss, reducing blood pressure and risk of heart problems, and avoiding gastrointestinal issues (nausea, vomiting, diarrhea, pain), urinary tract and/or yeast infections and fluid retention.

Below are some direct quotes from British Columbians who responded to the October 2016 and April 2018 surveys that describe what they like and dislike about current therapy:

"Long acting [sic] meds are appreciated."

- 55 to 69 year old person with type 2 diabetes, diagnosed 11 to 20 years ago, taking metformin, a sulfonylurea, an SGLT2 inhibitor and insulin

"This is easy to use, and seems to work very well."

- person over 70 years old with type 2 diabetes, diagnosed 11 to 20 years ago, taking a GLP-1 receptor agonist

"I strongly belief [sic] my quality of life has improved a lot."

- 55 to 69 year old person with type 2 diabetes, diagnosed 11 to 20 years ago, taking metformin, an SGLT2 inhibitor, a GLP-1 receptor agonist and insulin

"My sugars have never been so stable."

- 25 to 39 year old person with type 2 diabetes, diagnosed 6 to 10 years ago, taking metformin, a sulfonylurea, an SGLT2 inhibitor, a GLP-1 receptor agonist and insulin (long-acting and rapid)

"[Medications] are very expensive."

- 55 to 69 year old person with type 2 diabetes, diagnosed more than 20 years ago, taking metformin, a sulfonylurea and a GLP-1 receptor agonist

"I don't like the injections."

- 40 to 54 year old person with type 2 diabetes, diagnosed 6 to 10 years ago, taking an SGLT2 inhibitor and a GLP-1 receptor agonist

"All meds so far have created more stomach upset than without."

- 40 to 54 year old person with type 2 diabetes, diagnosed 3 to 5 years ago, taking an SGLT2 inhibitor and a DPP-4 inhibitor

"I don't like that I have to take so many medications."

- 40 to 54 year old person with type 2 diabetes, diagnosed 6 to 10 years ago, taking metformin, a sulfonylurea and an SGLT2 inhibitor

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

Experience with insulin glargine-lixisenatide (Soliqua)

At the time the April 2018 survey was available, insulin glargine-lixisenatide (Soliqua) had not yet received a Notice of Compliance from Health Canada. Consequently, few Canadians

had first-hand experience with the medication at the time to report on. Of those who participated in the April 2018 survey and responded to the questions specific to insulin glargine-lixisenatide (Soliqua) (n=3), none had ever taken it or could comment on the groups of people for whom it would be best suited.

All respondents (n=3) said that they feel having combination diabetes medications as a treatment option is “very beneficial” or “extremely beneficial”. They indicated that taking too many medications at a time is burdensome and implied that combination medications are easier to prepare and administer, which helps to promote more regular use and supports adherence to their prescribed regimen. One person said, *“the less medication [I] have to take, the better it is on my mental health.”* Some respondents were unsure how exactly a combination medication would affect their ability to afford diabetes therapies and injection supplies; one person said there would be no change. A few felt that combination medications would decrease the time and effort they spend administering medication, but others didn’t know what the possible impact could be.

In the October 2016 survey, some respondents commented on the advantage of having combination medications available for diabetes treatment. Several spoke about how burdensome it is to take several oral and/or injectable medications and that it would make a difference to their daily management and quality of life to reduce the number of agents they administer. When asked about hopes for new therapies, they explicitly said it would be beneficial to have a greater number of combination medication options available (*“more combo meds with GLP-1”, “mixed meds for one injection”*).

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.)

Diabetes is a disease that requires intensive self-management. Diabetes Canada’s 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada highlight the importance of individualized pharmacologic management of the condition. Specifically, after initiating healthy behaviour measures, the guidelines recommend selecting diabetes treatments based on a patient’s degree of glycemic control and other considerations. To achieve optimal blood glucose levels, personalized therapy is essential. This includes careful consideration of medication selection, route of administration, frequency of self-monitoring of blood glucose, benefits and risks that the patient experiences and/or tolerates, and lifestyle changes the patient is willing or able to make.

Our survey responses reinforce the message that different people with diabetes require different medications/treatment modalities to help effectively manage their disease. Their unique clinical profile, preferences and tolerance of therapy should direct physicians to the

most appropriate choice and combination of treatments for their disease management.

Many people with diabetes hope for less dependence on insulin and medications. While current therapies have generally led to improvement for many people with diabetes in blood glucose and hemoglobin A1c control, respondents hope for even better, more affordable antihyperglycemic agents that they can access equitably and in a timely manner, and that they can take consistently to help them lead a normal life. Insulin glargine-lixisenatide (Soliqua) may help people to achieve better glycemic control, which could potentially improve lives and save millions of dollars in direct health-care costs. For this reason, insulin glargine-lixisenatide (Soliqua) should be an option for people living with diabetes.

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?)

When asked about their expectations for new diabetes therapies, respondents to the October 2016 and April 2018 survey expressed a strong desire for medications that have been proven safe and can normalize/stabilize blood glucose levels and improve hemoglobin A1c without causing weight gain or hypoglycemia. They wish for new treatments to be affordable, enhance weight loss and improve health outcomes. Ideally, they'd like medications and diabetes devices to be covered in a timely manner by public and private plans. They want treatments that are easily administered, cause the least amount of disruption to lifestyle and allow for flexibility with food intake and choices. They also want medications that help them avoid polypharmacy and eliminate the need for injections while minimizing risk of any short-term medication-related side effects or long-term disease-related side effects. Several respondents hope future treatments will reverse or cure diabetes.

Below, respondents from British Columbia provided input on desired improvements to treatment and the impact these would have on daily life and overall quality of life:

"I want my medication minimal, and discrete [sic]."

"I hope it will give people with type 2 diabetes a chance for better control towards normal."

"Help with neuropathic pain."

"Better overall blood sugar levels. More cost effective...fewer side effects."

"Lower blood sugar and weight loss."

"I hope that there will be a drug to help reduce weight without all the side effects of other weight loss drugs."

"Better control of problems. Fewer problems/reaction with meds. Cheaper. Work faster and better."

"Ultimately I would like to see a medication or therapy that would either eliminate type 2 diabetes or halt the damage that type 2 does to the bodily organs."

"Make it easier to keep glucose levels in the desired range. Have no or minimal side effects."

"New and better understanding of the mechanisms of cause of type 2 diabetes will allow pharmaceutical companies to develop more efficient treatments that treat the cause of diabetes rather than just the symptoms. 'Boosting' the pancreas' ability to keep beta cell function and insulin production through better blood sugar control will allow healthier diabetics, with fewer costs to the healthcare system, and fewer complications overall."

