



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

Drug Under Review: Baqsimi (nasal glucagon)

Date Submitted: November 18, 2019

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:** Simon Trevelyan, Regional Director – British Columbia and Yukon
3. **Home Street Address:** Diabetes Canada (British Columbia and Yukon Region)
360-1385 West 8th Avenue
4. **City:** Vancouver, British Columbia
5. **Postal Code:** V6H 3V9

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, and among others, manufacturers/vendors of medications, supplies, and devices for diabetes and its complications.



These funds help the organization support community programs and services for people living 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 PharmaCare information sheet for this drug.

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 and progressive disease with no known cure. Type 1 diabetes occurs when the body produces either very little or no insulin. 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 precipitate an acute crisis, such as confusion, coma, and/or seizure that, in addition to each being potentially dangerous as an isolated event, may also 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 blindness, heart disease, kidney problems, and lower limb amputations, among other issues. The goal of diabetes management is to keep glucose levels within a target range to minimize symptoms and avoid or delay complications.

Hypoglycemia is a major challenge for people living with type 1 diabetes trying to achieve glycemic targets. Diabetes Canada's 2018 Clinical Practice Guidelines define hypoglycemia as: 1) the development of autonomic or neuroglycopenic symptoms; 2) a low plasma glucose level (<4.0 mmol/L); and 3) symptoms responding to the administration of carbohydrates. It can be severe and can result in confusion, coma or seizure, and require the assistance of others to bring blood sugar levels back into their target range. Frequent or severe hypoglycemia can negatively impact one's quality of life and bring about fear of future hypoglycemia. This fear can result in reduced self-care and poor glucose control for some people, which may lead them to intentionally run their blood sugars high in order to avoid going low.



This submission contains patient input from an online survey conducted in July 2019. The self-administered questionnaire was open for two weeks to people across Canada. The survey was directed at people living with type 1 diabetes and caregivers of people living with type 1 diabetes. It asked about respondents' lived experience with diabetes and diabetes medications, and expectations for new antihypoglycemic agents in Canada. Further, the survey posed several questions specifically about the drug under review, Baqsimi (nasal glucagon). Awareness of the survey was generated through Diabetes Canada's social media channels (Facebook and twitter).

A total of 272 people participated in the July 2019 survey, with 16 reporting residence in British Columbia. Of the 16 respondents, 8 respondents indicated living with type 1 diabetes and 8 respondents indicated being caregivers to someone living with type 1 diabetes. Respondents from British Columbia varied by age: 50.0% were aged 24 years and under, 25.0% were between the ages 25 to 54 years, and 25.0% were aged 55 years and over. Of the respondents, 43.8% had lived with type 1 diabetes for up to 5 years, 18.8% had lived with type 1 diabetes for 6-20 years, and 37.5% had live with type 1 diabetes for more than 20 years.

For all survey respondents, diabetes has negatively affected most or all aspects of their lives and limited opportunities and activities, including career and travel. They describe the disease as exhausting, stressful, time consuming, and a constant worry. They expressed frustration with the daily challenge of maintaining normalcy. Further, they described diabetes as a disease that interrupts daily life and forces then to live in a regimental way that makes their schedules inflexible.

Several respondents talked about diabetes contributing to losses in their life; some have had to give up careers, friendships, their sense of independence, and the ability to act spontaneously. Caregivers, especially those caring for children, express concern both for themselves and for the child they care for. A child living with type 1 diabetes means that the caregiver is always worrying and thinking about their child's disease. Below are select quotes from British Columbians that demonstrate the challenges of living with type 1 diabetes:

"Diabetes is a full-time job. No vacations, no breaks. I never stop worrying/wondering/thinking about my health now. I have to take it into consideration in everything I do - taking supplies with me everywhere I go, constantly monitoring my blood sugar, carefully planning for any kind of exercise, thinking about when I last ate and when my next meal is likely to be, treating hypos on the go, having enough supplies on hand for emergencies... the list goes on forever."



"Type 1 Diabetes is a full-time job on its own, part of you is always thinking and aware of it and checking in with yourself and how you're feeling. I often have a terrible sleep due to highs and lows in the night. Until I got my CGM I frequently worried about dying in my sleep due to a low blood sugar. First thing I deal with in the morning, manage it all day and the last thing I deal with before bed. Have to worry about being able to afford all of my diabetes medications and aides now and when I am too old to work."

"Diabetes is a condition that I have lived with for 35 years, 24 hours a day, 7 days a week, 365 days a year. I never get a break or a vacation. I never am able to give my loved ones a break, I have to rely on others all the time to be aware of how to treat me. It's expensive and physically exhausting. But day in and day out I fight to stay alive and healthy, for myself and those that care for me."

"Into my 37th year living with diabetes, a 24/ 7/ 365 chronic disease .Very time consuming to stay on top of this disease with appointments with Specialists, General Practitioner, dealing with Insurance coverage (happy I do have coverage !!), making sure supplies/medications do not run out. As I age, I seem to have more appointments."

"I have been diabetic for 45 years. I have reached the point where I am unable to work full-time any longer and am on federal disability benefits. I suffer from depression and fatigue as well as having had 3 islet cell transplants. I still have many low blood sugars, sometimes several a day."

"I used to have a life and a job and a marriage and friends. Now I have a child with type 1 diabetes. I wish I knew what I used to think about non stop every day. What did I use all that brain power on? Now I think diabetes 24 hours a day 7 days a week. I still have friends and a job and a marriage- not to mention another child- but that is only because they have agreed to take the leftovers I have to offer."

Respondents said that they experienced the following symptoms of hypoglycemia "sometimes" ("moderately"), "often" ("severely") or "very often" ("very severely") (n=16):

- Low plasma glucose level (<4.0 mmol/L): 100.0%
- Trembling, palpitations, sweating, anxiety, hunger, nausea, or tingling: 87.5%
- Confusion, weakness, drowsiness, or vision changes: 87.5%
- Difficulty speaking, headaches, or dizziness: 62.5%
- Unconsciousness, coma, or seizure: 12.5%



The majority of survey respondents reported that hypoglycemia has affected some or all aspects of their life. They described hypoglycemia as a condition that disrupted daily life (e.g., sleep, work, and other daily activities), is unpredictable, and time consuming. Further, they expressed that hypoglycemia caused severe emotional and mental distress; hypoglycemia was reported to cause participants to experience stress, anxiety, exhaustion, panic attacks, and a constant fear of adverse health outcomes and death. Below are select quotes from British Columbians that depict how hypoglycemia affects their overall quality of life:

“Actual incidences of lows have added stress, made us change plans or stop whatever we’re doing. They disrupt our sleep and increase our anxiety. The FEAR of a really bad hypoglycemia also impacts our quality of life in many ways. It’s the fear of a dangerous low that prevents us from often letting our daughter do specific things or go specific places. It’s the reason so many preschools aren’t willing to take T1 children and almost made us lose our spot at one.”

“Hypoglycaemia happens differently every time. Sometimes quickly sometimes slowly. You have to be ready and prepared to treat any where anytime, by myself or anyone around me. Anywhere I go I have to ensure those around me know what to do in case I cannot.”

“Constant fear of death. Anxiety and panic attacks. Feel like you’re dying and the physically and emotionally exhausted after the low finally passes. The tighter you manage your blood sugars and the better your A1C the more frequent the lows.”

“Many hypos happen for my T1. Lack of sleep due to night time checks, expense for glucagon, and extra foods when unexpected lows happen that are hard to correct, worrying and planning 24/7.”

“Interrupted sleep, being late for work and other activities to treat the low, hours of worry when the numbers are slow to rise, high stress.”



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? (Please list all of the drugs or other treatments and tell us about their experience with each. In particular, did they consider any of the drugs or treatments to be successful and why?)

Other drugs respondents have used to treat severe diabetes-related hypoglycemia is injectable glucagon (18.8%). Respondent reported the following side-effects related to the use of injectable glucagon: nausea (12.5%) and vomiting (6.3%).

Participants were asked to rate their satisfaction with injectable glucagon. Of the participants, 75.0% were neither satisfied nor unsatisfied with the use injectable glucagon, while 18.8% were very unsatisfied or unsatisfied with the use of injectable glucagon. Several respondents indicated that they were glad that injectable glucagon exists; however, they were unsatisfied with its short shelf life, cost, and complex administration. Below are some direct quotes from British Columbians that describe what they like and dislike about injectable glucagon:

"I like that it exists! I dislike the price, and difficulty to use. I wish it could be pre mixed or a spray or something less intimidating."

"It provides some piece of mind, even though we have never had to use it. However, it is very expensive and has a short shelf life."

"While we haven't used it yet on our T1, when we use expired glucagon to demonstrate how to administer it to her care providers, they find the whole thing very intimidating, especially the giant needle. The fact that you have to mix the powder with the liquid is also an issue. Everyone is scared they won't remember or know what to do in an actual emergency. But I appreciate that we have something that if needed could save my daughter's life."

"Never used one but I ALWAYS carry one or two with me just in case. I like the security of knowing if she does pass out that I can do something. An injection makes the most sense as you don't want someone to choke."

"I've never used it, but it really worries me that I would have to stop, open the box, mix the drug and water and then inject. That is going to take a minute and my child could die."



"It's complicated to use, not simple, must be mixed. I am nervous to have someone else do it."

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

No survey respondents reported having tried Baqsimi (nasal glucagon).

12. How do you think the patients in your group could benefit from using the drug under review? (For example: relief of existing symptoms; improvement in quality of life; or improvements to their condition and long-term health and wellbeing. 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 personalized care when it comes to the pharmacological management of the condition. Patients and physicians should have the capacity to choose the treatment that is best suited to a patient's condition and life circumstances.

It is important to prevent, recognize, and treat hypoglycemic episodes secondary to the use of insulin or insulin secretagogues. Alongside the introduction of a treatment for hypoglycemia, we recommend educational supports to help prevent hypoglycemia. It is important to counsel individuals who are at risk of hypoglycemia and their support persons about the signs of hypoglycemia and its treatment. Glucagon is a lifesaving agent that people with diabetes and their caregivers are thankful to have available, even though they hope to seldomly experience the emergency situations that forces them to make use of it. Access to glucagon that is administered in a way that patients and caregivers find less intimidating and does not contribute to the stigma of diabetes would fill a gap noted by this patient population.

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?)

British Columbian survey respondents rated the following criteria as "somewhat important" or "very important" when considering treatment for severe hypoglycemia: fast to administer (93.8%), small chance of error (93.8%), fast recovery (93.8%), cost of medication (68.8%), route of



administration is through the nose (50.0%), and route of administration is through injection (18.8%).

People living with type 1 diabetes and their caregivers would like to see a glucagon treatment that is easier to administer. Unfortunately, the current treatment has several barriers, it is injected with a large needle which people find intimidating. Before administering, it requires pre-mixing which people find overwhelming in emergency situations and leaves the administration process prone to human error.

Further, people living with type 1 diabetes and their caregivers are interested in glucagon that would be administered more easily and less visibly. People living with type 1 diabetes feel that if glucagon could be administered like an EpiPen, they would be less self-conscious of their disease because this process would garner them less attention. This would help decrease the stigma associated with managing their disease in public. The following are respondent quotes related to the administration of glucagon:

"I am hoping for a less intimidating way to administer than the injections, more affordable, fast acting, and will work every time!"

"Fast & safe with few side effects. Easy to administer..."

"In any case I hope they find an easier-to-use (more dummy-proof) format so anyone who needed to could figure it out quickly."

"Easier to administer, less chance of error"

Respondents feel that the cost of glucagon is burdensome. This treatment is lifesaving and something they are required to have and paying out of pocket can be prohibitive. The fact that it expires quickly exacerbates this problem. They would like to see glucagon be less expensive, covered by drug plans, and have a longer shelf life. The following are respondent quotes related to the cost of glucagon:

"I expect them to be covered by my provincial MSP/Pharmacare even though currently none of these are covered."

"That they will make my child's life better. That we will be able to afford them through our medical plan. That he will be able to afford them as an adult."

"...plus not too expensive. No use if nobody can afford it!"



"Anything that is cover cost of medical will be nice."

Awareness of new treatment options and autonomy over treatment plan is important to people living with type 1 diabetes and caregivers of people living with type 1 diabetes. Participants would like to be notified of new treatment options as they become available and would like to be involved in making decisions regarding their treatment plan. The following are respondent quotes related to awareness and autonomy:

"That Canada approves them and allows patients to choose their treatment with the help of their medical team."

"That diabetic clinics will inform patients of new options. Drug benefits will cover them."

"We should be made aware as soon as is possible."