



**BRITISH COLUMBIA MINISTRY OF HEALTH –  
PHARMACARE DRUG COVERAGE REVIEW  
YOUR VOICE PATIENT GROUP SURVEY**

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**Drug Under Review:** semaglutide (Rybelsus)

**Date Submitted:** April 21, 2021

**Confirmation of Eligibility**

The patient input surveys are reserved for patients, caregivers, or patient groups who have experience with the disease in question. Please select the category you identify as below:

- Patient
- Caregiver
- Patient group

I am a representative of a patient group that advocates for residents of British Columbia.

- Yes
- No

**Name of patient group:** Diabetes Canada

**Name of representation (first, last):** Ann Besner, Manager, Research and Public Policy

**Patient group street address:** National Office, 1300 – 522 University Avenue

**City:** Toronto, Ontario

**Postal code:** M5G 2R5

**Is your patient group registered with the Ministry of Health to provide input to our drug reviews?**



- No
- Yes

### **Conflict of Interest Declaration**

#### **Do you have any conflicts of interest to declare?**

To make sure the drug review process is objective and credible, everyone who provides input has to tell us about any possible conflicts of interest.

A conflict of interest exists if you or an immediate family member might benefit from the outcome of PharmaCare's drug review. For example, if you own stock in the company that makes a drug, there could be a financial benefit if PharmaCare decides to cover the drug.

Examples of conflicts of interest include, but are not limited to, financial support from the pharmaceutical industry (e.g., educational or research grants, honoraria, gifts and salary), as well as affiliations or commercial relationships with drug manufacturers or other interest groups.

Even if you or an immediate family member has a conflict of interest, your input will still be considered as long as you declare the conflict of interest in your answers to the questions. All information you provide is protected under the Freedom of Information and Protection of Privacy Act.

- No
- Yes

#### **Please 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 support a variety of services for people living with diabetes and contribute to education, research, policy and advocacy efforts



across Canada. No sponsor was involved in soliciting input for or developing the content of this submission.

**Have you read the drug information sheet?**

- No
- Yes

**Experience with Disease**

**On a scale of 0 to 3, how would you rate the physical pain and discomfort patients experience from this disease?**

3 – significant impact

**On a scale of 0 to 3, how would you rate the impact of this disease on patients' activities of daily living?**

3 – significant impact

**On a scale of 0 to 3, how would you rate the impact of this disease on patients' mental wellbeing?**

3 – significant impact

**Severity**

**Please describe the patients' experience with the disease. How severe is it? Consider factors such as symptoms, physical pain and discomfort, and mobility.**

Diabetes is a chronic, progressive disease of different types, but none with any known cure. Type 2 diabetes (for which the drug under review is indicated) occurs when the pancreas does not produce enough insulin or the body does not effectively use the insulin that is produced. Common symptoms that contribute to a diagnosis of diabetes include extreme fatigue, unusual thirst, frequent urination and weight change (gain or loss). Diabetes requires considerable daily 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.



It can be quite serious and problematic when glucose levels are not at target. A number of autonomic and neuroglycopenic symptoms are associated with low blood glucose, including trembling, palpitations, sweating, anxiety, tingling, difficulty concentrating, headaches and vision changes. Low blood sugar can precipitate an acute crisis, such as confusion, coma, and/or seizure that, in addition to being dangerous, may also contribute to a motor vehicle, workplace or other type of accident causing harm. High blood glucose can cause weakness, nausea, vomiting, abdominal pain and other symptoms. Over time, glucose levels above target can irreversibly damage blood vessels and nerves, resulting in issues like blindness, heart disease, kidney dysfunction and lower limb amputations. The goal of diabetes management is to keep glucose levels within a target range to minimize symptoms and prevent or delay complications.

To inform this submission, Diabetes Canada conducted online surveys in July/August 2020 and November/December 2020 that were advertised through social media and by e-mail to members of the Diabetes Canada Professional Section. The July/August survey was jointly created by Diabetes Canada, [JDRF](#) and [Type 1 Together](#). It was open for two and a half weeks (July 31-August 19) to people across Canada with type 1 and type 2 diabetes and their caregivers. It consisted of a self-administered questionnaire of closed- and open-ended questions about respondents' lived experience with diabetes and types of glucose monitoring. The November/December survey was open for two weeks (November 19-December 3) to people across Canada with type 2 diabetes and their caregivers. It consisted of a self-administered questionnaire of closed- and open-ended questions about respondents' lived experience with diabetes and diabetes medications (with specific questions about the drug under review, semaglutide [Rybelsus]), and expectations for new drug therapies in this country.

Of the 873 people who participated in the July/August survey, 36 identified as living with type 2 diabetes and 4 identified as caregivers to somebody with type 2 diabetes. Within this group of 40 respondents, the majority were 35 years or older, with the biggest concentration of people in the 65+ age category (38%, n=15). About 53% (n=21) reported living with diabetes for at least 11 years, with most in the 11-20 year range (n=16). Of the people and caregivers affected by type 2, a total of 15 resided in British Columbia, with the remaining respondents living in Quebec, Ontario, Manitoba, Saskatchewan and Alberta.

Fewer people participated in the November/December survey (n=15). There was a total of 13 people living with type 2 diabetes and 2 caregivers to somebody with type 2 diabetes. All



respondents were 35 years or older, with most in the 55-64 year age category (53%, n=8), and everybody reported having diabetes for 20 years or less. The greatest number of people have been living with the disease for 3-5 years (40%, n=6). Respondents resided in Newfoundland and Labrador (n=2), Nova Scotia (n=1), Ontario (n=5), Manitoba (n=1), Saskatchewan (n=1), Alberta (n=4) and British Columbia (n=1).

Respondents to the July/August survey and the November/December survey across the country reported experiencing the following alongside type 2 diabetes:

- hyperglycemia
- hypoglycemia
- high blood pressure
- high cholesterol
- eye problems
- foot problems
- kidney issues or disease
- digestive and sleep issues
- damage to blood vessels or brain
- weight management issues
- mental health concerns

Other problems cited include skin infections, gastrointestinal disturbances (nausea, diarrhea), metabolic changes, arthritis, lymphedema, fibromyalgia, chronic fatigue, epilepsy, celiac disease and other autoimmune disorders. The presence of comorbid conditions increases the burden of diabetes management.

### **Quality of Life**

**Please describe how the disease impacts patients' quality of life. Consider factors such as independence, social stigma, social functioning, mental wellbeing, and ability to care for others.**

There were responses in both surveys that indicated people viewed life with diabetes quite positively. One person said “having diabetes caused me to examine my diet and make changes for better health”. Another person commented “[I am] healthier now than before I was diagnosed. It was the trigger I needed to make necessary changes.” However, the overwhelming majority of respondents spoke negatively of their experience being chronically ill. Many people shared that diabetes is frustrating, difficult and tiring to manage. They expressed that it “decreases quality of life”, is “time consuming” and requires “more care for the body”. One respondent said “diabetes affects my life every day, all day”; another respondent characterized herself as “a literal slave to this relentless disease”. Several people made similar statements, illustrating the all-consuming nature of the disease.



Many respondents talked about how burdensome and preoccupying the condition is. People frequently mentioned that they are constantly thinking about and dealing with their disease. They expressed that it is always top-of-mind when making decisions, that the condition requires a great deal of planning to accommodate and that it is exhausting to manage. Respondents expressed that diabetes is even more of a challenge to live with when dealing with comorbidities or a disability, or when performing caregiver duties (for children, aging parents) on top of the daily self-care measures required for good health.

Respondents said that the nutritional aspect of diabetes management is challenging. Many mentioned not knowing what to eat and when, constantly wondering about the impact of intake on blood sugar and worrying about making the “right decisions” regarding food. They talked about being restricted in their choices and unsure about what options are appropriate when eating out. They alluded to the hassle of checking labels, counting carbs and trialing various diets. They mentioned challenges with exercise – making it part of a routine and managing resulting blood sugar variations. They also talked about dealing with weight gain or having to monitor weight as yet another consideration in managing their health. When it comes to monitoring blood sugar levels, many said that it is ongoing and burdensome; in some cases, monitoring was referred to as painful, unreliable and stressful. All of these aspects of diabetes management – healthy eating, regular physical activity, blood sugar monitoring – were described by many respondents as costly undertakings. People talked about the expense of engaging in these activities and the barrier that a high price and/or lack of public coverage or supports presents.

Respondents commented on the stigma they experience as a person living with diabetes and the difficulties they face within the health-care system. One person shared his story, saying “having too many doctors and health practitioners treat us as lying, lazy, gluttonous trash is demeaning and insulting. It's depressing and makes us avoid health care [sic] options for even non-dietary issues”. Another person mentioned “feeling I am not totally listened to”. They also spoke of the shame and guilt they experience as people living diabetes, especially when they feel they are implicating or burdening others in their own management.

Respondents said it is challenging to remember to take medication and that dosing and injecting insulin can be hard. Many people mentioned dealing with, and being apprehensive about, disease symptoms, medication side effects and diabetes complications. Respondents described generally being in pain, feeling unwell and



experiencing fatigue. People talked about the challenges of regulating blood sugar and dealing with the effects of fluctuations (highs and lows).

The impact of diabetes on mental health was something that respondents to the July/August survey also shared information about. They reported experiencing the following:

- depression
- a general sense of worry/anxiety
- diabetes distress (feelings of stress, guilt or denial in living with diabetes and the burden of self-management)
- diabetes defiance (e.g., eating a chocolate bar to express anger about diabetes)
- diabetes indifference/burnout
- post-traumatic stress disorder
- fear of hypoglycemia
- worry about not being able to afford diabetes medicines and supplies
- forgetting to check glucose levels or take medications
- emotional exhaustion
- negative social interactions due to diabetes (e.g., hurtful remarks, averting eyes during glucose test, teasing)

Below are some quotes from the two surveys from British Columbians and other Canadians that further illustrate the degree and extent to which diabetes affects daily living and quality of life of those with the disease:

*"Lots of time required for glucose monitoring and treating highs and lows. You never get a day to just relax."*

- caregiver to a person with type 2 diabetes living in British Columbia

*"Getting good healthy food is exceptionally expensive. Getting access to blood glucose monitoring is expensive as it is NOT fully covered. Getting access to supported physical assistance for movement and such is expensive."*

- caregiver to a person with type 2 diabetes living in British Columbia

*"Need to take several meds to control blood sugar."*

- person with type 2 diabetes living in British Columbia

*"I have built routines around my monitoring, exercise, medications, and eating so it doesn't intrude too much. I have continued to travel and do everything I always did."*



- person with type 2 diabetes living in British Columbia

*"Constant monitoring of levels, injecting insulin (2 types), limiting food options to low-carb, watching exercise exertion as it prompts a stress response and can cause spikes. Monitoring weight which is adversely affected by insulin use."*

- person with type 2 diabetes living in British Columbia

*"Numb feet. Days of nausea. Days of tiredness. Emotionally up and down."*

- person with type 2 diabetes living in British Columbia

*"Too many drugs and finger pokes."*

- person with type 2 diabetes living in British Columbia

*"It is an ongoing job, constantly testing, watching what you eat, making sure you get some exercise. It is a never-ending chore that you need to do to stay alive."*

- person with type 2 diabetes living in British Columbia

*"Diabetes influences every aspect of life, every day. It is a companion that no one wants. I am always wondering what is happening to my blood sugars. It is stressful to try to balance lifestyle with medicines and testing."*

- caregiver to a person with type 2 diabetes living in Saskatchewan

*"It has changed everything. I now think about every morsel of food that I put in my mouth. I plan my meals and watch every calorie. I feel like every workout I skip for any reason is harming me. When I get stressed at work, I'm enormously aware of the effects on my body. I have no bodily processes that happen without me having to monitor them. It consumes me."*

- person with type 2 diabetes living in Ontario

**Does this disease limit patients' ability to attend work or school?**

- No
- Yes

**On average, in the past 30 days, how many days did your patients miss from work or school as a result of this disease?**



These specific data are not available from the surveys conducted for this submission. However, research conducted by Diabetes Canada within the last few years revealed that 40% of people living with diabetes or caring for someone with diabetes miss work because of the disease, with many people requiring an extended period away from their job (more than a day here or there). The published literature has reported the negative impact of diabetes on employment, with an association between diabetes and high rates of absenteeism, productivity loss and early retirement. The burden of diabetes is felt by individuals and employers and has an effect on the workforce and economy as a whole.

It is also known that children regularly miss school because of diabetes-related illness and appointments. They are often excluded from various aspects of the education experience because of their disease (e.g., not able to participate in field trips because of a lack of protocols in place to address potential medical emergencies). Their ability to learn and participate in school can also be hindered by their diabetes, as blood glucose levels impact cognitive performance and ability.

### **Experience with Other Treatments**

**Please describe patients' experience with available treatments. Consider benefits, side effects, and route of administration.**

There were 13 respondents from across Canada who reported experience with antihyperglycemic agents in the November/December survey. The oral and injectable medications being taken at the time of survey completion included metformin (91%), SGLT2 inhibitors (44%), GLP-1 receptor agonists (38%), sulfonylureas (29%), combinations of DPP-4 inhibitors and metformin (22%), and DPP-4 inhibitors (17%). People also reported taking the following types of insulin: insulin glargine or insulin glargine biosimilar (50%), rapid-acting insulin (38%), intermediate-acting insulin (13%) and insulin glargine U300/other long-acting insulin (11%). Several respondents indicated that they had experience with certain medications in the past that they were no longer taking. These included sulfonylureas (43%), GLP-1 receptor agonists (25%), meglitinides (17%), SGLT2 inhibitors (13%), short-acting insulin (13%), premixed insulin (13%), U300/other long-acting insulin (11%) and metformin (9%).

Of the 13 respondents who provided information about medication, 54% reported being “very satisfied” or “somewhat satisfied” with their current treatments. When asked what



they like about their medications, one respondent said it helps with weight management. Another commented that it “isn’t insulin injections”.

About 31% of respondents said they were “somewhat dissatisfied” or “very dissatisfied” with their current treatments.” One person commented that he/she “want[s] to get off all of them”. Respondents shared the following feedback about what they dislike about their medications:

- ineffective regulation of post-prandial blood sugar levels
- expensive and not covered by the provincial drug plan
- difficult for someone with a disability to adjust independently
- cause gastrointestinal upset

The medication side effects experienced included:

- gastrointestinal issues (stomach pain, indigestion, nausea, vomiting, diarrhea, painful gas, flatulence)
- polyuria
- weight gain
- hypoglycemia
- genital infections
- mood swings
- muscle aches
- fatigue

When asked to compare their current medication regimen to previous courses of treatment, 55% of respondents said they are “much better” or “better” able now to meet their target fasting blood sugars. About 46% said that on current medications, they are “much better” or “better” able to meet their target blood sugar levels upon waking and 40% are “much better” or “better” able to meet their post-prandial blood sugar target. About 59% of respondents said they are now “much better” or “better” able to meet their target hemoglobin A1c levels and 46% are “much better” or “better” able to avoid hypoglycemia than before.

While 36% said they are “much better” or “better” able to maintain or lose weight on their current medication regimen, the same number reported gastrointestinal side effects to be “much worse” or “worse” on current meds. With respect to incidence and severity of yeast infections and urinary tract infections, while 27% and 18% respectively reported they were “much worse” or “worse” on current medications, the majority of respondents in both cases said their experience is “neither better nor worse” on their current regimen. People also shared that their current medications have made weight loss challenging, decreased appetite in some cases (and increased appetite in others), and contributed to emotional lability.



**Are there aspects of the disease that are not being addressed by current treatments?**

- No
- Yes

**What aspects of the disease are not being addressed?**

Respondents to the November/December survey expressed the following desires for diabetes treatments:

- reduced pill burden
- medications that have fewer unpleasant side effects
- less invasive route of administration for medications (i.e., medications that don't require an injection)
- therapies that allow people to resume a 'normal' way of living, to the greatest extent possible
- therapies that permit pharmacotherapy to be discontinued entirely
- more options for non-pharmacologic treatments (e.g., supports for healthy eating, access to nutrition education, more affordable exercise programs)
- greater access to supports that facilitate adherence to therapies (e.g., multidisciplinary diabetes care)
- greater investment into a diabetes cure

This feedback points to the following needs:

- more options for combination therapies
- longer acting medications
- oral forms of injectable medications
- more emphasis in practice on healthy behaviours/healthy behaviours + medications
- greater supports to make the healthy choice the easy choice
- better access to multidisciplinary diabetes care teams
- a cure for diabetes

**What trade-offs do patients consider when choosing therapy (e.g., more efficacy, less side effects)?**

The following considerations were reported as "very important" or "important" to respondents (n=12) when choosing pharmacotherapy for diabetes management:



- in 100% of respondents:
  - keeping blood glucose at satisfactory level during the day or after meals
- in 92% of respondents:
  - avoiding weight gain/reducing weight
  - avoiding gastrointestinal side effects (nausea, vomiting, diarrhea, abdominal pain)
- in 83% of respondents:
  - keeping blood glucose at satisfactory level upon waking or after fasting
  - avoiding low blood sugar during the day
  - avoiding low blood sugar overnight
  - reducing risk of heart problems
- in 75% of respondents:
  - avoiding urinary tract and/or yeast infections
  - avoiding fluid retention
- in 73% of respondents:
  - reducing high blood pressure

Below are some direct quotes from respondents that describe the things that are important to them when choosing a diabetes medication:

*"Effectiveness."*

- person with type 2 diabetes living in Alberta

*"That it works, and is covered."*

- person with type 2 diabetes living in Alberta

*"Staying healthy."*

- person with type 2 diabetes living in Saskatchewan

*"It would be nice not to have to remember to take a pill [two times a] day."*

- person with type 2 diabetes living in Ontario

*"It has to fit with my day. I take medication three times a day now."*

- person with type 2 diabetes living in Ontario



*"Is this helping with help with weight lost? If this gonna [sic] protect my kidneys and my heart? Is it save [sic] to use if I have retinopathy?"*

- person with type 2 diabetes living in Ontario

*"Helps keep blood glucose levels in control."*

- person with type 2 diabetes living in Nova Scotia

*"Maintain good A1c."*

- person with type 2 diabetes living in Newfoundland and Labrador

**Please describe patients' ability to access treatment. Consider factors such as financial barriers, social stigma, or any other factors beyond their control that may make it difficult to receive treatment (e.g., travel to clinic, time off work).**

The majority of respondents (75%) stated that they don't have trouble accessing their medications, though one expressed concern about benefits running out and being worried about the affordability of his/her treatments. Another said he/she fears his/her spouse will lose his/her job and subsequently not being able to pay for medications.

### **Drug-Related Questions**

**Do the patients you represent have any experience with the drug in question?**

- No
- Yes

**Please describe the positive and/or negative impacts this drug has had on patients' condition.**

Out of all respondents to the November/December survey, 23% (n=3; from Nova Scotia, Ontario and Alberta) are currently taking semaglutide (Rybelsus). Each person said the medication is covered fully or in-part by private insurance. No respondent residing in British Columbia reported any experience with semaglutide (Rybelsus).

The respondents currently on semaglutide (Rybelsus) said they like that the medication is helping them lose weight (or that it has the potential to help them lose weight) and that it is



an oral agent rather than an injectable. One person stated a preference for oral medications over injectables, because they're "easier to take", while another was indifferent ("injections don't bother me").

A respondent commented that he/she dislikes the loss of appetite and fear of eating experienced on semaglutide (Rybelsus). He/she said "if I had known the pill was going to make me this sick (vomiting and diarrhea for two months) I never would have started it...I don't leave the house. I don't eat. I don't enjoy food anymore. I am angry and irritable. My [spouse] is worried and tired...I have four other disabilities besides diabetes. Diabetes has now taken over my life and made me unable to leave the house, thanks to Rybelsus". Another person reported just having started the medication and trying to get used to it while dealing with some gastrointestinal side effects.

**How did this drug compare to other treatments patients have tried? Consider factors such as efficacy, side effects, and impact on quality of life.**

The following was reported about semaglutide (Rybelsus) (when respondents compared it to other medications they've taken):

- meeting target fasting blood sugar levels
  - "much better" or "better" – 67%
  - "about the same" – 33%
- meeting target blood sugar levels upon waking
  - "much better" or "better" – 33%
  - "about the same" – 67%
- meeting target blood sugar levels after meals
  - "much better" or "better" – 33%
  - "about the same" – 67%
- avoiding hypoglycemia (low blood sugar)
  - "much better" or "better" – 33%
  - "about the same" – 67%
- meeting target hemoglobin A1c levels
  - "much better" or "better" – 33%
  - "about the same" – 67%
- maintaining or losing weight
  - "much better" or "better" – 67%
  - "about the same" – 33%



- gastrointestinal side effects (diarrhea, nausea, vomiting, abdominal pain)
  - “about the same” – 33%
  - “worse or much worse” – 67%
- incidence of extreme thirst and/or dehydration
  - “about the same” – 67%
  - “worse or much worse” – 33%
- incidence/severity of yeast infections
  - “about the same” – 100%
- incidence/severity of urinary tract infections
  - “about the same” – 100%

**Are there subgroups of patients with this disease for whom this drug is particularly helpful? In what ways?**

This drug would be particularly helpful to people with type 2 diabetes who:

- prefer oral medications over injectable medications (for various reasons)
- are interested in weight management; semaglutide (Rybelsus) belongs to the class of GLP-1 receptor agonist medications, which are typically associated with weight loss

**Conclusion**

**Is there anything else you would like the Ministry to consider in their review of this drug?**

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 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 various other considerations.

To achieve optimal blood glucose levels, individualization of therapy is essential. This includes careful consideration of medication selection, route of administration (oral, injection, infusion), frequency and type of blood glucose monitoring, frequency and manner of managing dosage adjustments, 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 prescribers to the most appropriate choice and combination of treatments for disease management. Health-care providers must be supported in prescribing evidence-based therapies and, through public and private drug plans, patients should have access to a range of treatments that will allow them to optimize their health outcomes. For those paying out-of-pocket, costs should not be so high as to prohibit medication procurement.

While current therapies have generally led to improvement for many people with diabetes in blood glucose and hemoglobin A1c control, respondents hope for even more agents that they can access equitably and affordably, in a timely manner, and with good results to help them lead a normal life. Semaglutide (Rybelsus) may help people to achieve better glycemic control, which could potentially improve lives and save millions in direct health-care costs. For this reason, semaglutide (Rybelsus) should be an option on the provincial formulary for people living with diabetes in British Columbia.

Respondents shared the following final thoughts regarding their experience living with diabetes:

*"It is a burden that shapes all my daily decisions."*

- person with type 2 diabetes living in Alberta

*"I am getting so tired of all the meds they give me and the bad side effects I get."*

- person with type 2 diabetes living in Alberta

*"Once I leave my employment what will my costs be?"*

- person with type 2 diabetes living in Alberta

*"I'm about done with having [t]ype 2...I'd like to be cured from diabetes, and I'm sure everyone cursed with this disease feels the same."*

- person with type 2 diabetes living in Alberta

*"Diabetes affects my overall quality of life, my family's budget, how I plan meals and activities, and my level of concern about the pandemic."*

- person with type 2 diabetes living in Saskatchewan



*"It's time consuming - it requires testing multiple times a day - and unreliable - no matter how well you try to manage it, results aren't guaranteed."*

- caregiver to a person with type 2 diabetes living in Ontario

*"Always worrying about what I eat and when I eat. I always have to have my glucose kit and glucose meds with me in case of lows. I have to impose on friends and family when invited for dinner or get together because of a special diet. I have to read every label on everything to check in sugar and carb content. It's a daily burden that affects my quality of life and my mental health."*

- person with type 2 diabetes living in Ontario

*"It's all consuming all the time. Can I eat? Should I eat? What's [sic] my sugars? I hate it."*

- person with type 2 diabetes living in Ontario