

CADTH DRUG REIMBURSEMENT REVIEW

Patient Input

SEMAGLUTIDE (Rybelsus)

(Novo Nordisk Canada Inc.)

Indication: Diabetes mellitus, type 2

CADTH received patient input from:

Diabetes Canada

Type 2 Diabetes Experience Exchange

December 17, 2020

Disclaimer: The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations.

CADTH does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	TBC (semaglutide), Diabetes mellitus, type 2
Name of the Patient Group	Diabetes Canada
Author of the Submission	[REDACTED]
Name of the Primary Contact for This Submission	[REDACTED]
Email	[REDACTED]
Telephone Number	[REDACTED]

1. About Your Patient Group

If you have not yet registered with CADTH, describe the purpose of your organization. Include a link to your website.

Diabetes Canada is a national health charity representing approximately 11 million Canadians living with diabetes or prediabetes. Diabetes Canada leads the fight against diabetes by helping those affected by diabetes live healthy lives, preventing the onset and consequences of diabetes, and discovering a cure. It has a heritage of excellence and leadership, and its co-founder, Dr. Charles Best, along with Dr. Frederick Banting, is credited with the co-discovery of insulin. Diabetes Canada is supported in its efforts by a community-based network of volunteers, employees, health care professionals, researchers, and partners. By providing education and services, advocating on behalf of people living with diabetes, supporting research, and translating research into practical applications, Diabetes Canada is delivery on its mission. We will continue to change the world for those affected by diabetes through healthier communities, exceptional care, and high-impact research.

For more information, please visit: www.diabetes.ca.

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered **in Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

This submission contains patient input from online surveys conducted in November 2019, November 2018, and October 2016. The surveys were open for two weeks to people across Canada and consisted

of self-administered questionnaires. The surveys were directed at people living with type 2 diabetes and caregivers of people living with type 2 diabetes and inquired about respondents' lived experience with diabetes and diabetes medications, and expectations for new drug therapies in Canada. Further, the November 2019 and November 2018 surveys posed several questions specifically about the drug under review, semaglutide. Awareness about the surveys was generated through Diabetes Canada's social media channels (Twitter and Facebook); the October 2016 survey was also advertised to Diabetes Canada email subscribers through e-blasts.

The November 2019 survey had 20 respondents; 19 identified as living with type 2 diabetes while one identified as a caregiver to someone living with type 2 diabetes. Of the 20 respondents, eight indicated their age and date of diagnosis. The eight respondents varied in age, 62.5% were between the ages of 25 and 69 years, and 37.5% were over 70 years old. Further, of the eight respondents, 50.0% reported having lived with diabetes for 1 to 10 years and the other 50.0% reported having lived with diabetes for 11 to 20 years.

The November 2018 survey had 15 respondents; 13 respondents identified as living with type 2 diabetes while two identified as being a caregiver to someone living with type 2 diabetes. Of the 15 respondents, 6 indicated their age and date of diagnosis. Of the 6 respondents, all were over the age of 40 years, with 33.3% each in the 40-54, 55-69, and over 70-year age categories. The majority (n=4, 66.7%) reported having lived with diabetes for 6 years or more.

The October 2016 survey had 847 respondents; 790 respondents identified as living with type 2 diabetes while 57 identified as being caregivers to someone with type 2 diabetes. Of the respondents who indicated their age and date of diagnosis (n=379, 44.7%), 70.1% (n=266) were over the age of 55, with the largest number of respondents (55.7%, n=211) in the 55-69 year old category, and 60.2% (n=228) having lived with diabetes for over 10 years (17.2% of this group reported having lived with diabetes for over 20 years).

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

Diabetes is a chronic, progressive disease with no known cure. Type 1 diabetes occurs when the body produces either little or no insulin. 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 precipitate an acute crisis, such as confusion, coma, and/or seizure that, in addition to being dangerous themselves, 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.

Most respondents who participated in the November 2019, November 2018, and October 2016 survey spoke negatively of their experiences living with diabetes. Respondents expressed that diabetes is "manageable but a bother", "a constant battle every day", "a terrible way of life", an "emotional rollercoaster", inconvenient, frustrating, exhausting, and a constant source of worry. One respondent said it just "isn't fun to have to live with", while another commented "it has been life changing, not in a good

way.” A third responder indicated that their “whole life style has been changed.” A fourth respondent mentioned “it has definitely impacted my life and the things that I used to do, that I don't enjoy doing any longer”. Several people spoke about its permanence, emphasizing that there is no “holiday” from diabetes.

The majority of survey respondents spoke about the adverse impacts diabetes has had on their lives. They indicated that they are constantly thinking about and planning around their disease. Further, that diabetes affects their everyday activities including eating, exercising, working, and socializing. Overall, diabetes makes it difficult to be flexible and spontaneous, as it requires a rigid schedule. It is always at the center of decision-making and can be very stressful. Diabetes can be even more difficult to manage when someone is also dealing with diabetes-related complications, other comorbidities and disabilities, or is a caregiver to others. Constant monitoring of blood sugar levels and frequent visits to health care providers were described as burdensome.

Respondents indicated that meal timing, intake, and food choices are restricted, which takes away from the pleasure of eating, and that it is demoralizing to always be receiving diet instructions from people (e.g., health care providers, family, strangers) about what they should be consuming and avoiding. Further, respondents said it is challenging to always be taking medication and to experience variability in blood sugar control. 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.

A majority of the respondents mentioned dealing with, and being apprehensive about, disease symptoms, medication side effects, and diabetes-related complications. Respondents described being chronically in pain and feeling tired a lot. They cited problems ranging from weight management issues, neuropathy and nephropathy, to amputations, changes to circulation and increased risk of heart attack, vision problems, and sexual changes. They reported living with depression and anxiety.

Respondents to the October 2016 survey indicated that they experienced the following symptoms and condition “sometimes” (“moderately”), “often” (“severely”) or “very often” (“very severely”) (n= 691):

- Hyperglycemia (75.1%)
- Hypoglycemia (38.1%)
- High blood pressure (51.1%)
- High cholesterol (48.2%)
- Heart problems (17.7%)
- Mental health problems (30.1%)
- Kidney symptoms or disease (18.8%)
- Foot problems (44.9%)
- Eye problems (41.5%)
- Nerve damage (37.4%)
- Damage to blood vessels, heart or brain (10.1%)
- Liver disease (9.4%)

People shared that diabetes has negatively affected their relationship and lifestyle. It has made it hard for them to work, travel, be flexible, and drive a vehicle – one respondent mentioned experiencing challenges with a driver's license renewal because of diabetes. Diabetes decreases independence. People are fearful of complications and concerned about the long-term effects of the disease on their health, which can be emotionally taxing. They also mentioned the significant and overwhelming financial burden diabetes poses on themselves and their families.

Below are some quotes from survey respondents that further illustrate the degree and extent to which diabetes affects daily living and quality of life:

"Diabetes requires me to maintain a rigid schedule to ensure that my blood glucose levels are within a safe range. While at work, planning meetings and travel is harder as I have to have meals at regular times to ensure that my blood glucose levels don't go to low."

"Takes lots of work to figure out when and what to eat. It is quite expensive for the medications I take and I am low income senior and I worry about that a lot."

"These past couple of months I have very bad neuropathy[sic] pain in both feet...I do not have any med insurance so the costs of all of my drugs come out [of] our monthly income."

"I've been a type 2 diabetic for almost 20 years now and I'm very frustrated with my health! I heal slowly, I get hungry quickly...I need more sleep, my skin is so dry no matter what I do...and I can't loose[sic] weight."

"We liked to go to different restaurants and that is now limited as many do not have diabetic friendly[sic] food. Also there is a stigma associated with diabetes that others frown on things like taking your insulin in public...Never been able to see an educator for learning to use insulin, it has all been trial and lots of error, not much information available to starting on it."

"Diabetes[sic] has resulted in the need for dietary changes for everyone in the house. I have neuropathic pain that sometimes makes it difficult to rest comfortably and to be as active as I normally would. I need to pay extra attention to my feet to make sure I don't have sores or infections, as they could take longer to heal than if I was not diabetic. I also have nephropathy, which I hope never progresses to chronic kidney disease."

"I am a...mother...and hate the fact that I have developed diabetes and have to take medications for it. This disease gets in the way all the time (more trips to the doctor, more trips to the pharmacy, having to remember to take my medication and ensuring that I don't take too much medication so that I can drive my vehicle). My kids have to know what to do if I pass out, and that isn't the type of responsibility that young children should have."

"I have neuropathy in my legs and hands. I have diabetic neuropathy in my eyes. I can't drive any more and have to rely on help from family and [an accessible transit service]. I was off for a year with Charcots[sic] foot. I walk with a cane now. Before this happened I was walking 5 kms[sic] a day. Im[sic] lucky if I get to the end of my driveway. Diabetes has taken away all my independence[sic]."

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

In the November 2019 survey, 11 respondents reported their experiences using anti-hyperglycemic agents. The medications being taken by respondents at the time the survey was completed included: GLP-1 receptor agonist (n=4), DPP-4 inhibitor (n=2), DPP-4 inhibitor combined with metformin (n=1), SGL2 inhibitor (n=5), sulfonylurea (n=1), metformin (n=6), and meglitinide (n=1). Further, seven respondents were taking insulin. A few respondents cited use of certain medications in the past. These included GLP-1 receptor agonist (n=4), DPP-4 inhibitor (n=4), DPP-4 inhibitor combined with metformin (n=1), sulfonylurea (n=5), metformin (n=3), and orlistat (n=1). Reasons for discontinued use of these medications were not provided.

There were ten respondents who provided input on how their current medications compare to their past medications. Of those respondents, at least 50.0% said they were “better” or “much better” able to meet target blood glucose levels during fasting period (n=9), upon waking (n=7), and after eating (n=8). Further, of the ten respondents, at least 50.0% said they were “better” or “much better” able to avoid hypoglycemia (n=5), meet target hemoglobin A1c (n=6), and maintain or lose weight (n=5). On current medications, the following were cited as “about the same as before” by at least 33.3% of respondents: the occurrence of bone fractures, urinary tract infections, lung or upper respiratory infections, thirst and/or dehydration, and maintaining or losing weight. Four of the respondents indicated that their ability to avoid hypoglycemia, gastrointestinal side effects, or occurrence of yeast infections was “worse” on their current medication compared to their previous medications.

There were 667 respondents who reported their experiences with antihyperglycemic agents in October 2016. The medications being taken at the time of survey completion included metformin (n=371), GLP-1 receptor agonists (n=312), SGLT2 inhibitors (n=165), combination of SGLT2 inhibitors and metformin (45), DPP-4 inhibitors (72), combination of DPP-4 inhibitors and metformin (147), sulfonylureas (n=140), TZDs (n=10), combination of TZDs and metformin (n=17), combination of TZDs and glimepiride (n=4), meglitinides (n=9), and acarbose (n=9). Many people reported taking insulin (n=309). A number of respondents indicated that they had experience with certain medications in the past as part of a clinical trial. Some reported stopping certain medications due to reasons other than the end of a clinical trial. The most commonly cited medications in this group were TZDs (n=97), sulfonylureas (n=94), GLP-1 receptor agonists (n=94), and DPP-4 inhibitors (n=92).

Over 60% of respondents to the October 2016 questionnaire noted improvements in meeting target blood glucose levels (fasting, post-prandial, upon waking) and hemoglobin A1c levels after initiation on their current medication regimen, compared to before (when they were not on treatment). Approximately 46% said they were “better” or “much better” able to avoid hypoglycemia, and 39% said their current regimen helped them maintain or lose weight more effectively than in the past. Gastrointestinal side effects were “neither better nor worse” than previously in 39% of respondents. Close to two-thirds of participants indicated they were either “satisfied” or “very satisfied” with the medication or combination of medications they are currently taking for their diabetes management.

Below are direct quotes from respondents to the November 2019, October 2018, and October 2016 surveys that describe what they like and dislike about current therapy:

“Ease of administering them and their effectiveness.”

- 40-54 year old person with type 2 diabetes, diagnosed 1-2 years ago,

taking a GLP-1 receptor, SGLT inhibitor, and insulin.

"Its seeming to keep my blood sugar in a reasonable range most of the time"

- Person over 70 years old with type 2 diabetes, diagnosed 11-20 years ago, taking metformin and insulin.

"Nothing stands out though i[sic] would rather carry less meds in general if there were combined dosages."

- Person with type 2 diabetes taking GLP-1 receptor agonist, SGLT2 inhibitor, metformin, and meglitinide.

"The insulin my husband takes helps control his blood sugar levels. He tests his blood sugar level 3 times a day and adjusts his food intake accordingly."

- Caregiver to a person with type 2 diabetes taking metformin and insulin.

"Needles to administer insulin twice daily is[sic] painful but necessary. Current medications do not cause adverse side effects."

- 55-69 year old person with type 2 diabetes, diagnosed 6-10 years ago, taking combination of SGLT2 inhibitor, and metformin, and insulin.

"[A GLP-1 receptor agonist] has so far been the best choice for me. The only dislike I have is that it causes the odd nausea and gut discomfort."

- Person with type 2 diabetes taking a GLP-1 receptor agonist, metformin, and insulin.

"I have no [gastrointestinal] disturbance with my current meds[sic]. This is much better than when taking previous meds."

- 55-69 year old person with type 2 diabetes, diagnosed more than 20 years ago, taking metformin and insulin.

"[A GLP-1 receptor agonist] has been excellent, has decreased very substantially my need for both basal and bolus insulin as well as other medications, reduced hypoglycemia and achieved weight loss."

- Person over 70 years old with type 2 diabetes, diagnosed more than 20 years ago, taking a GLP-1 receptor agonist, SGLT2 inhibitor, metformin, and insulin.

"I have had poor control of my blood sugars over the years. I have tried products that either did nothing or caused more problems. [A GLP-1 receptor agonist] is assisting with better control. However, if my husband's health plan from work didn't cover it, I wouldn't be able to take it as the cost is about [a few hundred dollars] per. I take a lot of meds and wish I didn't have to."

- 40-54 year old person with type 2 diabetes, diagnosed more than 20 years ago, taking a GLP-1 receptor agonist, metformin, and insulin.

"I feel like I take a huge amount of meds for diabetes and [a second health condition]. Its[sic] scary at times. As my benefits are capped, it is expensive - very. I'd like to say I feel great, but those days are rare."

- Person diagnosed with type 2 diabetes taking an SGLT2 inhibitor, metformin, and insulin.

"There are so many of them [medications] and they cause a[sic] extreme dry mouth, nausea and diarrhea."

- 40-54 year old person with type 2 diabetes, diagnosed 11-20 years ago, taking a GLP-1 receptor agonist, metformin, and insulin.

"I dislike the amount of injections that I have to take in order to maintain control over my sugar levels."

- 25-39 year old person with type 2 diabetes, diagnosed 6-10 years ago, taking a GLP-1 receptor agonist, metformin, and insulin.

5. Improved Outcomes

CADTH is interested in patients' views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

When asked about their expectations for new diabetes therapies, respondents to the November 2019, November 2018, and October 2016 surveys expressed a strong desire for medications that can normalize/stabilize blood glucose levels and improve hemoglobin A1c without causing weight gain or hypoglycemia. They wish for new treatments that have been proven to be safe, minimize side effects and damage to organs, and improve health outcomes. Patients want affordable drug options; ideally, they would like medications and diabetes devices to be covered by public and private plans. They want treatments that are easily administered, that cause the least amount of disruption to lifestyle, and allow for flexibility with food intake and choices. They also want medications that minimize the risk of diabetes-related complications and that avoid polypharmacy. Several respondents hope future treatments will reverse or cure diabetes.

Below is feedback from respondents indicating what they desire in new treatments, the improvements they would like to see made to therapies, and the impact these would have on daily life and overall quality of life:

"Allow for a better quality of life, while reducing side effects and damage to other organs and protecting/enhancing cardiovascular health."

"Able to assist in maintaining normal BG levels while reducing the overall # of meds taken. Some point in the future to reverse the disease."

"Someday it would be lovely to just medicate once a month!"

"Hopefully easier attainment of targets, reduction of complication risks and less of a burden of disease."

"Improve diabetes control and health outcomes. I hope that these medications will be covered and available for all patients living with diabetes."

"I wish it was more affordable for the masses and covered by FNIHB [First Nations and Inuit Health Branch, Health Canada] for First Nation patients."

"Manage diabetes effectively without needing such a large variety of medications."

"Control glucose levels, cause little or no side effects, be reasonably priced."

"I hope that new drugs will eventually cure diabetes."

"I am hoping that the newer drugs are approved quicker by my insurance company."

"Expectations are that eventually there will be a medication that can be taken once a day that will help my pancreas produce the right amount of insulin to keep up with"

me (or possibly even cure the disease). I would hope that medications are made available to anyone living with diabetes and covered under by our government benefits.”

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways? If applicable, please provide the sequencing of therapies that patients would have used prior to and after in relation to the new drug under review. Please also include a summary statement of the key values that are important to patients and caregivers with respect to the drug under review.

Of those who participated in the November 2019 survey and responded to the questions specific to semaglutide (n=10), 30.0% reported taking semaglutide, 60.0% have never taken it, and 10.0% do not know whether they were on it. All three respondents who reported using semaglutide, indicated having switched to it from another medication and have their prescription covered through a private insurance plan. One respondent said semaglutide was better at helping them achieve their target hemoglobin A1c than previous therapies and one respondent said they did not know whether it was helping them achieve their target hemoglobin A1c. However, two respondents indicated that it was much better at helping them meet their target fasting blood glucose levels. One respondent reported semaglutide as “better” at helping them avoid low blood sugar and gastrointestinal side effects, while another responded indicated that it was “worse”. Further, two respondents indicated that they were very satisfied with the use of semaglutide.

7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments.

What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?
- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

TBC (semaglutide) does not have a companion diagnostic, therefore this question is not applicable to our submission.

8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

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 treatment modalities 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, pen, or pump), frequency with which someone monitors blood glucose and adjusts dosage, 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 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, in a timely manner, and with good result to help them lead a normal life. Semaglutide may help people to achieve better glycemic control, which could potentially improve lives. For this reason, TBC (semaglutide) should be an option for people living with diabetes.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

There was no assistance from outside Diabetes Canada to complete this submission.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

There was no assistance from outside Diabetes Canada to collect or analyze data used in this submission.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Samantha Ghanem, MSc
Position: Manager, Health Research and Policy Analysis
Patient Group: Diabetes Canada
Date: December 11, 2019

CADTH Reimbursement Review Patient Input Template

Name of the Drug and Indication	semaglutide (Rybelsus) diabetes mellitus, type 2
Name of the Patient Group	Diabetes Canada
Author of the Submission	██████████
Name of the Primary Contact for This Submission	██████████
Email	████████████████████
Telephone Number	██████████

1. About Your Patient Group

Describe the purpose of your organization. Include a link to your website.

Diabetes Canada is a national health charity representing over 11 million Canadians living with diabetes or prediabetes. The priorities of our mission are diabetes prevention, care and cure. Our focus on research and policy initiatives helps us to deliver impact at a population level, and our partnerships broaden our reach in communities across the country. We drive excellence in disease management by putting practical, evidence-based tools into the hands of health-care providers. We advocate for environments that make the healthy choice the easy choice. We continue our search for a cure, as well as for better prevention and treatment strategies, by funding the work of innovative scientists. In 1921, Canada changed diabetes for the world with the discovery of insulin. In 2021, we will change the world for those affected by diabetes through healthier communities, exceptional care, and high-impact research. For more information, please visit: www.diabetes.ca.

2. Information Gathering

CADTH is interested in hearing from a wide range of patients and caregivers in this patient input submission. Describe how you gathered the perspectives: for example, by interviews, focus groups, or survey; personal experience; or a combination of these. Where possible, include **when** the data were gathered; if data were gathered in **Canada** or elsewhere; demographics of the respondents; and **how many** patients, caregivers, and individuals with experience with the drug in review contributed insights. We will use this background to better understand the context of the perspectives shared.

This submission contains patient input from online surveys conducted in July/August 2020 and November/December 2020. 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. It was advertised through Diabetes Canada's, JDRF's and Type 1 Together's social

media channels (Facebook, Twitter, Instagram and LinkedIn) and by e-mail to Diabetes Canada volunteer advocates.

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. It was advertised through Diabetes Canada's social media channels (Facebook, Twitter, Instagram and LinkedIn) and by e-mail to members of the Diabetes Canada Professional Section.

A total of 873 people participated in the July/August survey – 36 identified as living with type 2 diabetes while 4 said they were caregivers to somebody with type 2 diabetes. Respondents resided in Quebec, Ontario, Manitoba, Saskatchewan, Alberta and British Columbia, with the most representation in Ontario (n=15) and British Columbia (n=15). The majority of respondents 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; most were in the 11-20 year range (n=16).

Fewer people participated in the November/December survey (n=15) – 13 people said they live with type 2 diabetes and 2 are caregivers to somebody with type 2 diabetes. Respondents resided in Newfoundland and Labrador, Nova Scotia, Ontario, Manitoba, Saskatchewan, Alberta and British Columbia; the highest number of people were from Ontario (33%, n=5). 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).

3. Disease Experience

CADTH involves clinical experts in every review to explain disease progression and treatment goals. Here we are interested in understanding the illness from a patient's perspective. Describe how the disease impacts patients' and caregivers' day-to-day life and quality of life. Are there any aspects of the illness that are more important to control than others?

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 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 can be quite serious and problematic. Low blood glucose 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 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 prevent or delay complications.

From both surveys, some respondents were very positive about their life with diabetes. 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 it is frustrating, difficult and tiring to manage

their diabetes. They said 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”; several others made similar statements, illustrating an all-consuming nature to 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. One person said “you never get a day to just relax”. 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).

When asked more specific questions about comorbidities, respondents to the July/August survey reported experiencing the following symptoms and conditions:

- 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

Other problems cited include skin infections, gastrointestinal disturbances (nausea, diarrhea), metabolic changes, arthritis, lymphedema and other autoimmune disorders.

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)

Respondents to the November/December survey reported comorbidity incidence, as follows (n=14):

- high blood pressure: 64%
- abnormal cholesterol levels: 29%
- mental health concerns: 43%
- eye problems: 29%
- weight management issues: 79%

Other problems cited include fibromyalgia, chronic fatigue, epilepsy, and celiac disease.

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

“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.”

“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 [sic] sugar and carb content. It's a daily burden that affects my quality of life and my mental health.”

“Decreases quality of life, making it hard to stay positive, difficult to find excellent information re: [type 2 and] proper eating, testing, etc. Government [sic] seem to not care if the items they approve...are the best for the patients.”

“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.”

“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.”

“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.”

“I do not have symptoms when I experience a low. They happen mostly at night, while I'm asleep. Going to sleep was terrifying before I started using a...[continuous glucose monitor], because, even if I woke up several times each night to take a finger-poke blood glucose test, my lows were sudden and unpredictable. I was exhausted, irritable and stressed out. This anxiety didn't help my glucose levels. My husband always wondered if this night, or that night, would be our last together. I had spent the years before acquiring a [continuous glucose monitor] allowing diabetes to control my every waking minute. A literal slave to this relentless disease.”

“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.”

“It is a burden that shapes all my daily decisions.”

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

4. Experiences With Currently Available Treatments

CADTH examines the clinical benefit and cost-effectiveness of new drugs compared with currently available treatments. We can use this information to evaluate how well the drug under review might address gaps if current therapies fall short for patients and caregivers.

Describe how well patients and caregivers are managing their illnesses with currently available treatments (please specify treatments). Consider benefits seen, and side effects experienced and their management. Also consider any difficulties accessing treatment (cost, travel to clinic, time off work) and receiving treatment (swallowing pills, infusion lines).

There were 13 respondents 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%), combination of DPP-4 inhibitors and metformin (22%), and DPP-4 inhibitors (17%). Many people also reported taking insulin as follows: 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 taking medication, 54% reported being “very satisfied” or “somewhat satisfied” with their current treatments. About 31% of respondents said they were “somewhat dissatisfied” or “very dissatisfied” 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”. In terms of what they dislike, respondents shared the following feedback: medications cause gastrointestinal upset, are difficult for someone with a disability to adjust independently, are expensive and not covered by the provincial drug plan, and aren't effective at regulating post-prandial blood sugar levels. One person said that he/she “want[s] to get off all of them”. When asked about side effects experienced, the following were reported: gastrointestinal issues (stomach pain, indigestion, nausea, vomiting, diarrhea, painful gas, flatulence), polyuria, weight gain, hypoglycemia, genital infections, mood swings, muscle aches and 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 said gastrointestinal side effects were “much worse” or “worse”. When it comes to incidence and severity of yeast infections and urinary tract infections, although 27% and 18% respectively said they were “much worse” or “worse” on current medications, the majority of respondents in both of these cases said their situation with respect to these side effects is “neither better nor worse” on their current regimen. People also reported that their current medications have made weight loss challenging, caused them in some cases to lose their appetite and in others to be hungry all the time, and contributed to emotional lability.

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 job and subsequently not being able to pay for medications.

Respondents who answered this question (n=12) reported the following considerations as “very important” or “important” when choosing pharmacotherapy for diabetes management:

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

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

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

“Maintain good A1c.”

“It has to fit with my day. I take medication three times a day now.”

“Effectiveness.”

“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?”

“Staying healthy.”

“That it works, and is covered.”

“To help keep blood glucose levels in control.”

5. Improved Outcomes

CADTH is interested in patients' views on what outcomes we should consider when evaluating new therapies. What improvements would patients and caregivers like to see in a new treatment that is not achieved in currently available treatments? How might daily life and quality of life for patients, caregivers, and families be different if the new treatment provided those desired improvements? What trade-offs do patients, families, and caregivers consider when choosing therapy?

When asked about their expectations for new diabetes therapies, respondents to the November/December survey expressed a strong desire to reduce their pill burden or to be off medication entirely. They'd like new therapies to allow them to resume 'normal living' to the greatest extent possible (e.g., to be able to eat without restrictions). They want treatments with fewer unpleasant side effects that are less physically invasive (i.e., don't require an injection). They also wish for ways to self-monitor blood sugar that eliminate the need for finger pricks. Several respondents said that they would like to see more investments into non-pharmacologic treatments for diabetes, like affordable exercise programs and nutrition education. One respondent talked about the need for greater access to allied health professionals and the benefit to management of multidisciplinary diabetes care. Several respondents hope future treatments will cure diabetes and are calling for more investment in diabetes research.

Below, respondents provided input on what they desire in new treatments and the improvements they'd like to see to therapies:

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

"I would take fewer pills, less often. I would enjoy eating again. The new treatment would not irritate my stomach."

"I'd like to see funding for [research]."

"No more pokes, sharps, lancets."

"New treatment must be [sic] supervised exercise program!...Could we meet our diabetes team (dietitian, nurse, [doctor]) in a gym while having free supervised exercise program by a kinesiologist anywhere in Canada[?]....Elementary school students need education with a dietitian in early age combined with their gym classes."

"Be able to afford a gym pass and a trainer to help [sic] exercise and get healthy."

"We need a team of professionals working with us. Dieticians [sic], nurses, psychologists and coaches."

"A cure."

6. Experience With Drug Under Review

CADTH will carefully review the relevant scientific literature and clinical studies. We would like to hear from patients about their individual experiences with the new drug. This can help reviewers better understand how the drug under review meets the needs and preferences of patients, caregivers, and families.

How did patients have access to the drug under review (for example, clinical trials, private insurance)? Compared to any previous therapies patients have used, what were the benefits experienced? What were the disadvantages? How did the benefits and disadvantages impact the lives of patients, caregivers, and

families? Consider side effects and if they were tolerated or how they were managed. Was the drug easier to use than previous therapies? If so, how? Are there subgroups of patients within this disease state for whom this drug is particularly helpful? In what ways? If applicable, please provide the sequencing of therapies that patients would have used prior to and after in relation to the new drug under review. Please also include a summary statement of the key values that are important to patients and caregivers with respect to the drug under review.

Out of all survey respondents who answered this question, 23% (n=3) are currently taking semaglutide (Rybelsus). Each person reported having the medication covered fully or in-part by private insurance. Respondents reported the following about how effective semaglutide (Rybelsus) is at the following when compared 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%

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 said “injections don't bother me”. A respondent commented that he/she dislikes the loss of appetite and fear of eating brought on by 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 said he/she has just started the medication and is trying to get used to it while dealing with some gastrointestinal side effects.

7. Companion Diagnostic Test

If the drug in review has a companion diagnostic, please comment. Companion diagnostics are laboratory tests that provide information essential for the safe and effective use of particular therapeutic drugs. They work by detecting specific biomarkers that predict more favourable responses to certain drugs. In practice, companion diagnostics can identify patients who are likely to benefit or experience harms from particular therapies, or monitor clinical responses to optimally guide treatment adjustments. What are patient and caregiver experiences with the biomarker testing (companion diagnostic) associated with regarding the drug under review?

Consider:

- Access to testing: for example, proximity to testing facility, availability of appointment.
- Testing: for example, how was the test done? Did testing delay the treatment from beginning? Were there any adverse effects associated with testing?

- Cost of testing: Who paid for testing? If the cost was out of pocket, what was the impact of having to pay? Were there travel costs involved?
- How patients and caregivers feel about testing: for example, understanding why the test happened, coping with anxiety while waiting for the test result, uncertainty about making a decision given the test result.

Semaglutide (Rybelsus) does not have a companion diagnostic.

8. Anything Else?

Is there anything else specifically related to this drug review that CADTH reviewers or the expert committee should know?

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 with which someone monitors blood glucose and adjusts dosage, 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 additional affordable agents that they can access equitably, in a timely manner, and with good result 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 for people living with diabetes.

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

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

“Most important [treatment] is supervised exercise [sic] program and to have access to your diabetes team at the gym...Not at the hospital and not [sic] [doctor’s] office.”

“Once I leave my employment what will my costs be?”

“I’m about done with having [t]ype 2. When there is a potential cure on the table, with the only thing stopping clinical trials is funding, I have to wonder why that’s even an issue. I’d like to be cured from diabetes, and I’m sure everyone cursed with this disease feels the same.”

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

Diabetes Canada had no outside assistance to complete this submission.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

Some of the data contained in this submission derive from a survey conducted in July/August 2020 that was jointly created by Diabetes Canada, JDRF and Type 1 Together. JDRF and Type 1 Together helped to advertise the survey through their organization's social media sites.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000

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 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.

Please see the attached list of Diabetes Canada's financial contributors.

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Ann Besner, MScA
 Position: Manager, Research and Public Policy
 Patient Group: Diabetes Canada
 Date: December 17, 2020

Diabetes Canada Financial Contributors

\$400,000+

Eli Lilly Canada, LifeScan Canada, Merck Canada, Novo Nordisk Canada

\$150,000-\$399,999

Ascensia Diabetes Care, AstraZeneca Canada, IA Financial Group, Janssen, Medtronic of Canada, Sanofi Canada, Scotiabank, Sun Life Financial

\$50,000-\$149,999

Abbott Diabetes Care, Boehringer Ingelheim (Canada), Dexcom Canada, Great-West Life Assurance Co., Insulet Canada, Manulife Financial, Medavie Health Foundation

\$25,000-\$49,999

Cenovus Energy, Danone Canada, Greeniche Natural Health, Hecla Mining Company, Heartland Food Products Group, McNeil Consumer Healthcare, Nestle Health Science, Pharmasave Central, Rexall Foundation, Ritchie Bros Auctioneers, Rubicon Pharmacies Canada, SaskCanola, Sweet and Friendly Co.,

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Semaglutide - diabetes mellitus, type 2
Name of the Patient Group	Type 2 Diabetes Experience Exchange
Author of the Submission	██████████
Name of the Primary Contact for This Submission	██████████
Email	██████████████████
Telephone Number	██████████

1. About Your Patient Group

Working under the principle that a story tells more than a survey, the T2D Experience Exchange <http://www.t2dxx.com/> creates an open, safe, and non-judgmental space to share your personal experience. Our Experience Exchanges are known to kick start new collaborative conversations in how we define, understand, and most importantly improve the outcomes and quality of life of the type 2 patient journey.

T2DXX is a community that exceeds 1,600 Canadians living with Type 2 Diabetes and our content is viewed by over 50,000 people per month. We're creating new opportunities to share the stories of people living with Type 2 Diabetes, in social media, video, the web and elsewhere, to influence, invite and inspire a reimagining of our perceptions of the experience of T2D.

2. Information Gathering

The Type 2 Diabetes community is disparate and multifaceted. People with Type 2 Diabetes are not a homogenous lot like those with Type 1 and their experience is not exclusively related to nationality. Understanding these differences is key to appreciating the Type 2 lived experience.

Data sources include:

- personal interviews and facilitated group discussions in our Experience Exchange forums
- social media conversation threads

3. Disease Experience

It's official. Living with Type 2 Diabetes is a non-stop balancing act in living between extremes. But even with diligence, patients pay a price with multiple complications including heart disease, nerve damage (neuropathy), kidney damage (nephropathy), eye damage, foot damage, hearing impairment, and skin conditions. It is very complex and has a striking burden on the physical, emotional, social, and economic status of the person.

The Type 2 Diabetes Diagnosis: Emotions

First, you grieve

A diagnosis of Type 2 Diabetes means the end of life as you've lived it.

Adding to the shock is the perception: Type 2 is the 'bad' diabetes. The one you've brought on yourself by your overindulgent lifestyle. Type 1 is seen as the 'good' diabetes: beyond your control.

Rarely is this the case: Type 2 Diabetes is most often 'written in the genes', thus confounding even the most diligent of health efforts.

■■■■ became an advocate as a result of seeing the impact of this devastating condition on her father and nephew, which evolved into her becoming a resource and Opinion Leader.

With a Type 2 diagnosis, going through the stages of grief is not uncommon: denial, anger, bargaining, depression and eventually – hopefully – choosing to accept.

But even with acceptance, this cycle of grieving is not finite. When you are diagnosed with a complication or told your A1C is higher and need a new medication, etc., the cycle of grieving can repeat.

When asked what one word describes their diagnosis, the dominant response from a group of 15 patients was "overwhelmed".

- ***Poorly managed health affects work opportunities. Disability as a result of complications such as limb amputation, the absence of employee benefits programs especially among lower income populations, interferes with capacity to self-manage and afford the costs of care and magnifies the physical impact of illness.***

Anger and denial

Even for those in ethnicities at high risk of T2, acceptance of a diagnosis can be devastating. ■■■■ is a nurse and Opinion Leader who, on a whim - and well into her career – decided to test herself: Being as she was in the hospital on the Diabetes unit. That was in 1989.

■■■■ (who gives an infectious giggle as she explains, 'it's pronounced like the Opera') is slim and fit and is certainly no slouch. When others might think of retiring, she's embarking on new careers as a radio and tv 'star'

A family history of diabetes meant ■■■■'s genes were indeed pre-programmed but that doesn't mean she expected her diagnosis,

7 years ago. Her reaction was to go into denial. As with many T2s, she felt no differently than before being diagnosed.

When ■■■■'s Diabetes required an insulin injection, she felt her reality shift. "I hate needles, even tho I have the tiniest one, I hate injecting myself. And I have to do this whenever my sugars aren't controlled."

Depression and bargaining

■■■■ and ■■■■ agree: "It's depressing, getting a diagnosis of Type 2 Diabetes".

- ***For anyone with diabetes, experiencing negative emotions such as anger, frustration, guilt and shame is very common as is depression. "Diabetes Distress", an attitude of feeling defeated by diabetes, affects a person in many ways.***

Trying to manage is often an emotional rollercoaster. In a video produced by Northwestern University's School of Communication specifically for medical school residents to better understand the lived experience, a young woman looks into the camera, her face full of confusion and upset. "This can't be. How can my values be so skewed? I thot I did everything right." She rhymes off her new rituals on her fingers: "I measured the protein, I exercised, I meditated, I injected." and as she says this, the very finger

she's using to count off her list of 'rights' begins to leak blood. Her shoulders sag. She shakes her head, looking at her hands. "My fingers," she says, almost to herself, 'Now they leak all the time.'

Acceptance

■■■■'s dedication as an Opinion Leader takes many different forms: care_giver for his first wife with Lupus, President (Past) of the Optimist club, he works with disabled children as one of their many projects, Canadian Diabetes Association Volunteer of the Year and a Patient Educator for people with Arthritis.

As with many trying to manage Type 2 Diabetes, lives are already complicated by other health conditions. To explain his head to toe issues, ■■■■ stands up to demonstrate starting with his balding head, ending 'an with enlarged aorta - I've got a big heart.'

Changing habits is hard enough for those who don't have Type 2 Diabetes – as evidenced by an industry devoted losing weight and healthy lifestyle strategies – which always include exercise. Another tough one even for the most determined.

This group of patient and caregivers are each Opinion Leaders who are committed to improving their own lives, and the lives of others with T2D.

They combine support and advocacy with a healthy dose of humour:

■■■■■ is slim, keeps a healthy diet and gets in a certain amount of activity in her job as head of a Diabetes Management Center, and has managed her Type 2 Diabetes for 22 years.

Family, friends and the world

As anyone with health issues knows, there's a ripple effect: it's never 'just about the patient'. ■■■■'s husband and children take an active role in helping their mother manage. This can be a bonus and a burden.

- ***Social interaction varies depending on age, gender, economic bracket. Diabetes complicates many social encounters. People suffer negative judgements of others. Peer pressure from friends in social situations can result in unwelcome consequences when combined with lack of control. Travel requires preparation. Food and drink are so often the focus of social interaction, requiring that each encounter be assessed through the lens of diabetes rather than through a person's preferences.***

■■■■ is an Opinion Leader who is active in several advocacy groups. As with many patients, ■■■■ feels he is not 'a medical expert'. Fortunately his sister - a nurse – helps him keep tabs on his health: ■■■■ feels lucky to have his sister 'interpret'. His observation: everyone needs a support person. However, since many family members have been uncomfortable when he has self-injected in front of them, ■■■■ minces no words when he says: "Family can also be a pain in the ass."

Stigma, Shame and the Blame Game

The stigma of the perception that the PWD only has 'himself to blame' is something Opinion Leaders are often faced with - contributing to shame and self-blame. For many, anxiety is a constant companion, along with the juggling and balancing to maintain the 'right' sugars that make up the day to day reality of a PWD.

■■■■■ exclaimed, "I've had psoriasis for over 30 years, and not once has anyone said it's my fault...with this diabetes, everyone has an opinion (even my wife!) on how I brought this on myself!"

Myths and realities

■■■■ family's perception of being on insulin is based on myths and misperceptions from generations back. She welcomes becoming more involved as an Opinion Leader and took heart from ■■■■ - an established Opinion Leader and nurse who diagnosed herself 22 years ago. Even with the daily rigors of managing, ■■■■ doesn't consider herself 'sick'.

Day to day: the social and the practical

PWD Face The Worry Of Family Reactions

Around the dinner table, the mood was relaxed and jovial – exemplifying the comfort and relief of a 'safe' environment. Even for these patient and caregiver Opinion Leaders, there's often anxiety about awkward reactions during meals when explaining "I have Type 2 diabetes": defending choices they have to make is but one of the social implications of a PWD.

Scheduling testing and taking necessary medication is such that often a PWD doesn't even want their family to know. As ■■■■ explains, "I have to hide it from my children."

- ***Stigma associated with Diabetes manifests itself in people's perception of self, disappointment with one's own self-care efforts, the perception of others that Diabetes is the fault of the individual, and that obesity and bad food habits cause Diabetes. "Fat or Carb Shaming" comes not only from friends and family but surprisingly from health care professionals as well.***

Stigma, being judged, misconceptions and interference – even if well meaning - are often everyday hazards for a PWD. Stigma because the assumption is if you weren't born with it, you've brought it on yourself. Being judged by what you eat: 'you only have yourself to blame – it was your undisciplined eating habits that 'got you here.'

■■■■ shares the conflict brought on by medication that made it impossible to maintain a healthy weight. As a diabetes nurse, she knew how to eat properly, but the meds caused such lows that she was unable to maintain a healthy weight.

Education

The rising number of PWDs hasn't led to the educational support needed. ■■■■ is a caregiver advocate for her father and brother. In her experience as Opinion Leader, she knows: education and choice are what's needed.

The cost of managing: hundreds of dollars

Cost is another factor that smacks even the most stalwart Opinion Leaders. For ■■■■, it's a monthly \$200 plus. ■■■■ comments: "insulin is covered but not the needles. What do they think ...you're going to drink it?" In addition to the insulin, there are tablets, glucometer testers and strips. Expense works against control.

- ***The cost of diabetes to lower income individuals inhibits and restricts social engagement.***

In their research, *Bringing patient centricity to diabetes medication access in Canada*, the authors point to the Charter of Rights:

"Medication access is a key right and responsibility noted in several sections of the Charter, given the central role played by medications in diabetes

There Is Little Attention Paid To The Burden of Cost

management.... 15% of PWD [people with Diabetes] indicated a lack of government and/ or private prescription drug coverage, while another 30% of PWD reported a lack of insurance to cover blood glucose monitoring supplies or equipment.”

Judith L Glennie, Katharina Kovacs Burns, Paul Oh, ClinicoEconomics and Outcomes Research
2016:8 599–611

Communication

At work, PWDs often feel they must not let their co-workers know that they are on insulin. As █████ pointed out: “There’s still a stigma and a misconception about insulin that if you’re on insulin, death is coming.” █████’s job involves many social functions, but worry about this perception has resulted in missed injections – risking further health complications.

*With Any Chronic Illness,
There’s So Much To Learn*

█████ is an Opinion Leader who describes himself as a ‘layperson without technical or medical knowledge’. He shares what many patients ‘take away’ from a hurried appointment with any healthcare professional: just the bad news. This is a communication issue that’s been proven in more than one study. █████, who feels healthcare professionals should make more of an effort to ensure patients understand, takes heart, hearing █████’s modus operandi “I’m impressed at how you treat patients.”

The Past and the Future

*A Week in the Hospital
Was Once Standard*

Since her own diagnosis, in 1989, █████ has witnessed a huge change in care for PWDs: back then testers were the size of toasters, and patients going on insulin were hospitalized for a week, using an orange to learn how to inject.

Now, testers are portable, clinics replace hospital ‘stays’ and patients are encouraged to become more empowered and engaged. However, █████ points out one of the barriers that he feels healthcare professionals could be more sensitive to: PWDs often don’t even know what questions to ask nor do they understand the language and terminology. █████ shares how, in her evolution as an engaged PWD, she now takes notes and then does her own internet research.

The Future of Patient Centered Care

These patients, caregivers and Opinion Leaders hold out hope that the future will see what █████ has described as the Gold Standard for Diabetes Management: incorporating team-work, cross-training and seeking partnerships, such as working with the Emergency Department to get patients with Type 2 Diabetes out of ER and into the Diabetes Management Centre.

“You can educate people until the cows come home. What patients need help with is managing - that’s why we’ve moved away from being a Diabetes Education Center to being the Diabetes ‘Management’ Center.”

4. Experiences With Currently Available Treatments

There is no singular course of treatment for Diabetes. There is widespread frustration among patients with the options available, how to assess, and even how to understand the nature of the disease itself which surprisingly is not exclusive to health literacy level.

"Doctors tell patients 'If you don't follow my orders I'll put you straight onto insulin'. Need to stop using insulin as a threat." - ██████████

- *"I have had diabetes for 5 years now and I swear my energy level and strength keeps going down. I have tried all sort of vitamins etc and sometimes I feel better for a while but then I go back to being exhausted and fatigued again. Is this really just the way I will feel for the rest of my life every day and nothing can be done?" - ██████████*

Patients struggle to manage their condition based on an algorithmic approach to treatment by their GP's and endocrinologists. Some are able to self-manage without medications while working with a team that includes nurse educators and dieticians. Increasing numbers of Type 2 PWD however escalate the use of medications ultimately reaching the last option of insulin therapy.

- *"I have type 2 diabetes which essentially means that I have 'diabetes of unknown cause'. The trouble is that this diagnosis is not sufficient to assure that I get proper treatment for my diabetes. It was six years ago that I started on my (own initiative) managing my diabetes with insulin. This was only after exhausting my options and concluding that as someone with type 2 I would be denied insulin until I basically ended up in the hospital." - ██████████*

Diabetes can cause severe nerve damage and can lead to amputation. The complexity of Type 2 treatment leads to any number of intervention or decision points along the journey that can either be enhanced or inhibited, depending on the awareness and access of optimal treatments.

- *"Ok. Back to the peak BS. Why would the doc Rx insulin injections when I hit 8.4 and the cardiac RN's tell me 8.3 is ok and I'm worrying needlessly?" - ██████████*

Treatment is further complicated by access inequities based on geography (urban vs. rural), Institutional protocols, access to Diabetes teams including nutritionists, social workers and other key professions like ophthalmology and vascular specialists. This lack of access means less choice for the PWD, their families and health care professionals.

- *"My biggest frustration with our healthcare system is that the person with the least decision-making power is me, the patient. I believe this stems, in part, from a system that elevates the physician's, the payer's, the industry's perspective over mine. It stems from a system that values my life less because of diabetes." - ██████████*

Treatment options are often determined not by the most effective therapy for the individual, but by the patient's insurance coverage and ability to afford the cost of a particular therapy. Patients are forced into financial trade-offs of therapy vs. basic needs. Such trade-offs include sub optimal dosing of Insulin and setting the sensors on pumps to double or triple times the length of manufacturers recommendations.

5. Improved Outcomes

Several relevant themes stand out from the experience of people in our community that affect peoples' access to proper therapy and improved outcomes.

1. The stigma of Needles. Once [REDACTED] was started on insulin, she kept it a secret from her family. Her needles were hidden and the locations of her injections were discretely kept from view. She felt as if having to have treatment escalated to insulin therapy meant that her efforts to control had been a failure. She now believes that greater efforts to educate patients about therapy options can have dramatic impact on outcomes.

[REDACTED] tells us “There really is stigma about injecting. I've been doing it for over 30 years and people still make me feel dirty.” [REDACTED] concurs, “The longer I stay away from injections or insulin...the better off I will be.”

2. Needles are assumed to relate to insulin. Many patients immediately associate needles with insulin without awareness or knowledge that there are other drugs that are administered by injection before insulin therapy might be recommended. [REDACTED], like many others, thought “injection” automatically meant insulin.

[REDACTED] sums it succinctly for many patients, “I have a fear of needles so the day I need to go on insulin will not be a good day for me.”

3. Relationships with health care providers matter – a lot. [REDACTED] clearly stated that she had to be more proactive with her HCP's in order to get the best information available and make the most of the short times allocated for consultation with endocrinologists and other providers.

[REDACTED] also tried an endocrinology clinic, but felt he was treated on an assembly line, with little care for his human experience. He compared it not too generously with going to a “Walmart for endos”. His final frustration was the clinic's refusal to send reports to his GP. This disconnect between providers was infuriating. Ultimately he returned to his GP for care, but still has concerns about his GP's access to the latest therapeutic information given the complex nature of diabetes and the many other competing illnesses his GP has keep up with.

[REDACTED] expressed concern about his GP's ability to help manage his condition and didn't know how to seek a referral to a specialist.

[REDACTED] was unable to establish a satisfactory relationship with her GP and sought out other practitioners, including an internist and specifically a pharmacist to manage. Her GP relationship is still contentious and there is a lack of coordination between her other HCP's and her GP as a result.

4. Oral medication vs injection. [REDACTED] was unequivocal. “Once a day oral would be preferable - taking one pill a day would be attractive vs a once a week injectable.” There is some shame associated with diabetes and there is a stigma to injection. He felt he could come to terms with it if he had no other choice but questions whether others would be able to.

[REDACTED] added that the implication of injection is that your condition is getting worse – and this is worrisome. He might lean to the once per week injection and if it worked would continue. He takes pills daily but has on occasion forgotten to take his pills.

5. Health Care Provider knowledge and education. HCP education can be a barrier to access, decrease clinical outcomes, and lower quality of life indicators. The education of a treating physician may have an impact on how you treat your diabetes. The more education your HCP has in treating diabetes allows greater access to information and new medications.

[REDACTED] described how her GP was only treating her with metformin and insulin but since she started seeing an Endocrinologist, she is using a variety of different medications and managing better. Still, she makes sure that she is well prepared with questions before every consultation.

[REDACTED] pointed out the lack of interdisciplinary communication in healthcare. Her main source of information is her pharmacist. She then takes that information to her internist as she doesn't see an endocrinologist. Her GP is not involved in her diabetes management as she's lost trust in that provider.

█'s experience with his endocrinologist who wouldn't take the time to follow up with his GP underscores a key gap in patient support and access to team management. He has often been faced with conflicting advice between HCPs such as one recommending regular blood glucose checking while another said it wasn't necessary.

- *“What’s a patient supposed to do when doctors aren’t on the same page?”*

6. Experience With Drug Under Review

While there are no patients available in Canada to report on this particular oral formulation of semaglutide, the experience of those using the weekly injectable semaglutide (Ozempic) has been widely shared.

Nausea and upset stomachs are reported as initial side effects that disappear after tolerance is developed. Starting at low dose with slow, gradual increases, delivers the best outcomes. The drug reduces appetite and lowers blood sugar resulting in weight loss.

- *“Drum roll please... had my first checkup (Sept 24) since going on Ozempic in May. A1C = 5.6 and weight down about 30 pounds. My endo is super impressed.” – █*

█, a prominent member of the T2DXX community, described how he had already lost 150 pounds on his own by strict adherence to a keto diet, and was on a number of oral medications, but still struggling with A1C control...now?

- *“Started Ozempic and I don't even think of my diabetes much anymore! My numbers are bang on and I've lost another 10 pounds..”*

This affects social and emotional impacts of the condition in positive ways equating to an improved quality of life, as well as reduced stress from stigma and bias. There is improved control of blood sugar, reduced fear of hypoglycemia and simplified dosage management resulting in improved treatment adherence.

- *“I still take my long lasting insulin at night, but no meal insulin. I had to stop meal insulin immediately. I kept crashing.” – █*

This is especially important for patients with concomitant conditions who generally will pay attention to the one condition that is causing the most pain to the detriment of the others.

- *“This is my 4th week on ozempic. I was previously on novolog and levimir for 6 years...never had a endocrinologist..just used my primary care...Endo took me off of both insulins...put me on metformin and ozempic....I have lost 17 pounds in 4 weeks.. I'm hungry but nauseated...my A1C was 9.2 4 weeks ago...my current blood sugars average at 135-140. .fasting blood sugar was 116...I can't wait until my next A1C check.”- █*

Ozempic is used as part of a therapeutic plan rather than a singular therapy and in some cases demonstrates effectiveness in avoiding or reducing insulin use.

- *“Mine are significantly lower since starting it two weeks ago. I've been on insulin for 7 years and was able to drastically decrease how much I need.” – █*
- *“I went from 80 units of insulin to 0.”- █*
- *“Just this week I had to cut the tresiba from 28 to 22 units.” – █*

Caregivers benefit from a reduced burden, improved emotional state and restored balance in relationships. There continues to be an issue of affordability and coverage.

- *“I take my 4th dose of ozempic in the morning. I can tell a big difference in my blood sugar and in my weight. 2 years ago I had to have a pacemaker/defibrilator, Evidently my heart dr. Can see a difference. She called me yesterday to make sure I was ok.” – █*

7. Companion Diagnostic Test

Managing one's glycaemia is a constant 24/7 endeavor. This is becoming even more complicated with the newer monitors and pumps and the evolution of moving "beyond A1C" to "time on target" or "time in range". Companion diagnostics include lancets, monitors, BG test strips, ketone strips, needles, pumps, pump supplies, CGM. All this adds significant cost, inconvenience and emotional distress to patients when you also add in the fragmented reimbursement landscape which complicates and adds barriers to access.

When factoring in age, income and the full spectrum of the social determinants of health, the optimal management of one's diabetes faces significant obstacles to treatment when looking through the lens of the "whole patient".

8. Anything Else?

Treating The Whole Patient:

There is a complete underestimation of the importance of managing glycaemia (in lieu of managing an A1C number) as the whole patient. Fear of hypoglycaemia and more commonly the fear of being judged do not always appear on a patients' chart. The reasons are multi factorial, but it is very clear from the patient voice that it is far more than just the clinical manifestations of the features and benefits of drug A vs drug B.

Finally, patients raise system issues that affect decisions and choices across the continuum of care and experience.

Healthcare Provider Relationships

Beyond each person's family and social circles, there's the healthcare world and its inconsistencies. [REDACTED] and [REDACTED] share what they've seen time and again in their role as Opinion Leaders: the 'credibility' factor: health care practitioners that PWDs can't relate to – whether it's a healthcare professional who is totally out of shape, or in 'Iron Man' top condition. This applies across the board: physicians, nurses, foot doctors and even dietitians.

The 'Unspoken Impact of a Provider's Health

- ***Many Type 2 feel marginalized in the therapeutic relationship by an apparent bias toward treating Type 1 Diabetes as the more authentic condition.***

There is much to be learned by PWDs and the world around them: Often there's the perception that one-size-fits all. That just doesn't apply to a PWD - where one PWD's normal may be a '6', for another it's something else. [REDACTED] pointed out, it takes an effort and 'a lot of talking' to establish what's 'right' for each PWD.

Living the Life of a PWD For a Week

In an effort to ensure everyone she works with gets a sense of the day to day for a PWD, [REDACTED] has every new staff member live for a week like a PWD. She gives them props – empty needles and 'smarties' for pills. They have to record what they eat and drink and how they've exercised. This goes a long

way to being more empathetic to the 'lived experience' of PWDs.

Government: out of touch with the reality of PWDs

■ points to larger problems: A Government that's out of touch with health costs for PWDs— a particular hardship for many who have no insurance coverage.

The Lucky Few Have Health Programs and Pensions.

From “*Bringing patient centricity to diabetes medication access in Canada*”:

Those with Type 2 Diabetes spend on average between \$723 and \$1,914 Annually. Seniors pay 36%-70% out of pocket for Type 2 Diabetes treatment.

Future implications for the health system: Canada doesn't stack up well

Also from “*Bringing patient centricity to diabetes medication access in Canada*”

Against international comparisons, Canada also performs poorly with respect to diabetes-related hospitalizations, mortality rates, and access to medications. Diabetes and its comorbidities pose a significant burden on people with diabetes (PWD) and their families, through out-of-pocket expenses for medications, devices, supplies, and the support needed to manage their illness. Rising direct and indirect costs of diabetes will become a drain on Canada's economy and undermine the financial stability of our health care system

A personalized approach to medication access, to meet individual needs and optimize outcomes, is also a key enabler. PWD and prescribers need reimbursement approaches that allow them to use existing tools (i.e. medications and supplies) to manage diabetes in a timely manner and to avoid and/or delay major downstream complications

Understanding the Type 2 Diabetes Experience Exchange (T2DXX) online community.

T2DXX fills a large gap in the patient group landscape. First, it is exclusive to people with Type 2 Diabetes. Second, it is focused on enriching our members' understanding of the human experience, which differentiates it from other groups whose mission is primarily research based. The robust engagement on our social platforms is unlike any other Canadian group and reveals important insights about the individuals who live with Type 2 Diabetes.

Key data indicate that the Type 2 community is not homogenous, lacks a coherent and unified community identification, and suffers from a wide range of social and emotional barriers to fully participate in social media in a highly activated manner. For example, a North American database of over 100,000 patient influencers, across all disease states, identifies only 420 of them as having Type 2 Diabetes. Only ONE of the 420 is Canadian. There is no social media community unifying Canadian T2D patients in spite of Statistics Canada reporting that 7.0% of Canadians aged 12 and older (2.1 million people) have T2D.

In comparison to other disease states with smaller population totals than diabetes, the participation rates of T2D people in social media is dramatically less than communities of other disease populations.

The wide range of age groups, populations, multiple co-morbidities, social stigma and bias all mitigate against a unified and coherent voice. It reflects the complexity of treatment and the need for greater variety of treatment options to address individual needs. It also highlights the barriers facing effective policy making given that there is no singular voice of the authentic T2 patient experience.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

No.

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

No.

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Julie De Vos

Position: Social Media Volunteer

Patient Group: Type 2 Diabetes Experience Exchange

Date: December 11, 2019