CADTH

CADTH Reimbursement Review
Patient Input Template

Name of the Drug and Indication	**liraglutide (Saxenda)** **chronic weight management in adult patients with prediabetes**
Name of the Patient Group	**Diabetes Canada**
Author of the Submission	**Ann Besner**
Name of the Primary Contact for This Submission	**Ann Besner**
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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 December 2020/January 2021. 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 December 2020/January 2021 survey was open for two weeks (December 21, 2020-January 4, 2021) to people across Canada living with overweight or obesity and diabetes (type 1 or type 2) or prediabetes, and their caregivers. It consisted of a self-administered questionnaire of closed- and open-ended questions about respondents' lived experience with weight management, diabetes or prediabetes, medications (with specific questions about the drug under review, liraglutide [Saxenda]) and expectations for new drug therapies in this country. It was advertised through Diabetes Canada's social media channels (Facebook, Twitter, Instagram and LinkedIn).

Per the product monograph, liraglutide (Saxenda) is:

> *indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:*
> *• 30 kg/m2 or greater (obese), or*
> *• 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes, or dyslipidemia) and who have failed a previous weight management intervention.*

The manufacturer's requested reimbursement criteria for liraglutide (Saxenda) are:

> *an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients who have been diagnosed with:*
> *• Obesity (BMI 30 kg/m2) AND prediabetes, or*
> *• Overweight (BMI 27 kg/m2 and 30 kg/m2) with one or more weight-related comorbidity AND prediabetes*

While liraglutide (Saxenda) is a medication available by indication for people living with overweight or obesity who may or may not have diabetes, it is currently being considered for reimbursement for those with prediabetes. As such, this submission will include responses from people living with overweight or obesity, as well as from people living with prediabetes or type 2 diabetes, to which prediabetes can progress. It will also incorporate feedback from caregivers of people with prediabetes and type 2 diabetes, where available.

A total of 873 people participated in the July/August survey – 36 respondents identified as living with type 2 diabetes while 4 said they were a caregiver to somebody with type 2 diabetes. This survey did not include people living with prediabetes. 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 respondents were in the 11-20 year experience-with-diabetes range (n=16).

Fewer people were involved in the December/January survey (n=16) – 11 people reported living with type 2 diabetes and 1 with prediabetes. There were no caregivers who participated in this survey. Respondents resided in Ontario, Manitoba and Alberta; the majority of people were from Ontario (75%, n=9). All respondents were over the age of 25, with most in the 45-54 year age category (50%, n=6). There was a much diversity in the length of time living with diabetes or prediabetes reported. Of the respondent with type 2 diabetes, 1 person reported having it less than 1 year, 1 for 1-2 years, 3 for 3-5 years, 1 for 6-10 years, 2 for 11-20 years and 3 for more than 20 years. The respondent with prediabetes has lived with it for 1-2 years.

From the December/January survey, of those who reported living with type 2 diabetes or prediabetes (n=12), 10 respondents (83%) said they identify as living with overweight or obesity and 8 respondents (67%) said they have been formally diagnosed with overweight or obesity by a health-care provider. The amount of time respondents said they have been living with overweight or obesity ranged from 5 years to "most of my life"; several people shared that their experience with overweight or obesity has lasted for decades.

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?

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Liraglutide (Saxenda) is a GLP-1 receptor agonist indicated for chronic weight management in people diagnosed with obesity or overweight. Reimbursement is being requested specifically for people in this disease category who are also living with prediabetes. Prediabetes is a precursor to type 2 diabetes.

Obesity is a chronic, often progressive condition with complex, multifactorial etiology. It is characterized by excess or abnormal body fat that can impair health. Its effects are numerous and far-reaching, impacting mental, mechanical, metabolic and monetary health. Overweight and obesity are associated with a higher risk for several other chronic diseases, including type 2 diabetes. Having diabetes can also increase risk for overweight or obesity for different reasons. It is estimated that 80-90% of people with type 2 diabetes live with overweight or obesity. Overweight and obesity can be challenging to treat and managing the condition is usually a life-long process. Management is multipronged and should be individualized to a person's circumstances and needs. It may include behavioural interventions, emotional and mental health supports, nutrition, physical activity and, in some cases, medications and/or bariatric surgery. A big part of treating obesity is addressing the weight stigma, discrimination and bias that people experience in their daily lives.

Prediabetes is a term used to describe the condition of elevated blood sugar that, while abnormal, is not sufficiently high to constitute a diagnosis of diabetes. Prediabetes may refer to impaired fasting glucose and/or impaired glucose tolerance and/or a higher-than-normal hemoglobin A1c. With behavioural modifications, including attention to nutrition and physical activity, and pharmacotherapy for some, people with prediabetes can revert to normoglycemia. However, it significantly increases risk for type 2 diabetes and those with elevated values can also go on to develop the condition. For people living with overweight or obesity and prediabetes, various weight management approaches can help reduce likelihood of progression to diabetes.

Diabetes is a chronic, progressive disease of different types, but none with any known cure. 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. Inadequate glucose control (i.e., hyperglycemia and hypoglycemia) can be quite serious and problematic, with damage that may occur to the body that is irreversible. The goal of diabetes management is to keep glucose levels within a target range to minimize symptoms and prevent or delay complications, which include, but are not limited to, cardiovascular disease, kidney disease, vision loss, foot ulcers and lower limb amputation.

In the December/January survey, respondents (with type 2 diabetes or prediabetes) shared the ways in which overweight or obesity has impacted their daily life and overall quality of life. They said:

"[It] slows me down and causes mental distress."

"It's like I'm in my very own prison that I have a hard time fitting into."

"Extra weight affects my mental health."

"It's frustrating to know that no matter what you do, weight management will always be an issue. Eating right is not always good enough - and the older I get the more difficult it is to keep the weight off."

“It affects and limit [sic] my activities.”

“[It causes] increased knee and joint pains.”

A few people said they weren’t really sure about the impact on their life or that they didn’t have any problems to report. One person said “other than finding clothing that I like it really does not have that much impact.”

Some respondents were very positive about their experience with type 2 diabetes or prediabetes. 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.” One respondent shared that “other than being more aware of what I am eating and how often I am exercising so far there has been no real impact on my life”. Still, the overwhelming majority of respondents spoke negatively of their experience living with type 2 diabetes or prediabetes. Many people shared that it is frustrating, difficult and tiring to manage their health. They said diabetes “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 mentioned that they are constantly thinking about and dealing with their condition. 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 said that the nutritional aspect of diabetes management is challenging, as is 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, many said it is a burdensome task. All aspects of diabetes management – healthy eating, regular physical activity, blood sugar testing – were described by many respondents as costly undertakings. People talked about the cost of treatments and the barrier that a high price and/or lack of public coverage or supports presents. The shame and stigma that people experience with diabetes was also mentioned as a problem.

When asked specific questions about comorbidities, respondents to the December/January survey who identified as living with overweight or obesity and type 2 diabetes or prediabetes (n=10) reported experiencing the following:

- high blood pressure (n=2)
- abnormal cholesterol levels (n=4)
- kidney issues or kidney disease (n=2)
- mental health concerns (n=3)
- eye problems (n=3)
- foot problems (n=4)

Below are some quotes from the two surveys that further illustrate the extent to which type 2 diabetes or prediabetes affect daily living and quality of life of those with either condition

“Changes in lifestyle and food awareness, daily monitoring and medication.”

“Affected my spouse, children and myself . Every decision I make has my diabetes in the back of my head. Multiple surgeries, wound care, amputation of a couple toes, depression .”

“It affects the quality of life by increasing my anxiety regarding my lifespan, limbs, blood sugar regulation, Covid risks and heart disease higher risks.”

“I manage my diabetes fairly well, but do wrestle with my weight.”

“Lack of energy, some dizziness, brain fog.”

"Moods swings when having a high [blood glucose]."

"In starving most days to keep my sugars low as my doctor keeps changing my meds month to month."

"I have problems with neuropathy in my hands and feet that makes it difficult to do certain tasks."

"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."

"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 togethers 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."

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).

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In the December/January survey, only 1 of the 12 respondents with type 2 diabetes or prediabetes reported taking prescription medication for overweight or obesity. The person said he/she was "very satisfied" with the medication.

Aside from medication, respondents reported on various methods they are using for weight management. Of those who responded to this question, 50% said they are eating healthy, 60% said they are engaging in physical activity and 18% said they are taking herbal remedies or over-the-counter supplements. Nobody reported using a commercial weight loss program (e.g., WW, Jenny Craig, Herbal Magic, etc.) or following a medically-supervised obesity management program, though a few reported having done this in the past. Nobody has had bariatric surgery. Respondents provided the following feedback on how manageable and successful these approaches were:

"The exercise helps build muscle and the food helps control sugars and weight."

"The only thing that will help you lose weight is hard work, exercise, strength training and precise measurement of foods and eating a balanced whole food holistic diet. I've tried every diet out there since I was a 9 year [sic] sitting in a weight watchers [sic] meeting ."

"I cannot go to the gym and cannot work out as I need to during Covid. Working out helps me but hard to sustain."

"Due to being homeless and poor, many strategies did not work for me."

"Not very effective although they do allow me to maintain rather than gain weight."

"I have not really been on one program long enough."

Respondents who answered this question reported the following considerations as important when choosing a medication for weight management:

"Ease of access and consistency of access."

"No side effects that can add to my stress."

"Epilepsy concerns."

"Coverage by provincial health plan."

"If it has to be taken on a strict schedule it would probably not work for me, especially if it is only injectable."

Of the 12 respondents living with type 2 diabetes or prediabetes, 11 (all with type 2) reported experience with antihyperglycemic agents in the December/January survey. The oral and injectable medications being taken at the time of survey completion included metformin (82%), SGLT2 inhibitors (18%), sulfonylureas (18%), GLP-1 receptor agonists (9%) and a combination of DPP-4 inhibitors and metformin (9%). Additionally, 45% of respondents had experience with some type of insulin. When asked about their feelings regarding their diabetes medications, 45% said they were "somewhat satisfied" with them, 45% said they were "neither satisfied nor dissatisfied" with them, and 9% said they were "somewhat dissatisfied" with them. They shared the following comments about their medications:

"Allows me some confidence in my health."

"I'm in good control at the moment but it's been erratic at best in my history which has lead to numerous complications for somebody so young."

"It is stressful to take medications every day."

"Doctor keeps changing them, so I have to keep adjusting."

Most respondents stated that they don't have trouble accessing their medications, though one said medications were difficult to obtain "after a while" and that "the cost was too prohibitive".

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?

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

"I want to prevent macular degeneration and maintain eye sight health most importantly and also very important, nerve issues in my feet or fingers."

"Reduce the costs if possible to make them more affordable."

"Steady weight loss would help reduce joint pain so I can return to work, steady blood glucose levels would reduce the stress of always starving myself to keep sugars under control without insulin."

"No side effects that can add to my stress."

"Good for sensitive stomach."

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.

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Of all respondents in the December/January survey, only 1 person reported experience with liraglutide (Saxenda). The respondent said the cost of medication was covered in full or part under private insurance. Weight loss was much improved on liraglutide (Saxenda) and the gastrointestinal side effects (vomiting/nausea) were "not pleasant - but not significant enough to interfere with daily life". He/she also said liraglutide (Saxenda) "helped greatly with weight control and appetite control". He/she commented on the price of the medication, recommending the cost be reduced "if possible to make [it] more affordable".

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.

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Liraglutide (Saxenda) 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?

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Overweight, obesity, prediabetes and diabetes are conditions that require 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 treatment. Survey responses reinforce the message that different people require different modalities to help effectively manage their diseases. 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, 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. Liraglutide (Saxenda) may help people to better manage their weight, which could potentially delay or prevent the progression of prediabetes to type 2 diabetes, improve lives and save millions in direct health-care costs. For this reason, liraglutide (Saxenda) should be an option for people living with overweight or obesity and prediabetes.

Below are some final thoughts from respondents on overweight, obesity, prediabetes and diabetes:

"Diabetes is not fun ..it's horrible when you're obese ... keto is not a sustainable weight loss option."

"It is extremely challenging and I do not believe that Health Canada or [sic] Canadian govt [sic] is able to help me with my diabetes and the programs have not been realistic or helpful and only superficial."

"It would be good to have more options for food choices that are sold that [sic] diabetes friendly."

"I am always concerned with side effects. I have had side effects from some medications that continue to bother me even 2 years after stopping taking the medication."

"Doctors need to understand that weight loss its [sic] easy when sugars can drop suddenly with the slightest bit of activity, and increased activity while dealing with pain is difficult as well."

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.

   Diabetes Canada consulted with colleagues at Obesity Canada regarding the creation of the patient input survey. Obesity Canada helped to advertise Diabetes Canada's survey on 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: January 22, 2021

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.,