CADTH

CADTH Reimbursement Review

Patient Input

liraglutide (Saxenda)

(Novo Nordisk Canada Inc.)

Indication: Chronic weight management in adults

CADTH received patient input from:

Diabetes Canada
Gastrointestinal Society
Obesity Canada

January 22, 2021

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	[redacted]
Name of the Primary Contact for This Submission	[redacted]
Email	[redacted]
Telephone Number	[redacted]

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., hyperglymemia 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?

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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 covered in full or part under private insurance. Weight loss was much improved on the liraglutide (Saxenda) and that 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 with 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 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 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 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.,

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	**Saxenda® (liraglutide) for chronic weight management in adults**
Name of the Patient Group	**Gastrointestinal Society**
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.

As the Canadian leader in providing trusted, evidence-based information on all areas of the gastrointestinal tract, the GI (Gastrointestinal) Society is committed to improving the lives of people with GI and liver condition, supporting research, advocating for appropriate patient access to healthcare, and promoting gastrointestinal and liver health. We have been covering obesity-related issues for many years, a summary can be found here https://badgut.org/?s=obesity.

The GI Society is a national charity formed in 2008 on the groundwork of its partner organization, the Canadian Society of Intestinal Research (CSIR), which was founded in Vancouver in 1976. We receive national and international attention, simply because we have earned the respect of both the gastrointestinal medical community and Canadians who battle GI and liver issues daily. During 2020, our English (www.badgut.org) and French (www.mauxdeventre.org) websites had 6,379,282 page views by 4,693,479 unique users.

All our programs and services focus on providing Canadians with trusted, commercial-free, medically-sound information on gut and liver diseases and disorders, including obesity, in both official languages. Our BadGut® lectures (currently on hiatus due to the pandemic), quarterly *Inside Tract*® newsletter, pamphlets, and educational videos arm Canadians with the information they require to better understand and manage their specific needs. We also work closely with healthcare professionals and governments at all levels toward system-wide improvements in care and treatment.

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.*

Data for this submission came from a variety of sources, including contact with patients and patient caregivers, the results of published studies, and a survey we conducted from October 6, 2020, to January 10, 2021, open to individuals who had experienced obesity. The survey was open internationally, but the majority (96%) of respondents were from Canada. In total, we had 2,050 respondents answer many questions and, of those, 1,550 individuals completed the survey. 88 respondents had used liraglutide in the past or currently use it.

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?

Obesity is a multi-factorial, chronic, relapsing disease that occurs when a person has an excessive amount of body fat (adipose tissue) that might increase health complications. Obesity is defined as having a BMI of 30 kg/m^2 or greater. Over the past few decades, obesity has become common in Canada and other developed nations. Several health organizations, including the Canadian Medical Association and the World Health Organization, classify obesity as a chronic disease. The European Union Commission has listed obesity as one of the high risk groups who are "medically vulnerable".

Many health complications can arise from obesity, especially in individuals who have the disease for a long time or those living with class III obesity (BMI of 40 kg/m^2 or greater). Excess weight influences biology in diverse ways, which can range from excess pressure in the abdominal region to hormonal effects, since adipose tissue can lead to certain hormone levels increasing. This can lead to many serious conditions, including type 2 diabetes, high blood pressure, heart disease, sleep apnea, endocrine conditions, mental health problems, and osteoarthritis. While these conditions can occur in individuals of any weight, they are more common in those living with obesity. Obesity can increase healing time and the chance of infection after surgeries and obesity in women can lead to increased risks during pregnancy. Obesity has also emerged as a factor that causes worse outcomes in those who develop COVID-19.

When presented with a list of comorbid conditions, only 9% of respondents said that they did not have any of them. The most common comorbidities were arthritis (51%), hypertension (33%), sleep apnea (30%), gastroesophageal reflux disease (29%), irritable bowel syndrome (29%), high cholesterol (25%), and diabetes (24%). These conditions come with their own symptoms, risks, and treatments, which can further complicate the management of obesity. In addition, when asked how much of an effect obesity has on their mental health, 64% chose between 7 and 10 on a ten-point scale, with ten being completely affects them and one being does not affect their mental health at all. Only 2% said that obesity does not affect their mental health.

On top of this, obesity itself can affect many areas of life. There is a strong stigma against individuals living with obesity, which can lead to mistreatment in many areas of life, including feeling ignored by physicians and being seen as lazy by potential employers. In fact, 72% of our survey respondents experienced social stigma as a result of their obesity. Many of our survey respondents said that they avoid getting medical care as they feel that their physician shames them for being fat, which can lead to more health problems because they don't get timely treatment for any conditions they might develop, whether or not it is related to obesity. In the words of one survey respondent, "I don't go to the doctor as often as I should because I feel like a failure and that all my medical issues are caused by my obesity." According to another respondent, "I've received the most shame about my weight from doctors to the point I'm scared to go. They should help, not shame."

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).

Diet and Exercise

The most common treatment for obesity is lifestyle modifications. This involves reducing the amount of food an individual eats and/or increasing the amount of exercise in which an individual participates. It is a complex treatment that involves persistent effort. Telling patients that the only way to cure their disease is to constantly monitor their food and intake and eat at a deficit puts a lot of pressure on individuals to cure their own disease, and increases stigma that obesity is easily fixed by diet alone. In reality, weight loss is much more difficult and complex. The body has hormonal influences and metabolic adaptations that fight hard to keep a person from losing weight long-term. In one American study, three years after participants concluded a weight loss program, only 12% had kept off at least 75% of the weight they had lost, while 40% had gained back more weight than they had originally lost. Many individuals with obesity are constantly yo-

yoing in weight, often successfully losing hundreds of pounds over and over in an endless cycle. When this is the only option, patients often feel hopeless.

Medications
For a disease that affects 26.8% of Canadians, there are very few medication options, and those that are available do not have full public or private coverage. As each individual reacts differently to medications, and might have different root causes to their obesity, having a wide variety of medications accessible is extremely important. Available medications include:

- **Naltrexone and bupropion (Contrave®)**: supresses appetite by affecting two areas of the brain involved in the regulation of food intake. It is available in pill form, starting with a once-daily dosage and increasing gradually to two pills twice daily. Side effects can include nausea, constipation, and headaches.
- **Liraglutide (Saxenda® for weight management or Victoza® for type 2 diabetes treatment)**: regulates appetite level. Patients self-administered it subcutaneously daily, starting at a low initial dose and slowly increasing to the maintenance dose. Side effects most commonly include digestive symptoms such as nausea and diarrhea, which usually disappear after a few days or weeks. It can also cause low blood sugar, headaches, and dizziness.
- **Orlistat (Xenical®):** inhibits the enzyme that breaks down dietary fat into absorbable components (lipase). Individuals who take this medication are unable to absorb all the calories from the fats they eat, so these fats are instead eliminated with bowel movements. Side effects can include diarrhea, oily stools, oily discharge when passing gas, and bowel urgency.

However, many respondents expressed concerns over both obtaining prescriptions for medications and paying for the often exorbitant costs of these drugs.

- "Obesity has been classed as a chronic disease yet there is no funding for medications in the same manner as other chronic diseases."
- "I have a good benefits plan but they do not cover the cost of weight loss medication."
- "Most of us who could benefit from the medication do not have coverage to use the medication that could actually be beneficial."
- "I would be more than willing to try weight loss medications but they are so cost prohibitive."
- "I've asked my doctor for weight loss medication and she says no."
- "I have tried going on weight loss medication but unfortunately it has never gone past the discussion point. I have been eagerly looking forward to trying any sort of medication for my weight loss."
- "My doctor refused to try any weight loss drugs for me."

Bariatric Surgery
Surgery is typically quite effective, but many patients and physicians prefer to leave it as a last resort because it can have serious side effects. There are four types of surgery currently available in Canada:

- **Gastric Sleeve:** a surgeon will remove part of your stomach, leaving just a thin sleeve, approximately the size of a small banana, behind. This method simply reduces the amount of food you can eat during a window of time.
- **Gastric Bypass:** a surgeon removes part of the stomach, leaving just a small pouch, and then connects the small pouch to the middle of the small intestine. Roux-en-Y is another name for this process. This surgery works in two ways: you can't eat as much because the stomach is smaller, and your body won't absorb as many calories because of the small intestine bypass.
- **Gastric Band:** a surgeon will place a band around the upper part of the stomach to create a smaller pouch. The surgeon can adjust the band to make the available stomach area smaller or larger, as needed. However, surgeons do not often recommend it anymore, due to poor results.
- **Intragastric Balloons:** this is a newer and less common form of surgery at this time. It is a temporary measure that involves placing a fluid-filled balloon into the stomach that delays the rate of gastric emptying. It is different from other methods of surgery as it does not involve modifying the structure of the digestive tract and it is reversible, but it still has risks.

Bariatric surgery often leads to significant weight loss and reversal of several obesity-related diseases, such as type 2 diabetes and high blood pressure. However, it can cause severe side effects; of those who have bariatric surgery, 5% experienced complications while in hospital and 6% needed hospital readmission

within a month of release due to complications. The mortality rate for bariatric surgeries is between 0.1-2%. Severe nutritional deficiencies and gastrointestinal symptoms can also occur. Many individuals would prefer not to have surgery; in our survey 33% indicated that they would never consider bariatric surgery to treat their obesity. For the persons who do want bariatric surgery, the wait lists are often very long and it can be out of reach financially for many individuals.

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?

The primary goal for treating obesity is weight loss. This weight loss then leads to improvements in other symptoms and conditions. However, most treatments for obesity are not effective long term. Even in individuals who lose a significant amount of weight, many of them gain the weight back within five years. A medication that can be taken for chronic management of obesity will be extremely beneficial for the population, as part of a larger management program that includes lifestyle modifications. Those living with obesity who have tried liraglutide found it easier to adhere to lifestyle modifications while taking that medication.

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?

Patients have had access to liraglutide under the name Victoza® to treat type 2 diabetes for more than a decade. In addition to good management of blood sugar levels, many of these individuals experienced reduced appetite and weight loss, and some physicians prescribed Victoza® off label to treat obesity. One individual who took our recent survey indicated that their "health has greatly improved and my blood sugar levels are normal while using liraglutide, with the bonus of exceptional weight loss." According to another respondent, "Liraglutide triggered my brain to stop craving food every minute of the day."

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.*

It is fairly easy to monitor whether a drug is positively affecting a person living with obesity, as they lose weight, which is easy to measure. The true benefit comes for the effect of this weight loss on other health conditions, requiring a wide range of tests, depending on the condition.

8. Anything Else?

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

Obesity is a complex condition and we had a wide range of comments from our survey. This woman from Ontario said, “I feel that there are way less resources allocated in our current healthcare system towards the prevention and treatment of this disease. Obesity is becoming a pandemic now and I have seen first hand how it had destroyed the health of so many near and dear ones in the family; it’s still so hard to get the healthier food because most of the healthier food is just way too expensive to be afforded by an average Joe. Also, a lot of effort is needed to pinpoint what causes one child to be obese and the other to be skinny in the same family - what genetic factors predispose someone to gain weight or not being able to lose it like others can? Or what resources are there to psychologically help obese people because often times, the dependency on food is there to mask other personal traumas that are mentally linked! Then there is this whole thing about some meds being insured by govt and some not. What if there is no private health coverage in place? There’s a lot of work needed in this field if we want our next generations to be less obese and more healthy. Having this survey is a positive step towards getting answers in this regard.”

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. Furthermore, we did not receive any funding from any pharma company to conduct our survey or to complete this submission. The Canadian Society of Intestinal Research, our partner registered charity, provided funding support for the survey.

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
Novo Nordisk Canada Inc. for 2021 support of our *Inside Tract*® newsletter and pamphlet on Obesity.			27,800	

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: Gail Attara
Position: Chief Executive Officer
Patient Group: Gastrointestinal Society
Date: 2021-01-20

CADTH

CADTH Reimbursement Review
Patient Input Template

Name of the Drug and Indication	**Saxenda – Liraglutide for obesity**
Name of the Patient Group	**Obesity 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

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

Obesity Canada-Obésité Canada, previously known as the Canadian Obesity Network-Réseau canadien en obésité, is Canada's leading obesity registered charity association for health professionals, researchers, trainees, students, policy makers and Canadians living with obesity. Currently, Obesity Canada-Obésité Canada has more than 20,000 professional members and over 25,000 public supporters.

Our mission: To improve the lives of Canadians through obesity research, education, and advocacy.

Our Vision: A day when people affected by the disease of obesity are understood, respected, and living healthy lives.

Website: https://obesitycanada.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.

Obesity Canada engaged persons living with obesity through an online survey and individual interviews. We conducted the survey between November and December 2020. The survey was published through social media, newsletters as well as in our online patient community, OC-Connect. There were 73 survey responses from Canadians living with obesity (patients) living in Ontario, Alberta, British Columbia, Quebec, Newfoundland and Nova Scotia. The survey respondents were 86% female with 22% being 35-44 years of age, 34% being 45-54 years of age and 26% being 55-64 years of age. All respondents had experience with medically supervised obesity treatment and 60% (34) had direct experience with Saxenda. We also conducted 5 interviews with individuals who have direct experience with Saxenda for obesity management.

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?

Obesity is a prevalent, complex, progressive and relapsing chronic disease, characterized by abnormal or excessive body fat (adiposity), that impairs health[1].

Population health studies measure the prevalence of obesity using a crude measure called the Body Mass Index (BMI). Although this measure is helpful for population health surveillance, it is not a tool that can be used to clinically diagnose people with obesity. At the individual level, obesity complications occur because of excess adiposity, location and distribution of adiposity and many other factors, including environmental, genetic, biologic and socioeconomic factors. Based on existing population surveillance studies, the prevalence of obesity in Canada has increased significantly over the past three decades.

In Canada, the prevalence of obesity (BMI > 30 kg/m^2) in adults rose dramatically, increasing three-fold since 1985 and affecting 26.4% or 8.3 million Canadians in 2016. Severe obesity (BMI ≥ 35kg/m^2), the fastest growing obesity subgroup, increased disproportionately over this same period. Since 1985, severe obesity increased 455% and affected an estimated 1.9 million Canadian adults in 2016[2].

[1] CMAJ August 04, 2020 192 (31) E875-E891; DOI: https://doi.org/10.1503/cmaj.191707

[2] Twells LK, Janssen I, Kuk JL. Canadian Adult Obesity Clinical Practice Guidelines: Epidemiology of Adult Obesity. Available from: https://obesitycanada.ca/guidelines/epidemiology.

Adipose tissue not only influences the central regulation of energy homeostasis, but excessive adiposity can also become dysfunctional and predispose the individual to the development of many medical complications, such as type 2 diabetes, non-alcoholic fatty liver disease, high blood pressure, heart disease, stroke, arthritis, many forms of cancer, and other important health problems. Obesity can have serious impacts on those who live with it. Most concerning, it increases the risk of developing cardio- vascular disease and cancer, two primary causes of premature mortality in Canada, resulting in a reduction of life expectancy by six to 14 years. It is estimated that 20% of all cancers can be attributed to obesity, independent of diet[3].

Obesity affects individuals, families and society. The economic cost is significant. In 2014, the global economic impact of obesity was estimated to be US $2.0 trillion or 2.8% of the global gross domestic product (GDP). In Canada, obesity and its related illnesses result in a large cost to society due to increases in direct (i.e., physician, hospital, emergency room use) and indirect costs (i.e., lost productivity, absenteeism, disability), estimated to be $7.1 billion in 2010.

Beyond its effects on overall health and well-being, obesity also affects people's' overall social and economic well-being due to the **pervasive social stigma associated with it**.[5] As common as other forms of discrimination — including racism — weight bias and stigma can increase morbidity and mortality.[6] Obesity stigma translates into significant inequities in access to employment, healthcare and education, often due to widespread negative stereotypes that persons with obesity are lazy, unmotivated, or lacking in self-discipline.[7,8]

Obesity has long been misunderstood, trivialized, and stigmatized as a simple "lifestyle" issue that can be effectively addressed by the mantra of "eat-less-move-more". This simplistic view of obesity disregards both the lived experience of persons with obesity as well as the vast body of scientific evidence showing that, like other chronic diseases, obesity is a rather heterogeneous condition resulting from the complex interaction of a multitude of socio-psycho-biological factors that promote excessive weight gain, and ultimately impairs health.

Obesity is caused by the complex interplay of multiple genetic, metabolic, behavioural and environmental factors, with the latter thought to be the proximate cause of the substantial rise in the prevalence of obesity. A better understanding of the biological underpinnings of this disease has emerged in recent years. The brain plays a central role in energy homeostasis by regulating food intake and energy expenditure. Importantly, research indicates that powerful neuro-hormonal factors effectively defend our bodies against weight loss, thereby often making obesity a life-long problem, where weight regain (or relapse) is the rule rather than the exception[4].

[3] Ibid.

[4] CMAJ August 04, 2020 192 (31) E875-E891; DOI: https://doi.org/10.1503/cmaj.191707

Obesity is a chronic disease, not simply a risk factor for other diseases. The World Health Organization, the Canadian Medical Association, the Ontario Medical Association along with the Saskatchewan and Yukon medical associations as well as virtually all expert scientific organizations globally recognize obesity as a chronic disease. In Canada, specifically, the lack of recognition of obesity as a chronic disease by provincial and territorial governments has a significant impact for Canadians. Obesity is more prevalent than diabetes, hypertension or virtually any other chronic diseases and also carries with it a more significant economic burden when left un managed, yet no provincial or territorial government has taken serious steps to treat and manage this disease. Only a few provincial governments have focused their attention on health promotion among children and families and most have not implemented obesity treatment programs for Canadians living with obesity. This approach by itself is not evidence-based and ignores the more than 8 million Canadian adults currently living with obesity, condemning them to ineffective self management of a complex chronic disease.

The recently published Canadian Clinical Practice Guidelines for the Treatment of Obesity, outline the current evidence and best practices for obesity management. ***However, pervasive weight bias in our society is a major barrier to access to obesity care.***

Obesity Canada's report card on access to obesity treatments shows that:

1. There is a profound lack of interdisciplinary teams for obesity prevention and management at the primary care level in Canada;
2. Anti-obesity medications are not covered by provincial public drug benefit programs or any of the Federal public drug benefit programs, and that
3. There are significant disparities in the access to bariatric surgery, with only 1 in 171 (0.58%) adults living with severe obesity having access to surgery every year. In many provinces and territories, wait times for bariatric surgery can go up to 5 years.

Due to lack of availability of evidence-based treatments in the health system, Canadians affected by obesity are left to navigate a complex landscape of weight-loss products and services, many of which lack a scientific rationale and openly promote unrealistic and unsustainable weight-loss goals.

"The engendered bias and discrimination are rampant in healthcare, where obesity continues to be grossly misunderstood and is not treated with the same fundamental dignity and rigor as other diseases. We deserve and demand better," says Lisa Schaffer, obesity advocate and chair of Obesity Canada's Public Engagement Committee. "As one of millions of Canadian living with obesity, I find it reprehensible that our healthcare systems have not made any significant improvements in access to care."

Living with obesity is challenging on a day-to-day basis. Many experience limited mobility, chronic pain, difficulty with daily tasks and other physical limitations. Further, the environments

we are expected to navigate for work, school, healthcare and even at home, are not typically designed to accommodate larger bodies and thus accessibility becomes a major obstacle. The societal bias and stigma associated with obesity is also a significant barrier to quality of life. There is an overwhelming incorrect perception that obesity is a self-inflicted condition that simply requires more willpower on behalf of the individual. This perception is amplified by the lack of recognition of obesity as a chronic disease by provincial health authorities and the severe lack of access to effective, evidence based treatments. Living in a world that poorly misunderstands the chronic disease you live with and leaving the management of a complex chronic disease up to the individual using ineffective methods creates a cycle of failure and disease progression. This all can lead to further healthcare avoidance, lowered quality of life and increases in mental health issues.

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).

Like many other chronic diseases, obesity is a manageable disease. In 2020, The Canadian Adult Obesity Clinical Practice Guidelines were published, marking a much-needed significant update in the evidence-based best practices. The guidelines describe three pillars of obesity treatment that improve obesity outcomes and support successful behavioral interventions. These pillars include psychological and behavioural therapy, anti-obesity medications (currently 3 approved in Canada) and bariatric surgery.

Despite the comprehensive evidence covered in the Clinical Practice Guidelines, there remains a gap in access to obesity care in Canada.[13] While we have evidence that the three pillars of treatment are effective and AVAILABLE in Canada, none of them are appropriately ACCESSIBLE.

"It is so frustrating and demoralizing that the things that work for me are unattainable, I cannot afford the medications or to see a therapist regularly and the wait time for surgery is several years. I am left to try and manage on my own and it is just not possible"

"It is difficult enough as it is to afford life with a limited income and disability, it is out of the question to try to buy medications that cost hundreds of dollars a month. It is something I

need and my doctor believes will help and it is sitting right there in front of me but I cannot use it."

Obesity has not received official recognition as a chronic disease by the federal government or any of the provincial/territorial governments, despite the Canadian Medical Association and the World Health Organization's declarations. [14,15] The lack of recognition of obesity as a chronic disease by public and private payers, health systems, the public, and media has a trickle-down effect on access to treatment. Obesity continues to be treated as a self-inflicted risk factor, which affects the type of interventions and approaches that are implemented by governments or covered by health benefit plans.[16]

While our current health system theoretically allows for most people with obesity to receive health care in a structured and systematic way, compelling evidence indicates that obesity is "not effectively managed within our current health system".[13,18] Canadian health professionals feel ill-equipped to support patients with obesity. [19-21] In addition, despite the important role health professionals can play in obesity management, they are an underutilized resource; most Canadians do not look to them for advice. A startling 89% of Canadians with obesity have never asked any licensed healthcare professional (family doctor, dietitian, pharmacist, etc.) about obesity. [23] Rather, consumers turn to a multi-billion-dollar commercial weight-loss industry. Many products and services offered in this space are unregulated and untested, but entice consumers with promises of significant and easy weight loss. While some approaches may actually achieve significant weight loss, more than 95% of diets and other approaches fail and result in weight regain, often to an even higher weight. An inability to lose and/or maintain weight loss perpetuates a vicious cycle of "yo-yo dieting," which too often results in frustration, depression, poor self-esteem, and further weight gain.[23]

"I cannot tell you how many times I have lost 20 or 30 lbs on some new diet. The weight flies off fairly quick, but it never lasts. It is almost impossible to diet forever and the weight always comes back with a vengeance. I just feel like giving up."

Understanding the perspectives of patients living with obesity is vital to achieving patient-centred care in primary care and improving health outcomes.[27]

All participants of our survey reported attempts for self-management of obesity through restrictive dieting, exercise and over the counter supplements with 86% stating that they were not effective long term. This is consistent with what we know from the evidence and speaks to

the complexity of the disease. Focusing solely on behavioral modifications like diet and exercise do not address the root drivers and biological, psychological or environmental factors that contribute to the disease. Given the lack of accessibility of obesity treatments in Canada however, this is what patients are ultimately left with to manage their obesity.

"I have never been able to follow a diet of any kind on my own...it certainly didn't improve my health or quality of life...it made me feel very low in my self-esteem."

"I have tried countless diets and participate in a number of activities that support physical health. They are not effective at lowering weight and keeping weight at a healthy level for a long period of time. I have ended up gaining back the lost weight and even gaining more. It was very frustrating and took away from my quality of life."

Many patients report a great deal of success through bariatric surgery which is considered the current gold standard for obesity treatment, however, surgical intervention is not appropriate for all individuals living with obesity and it is not scalable for the population that could benefit from it, which is evident by the multi-year wait from time of referral across the country. This is a gap in care that effective anti-obesity medications can help fill.

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?

With outcomes for obesity treatment, patients look for a number of outcomes but many go beyond simple weight loss efficacy. Many patients are looking for quality of life measures for things that they have been limited in due to their obesity. Outcomes related to improvement in related comorbidities (diabetes, hypertension, sleep apnea) as well as outcomes related to everyday life such as productivity, energy levels, sleep, activity and mental health. While weight loss is typically the primary outcome measure for the efficacy of an anti-obesity therapy, from a patients' viewpoint it goes much deeper and the weight loss is viewed as a needed step to the more meaningful quality of life outcomes.

"I need to lose weight so I can have the energy and mobility to play with my kids/grandkids" or "I am so preoccupied with worrying about my weight that my productivity and mental health suffer, if I can lose some weight, everything else will get better."

Hence, from a patient's view, the actual weight loss is less important than the impacts on the other outcomes.

If new treatments provide a positive impact on these outcomes, the quality of life of patients, caregivers and families would be drastically different. Obesity is a disease that impacts virtually all aspects of an individual's daily life. Improvement in sleep, productivity, energy levels, reduced stress of other conditions, improved mental status would all make a significant difference. These outcomes will also positively impact social aspects of life where individuals living with obesity would be better equipped and more comfortable engaging in social situations.

Typically, when considering a therapy for obesity, patients tend to assess the trade-offs between the desired outcomes mentioned above and the potential side-effects of the therapy, the ease of use of the therapy, and the cost of the therapy. In many cases, the potential for moderate benefits of a therapy will outweigh many manageable side effects. Cost seems to be the most significant determining factor in choosing a therapy for obesity.

No provincial drug formularies include anti-obesity medications and very few private drug plans cover them, so patients are left to pay out of pocket for their chronic disease management which in many cases, is unsustainable. In Canada, severe obesity has increased by 455% over the last three decades. This is in part due to the lack of treatments available for people who are affected by obesity. If we do not provide access to evidence-based treatments to patients living with obesity, their disease may continue to progress, which will impact their health and quality of life.

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.

Saxenda has been approved for use in Canada for several years. A small number of patients report having some coverage for the medication though their private insurance, with the average percentage covered being 50% for those individuals. The majority of individuals are required to pay out of pocket making the treatment cost-prohibitive.

Saxenda is generally a well-tolerated and effective treatment option as part of an individual's disease management plan. Patients in our survey with experience with the medication reported an average of 11% weight loss which is far more than the clinically significant cut off of 5% needed to see health improvements. 42% of respondents indicated experiencing some degree of side effects with the medication, with 75% indicating the side effects were short lived and manageable.

While a small percentage of people experienced side effects such as nausea or constipation that became unmanageable, patients have reported relatively positive results with Saxenda. For many patients, Saxenda is a tool that helps with appetite suppression and food intake which can be life altering for someone living with obesity. For many patients, the neural-hormonal pathways that regulate weight contribute to constant and uncontrollable food drive and insatiable appetite. Saxenda is a medication that addresses this and enables the individual to better adhere to behavioral modifications that support health.

"I have gained and lost weight a number of times and have been living with obesity for my entire adult life. For the longest time I felt as if I was defective because I could not control my obesity. This filled me with shame and despair and made me pull back from living my life. The one thing that was different for me than my friends and family that were not living with obesity is that my brain never shut off its food drive. It was all consuming and I was always thinking about food and what I was going to eat. There was no amount of willpower that would overcome this constant pressure. Taking Saxenda was the first time in my adult life that I experienced what it was like to be "normal". I was able to wake up in the morning and go through the day without the obsessive, constant drive to eat. Taking Saxenda was life changing in that I was able to focus my brain power and energy on things other than fighting the food drives. I am more productive; I am better able to stay on track with my nutrition and I have energy to live the active lifestyle I always wanted. I am so much healthier now."

"I have been on Saxenda, for 8 months and lost 40lbs. Sustained loss for the 9th month and will continue to use it."

"I have just started using Saxenda. I for the first time in my life feel like I have control over my food intake. After failing on meal replacements, I tried Saxenda and with the supervision of the health team created a plan to lower my weight and to sustain the weight loss."

"I lost substantial weight via bariatric surgery and then was able to manage a 60 lb regain post-op with medications. Medical management of my obesity has been a lifesaver, my quality of life is better than ever imagined, my health has improved immensely, no more hypertension, no more sleep apnea, no more joint pain and mobility issues and no more mental strain caused by trying to obsessively focus on managing obesity."

Saxenda is an innovative and effective tool that can have life-altering benefits for individual's living with obesity. For a chronic disease that is woefully mismanaged in Canadian healthcare and one that has a significant impact on quality of life, productivity, along with significant impacts on co-morbid conditions, patients need improved access to effective and innovative treatments.

When considering the relationship of obesity with other co-morbid conditions, particularly with diabetes, we need to consider the further benefits of appropriate obesity management and how that will impact the other conditions. Effective treatment of obesity is diabetes prevention. This is clearly identified in the outcomes of effective treatments like bariatric surgery where there is significant resolution of type 2 diabetes with patients undergoing that treatment. It is reasonable to expect a significant improvement in diabetes management for individuals with both conditions who receive effective obesity treatment AND perhaps most importantly a degree of diabetes prevention for individuals living with obesity who are able to manage their obesity through effective treatment.

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 favorable 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.

8. Anything Else?

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

Evidence on the close association between Covid-19 and underlying obesity provides a new urgency to treat obesity. A recent meta-analysis of 75 studies indicates that individuals living with obesity are at increased risk for COVID-19 infection (46% higher), hospitalization (113% higher), ICU admission (74% higher), and mortality (48% higher)[5]. We are pleased to see that the Public Health Agency of Canada has now included obesity as a risk for more severe COVID-19 disease or outcomes. This is an important step for ensuring that people with obesity have access to health services they need.

Providing access to obesity treatments for patients living with obesity is critical if we want to prevent obesity related chronic diseases and the impact of future pandemics such as COVID-19.

Unfortunately, there is pervasive weight bias in our society and obesity treatments are also stigmatized. Studies show that healthcare professionals believe that weight control is simple and that people with obesity are just not trying hard enough. We also have studies that show that many healthcare professionals do not believe that obesity is a serious chronic disease but rather they believe it is a lifestyle choice that their patients make. Many healthcare professionals believe that obesity is an individual's responsibility and if they just pulled themselves together, they would not have this "weight problem"[6].

The belief that weight can be controlled through individual behaviours such as healthy eating and exercise, leads to many health professionals and patients having biased beliefs about obesity treatments such as psychological therapy, medications, and bariatric surgery. Many believe that these treatments are ineffective and unnecessary.

Many patients blame themselves for their obesity. The idea that they have "failed to control their weight" can lead to feeling like a failure and feeling less capable as a whole. Patients often fail themselves rather than the treatments. Many patients also believe that obesity management is their own responsibility and that they should not need to go to their healthcare provider for help.

Educating patients about obesity as a chronic disease just like we educate any patient about their disease, may help reduce internalized weight bias and their understanding of obesity

[5] Popkin BM, Du S, Green WD, Beck MA, Algaith T, Herbst CH, et al. Individuals with obesity and COVID-19: A global perspective on the epidemiology and biological relationships. Obesity Reviews. 2020;21(11):e13128.

[6] https://obesitycanada.ca/action/

treatments. For example, patients should get help to understand that obesity must be managed in the same way as any other chronic disease. Simply using individual behaviour approaches such as nutrition and physical activity may not be enough for obesity treatment, just like it is not enough for the treatment of any other chronic disease. Healthy behaviours such as healthy eating and regular physical activity should be part of any chronic disease management approach. To date, however, this is all that patients living with obesity have been offered from the healthcare system.

At the moment, Canadians living with obesity do not have access to treatments in a just and fair manner. Patients living with obesity deserve to have access to evidence-based treatments. Not providing access to these treatments contributes to growing health disparities and social inequalities for people living with obesity. Although Saxenda may not work for all patients living with obesity, it may help some patients. For many patients, this medication will improve their health and quality of life.

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.

   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
Novo Nordisk				x

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: Ian Patton
Position: Director of Advocacy and Public Engagement
Patient Group: Obesity Canada
Date: 21/01/2021