

Patient Input for CADTH Reimbursement Review

Name of Drug: Wegovy (semaglutide injection) 2.4 mg

Indication: Wegovy (semaglutide injection) 2.4 mg 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 (obesity), or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, dyslipidemia, or obstructive sleep apnea.

Name of Patient Group: Diabetes Canada

Author of Submission: Ann Besner

1. About Your Patient Group

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

2. Information Gathering

This submission contains patient input from an online survey conducted in March 2022. It was open for two weeks (from March 10 to March 24) to people across Canada with prediabetes or type 2 diabetes, many of whom are living with overweight or obesity, and their caregivers. It consisted of a self-administered questionnaire of closed- and open-ended questions about respondents' lived experience with weight management, prediabetes or diabetes, medications (with specific questions about the drug under review, Wegovy [semaglutide injection] 2.4 mg) and expectations for new drug therapies in this country. Participation in the survey was solicited through Diabetes Canada's social media channels (Facebook, Twitter, Instagram and LinkedIn).

Wegovy (semaglutide injection) 2.4 mg is a weight management medication indicated and currently available for people living with overweight or obesity who may or may not have prediabetes or diabetes. Consideration is being requested by the manufacturer for reimbursement of this medication for adult patients with an initial body mass index of 35 kg/m² (Health Canada health risk

classification: obese class II) or more and prediabetes. As such, this submission features input from people living with overweight or obesity, as well as from people with prediabetes or type 2 diabetes, to which prediabetes can progress.

A total of 29 people participated in the survey – 3 identified as living with prediabetes and 26 identified as living with type 2 diabetes. There were no caregiver respondents. Respondents resided in Newfoundland, Quebec, Ontario, Manitoba, Saskatchewan, Alberta and British Columbia, with the most representation from Ontario (n=12) and Alberta (n=6). Respondents' ages ranged from 25-84 years, with the biggest concentration of respondents (n=8) falling in the 45-54 year grouping. About 76% (n=22) reported living with diabetes for 10 years or less (with 3 having had it for less than 1 year). There were 4 respondents who have been living with diabetes for 11-20 years and 3 for more than 20 years.

Among those who answered the question (n=21), 19 respondents (90%) said they identify as living with overweight or obesity and 15 respondents (71%) 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 4-6 years to 30 years plus; people shared that their experience with overweight or obesity has lasted “most of my life”, “since my childhood years” and was present “even in adolescence”.

Of those who responded to the question, 2 people said they have experience with the drug under review, Wegovy (semaglutide injection) 2.4 mg. In total, 1 person reported currently take Wegovy (semaglutide injection) 2.4 mg along with other diabetes medications, while 1 person reported having taken Wegovy (semaglutide injection) 2.4 mg in the past, but not anymore.

3. Disease Experience

Wegovy (semaglutide injection) 2.4 mg is a GLP-1 receptor agonist medication that is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients living with overweight or obesity. Reimbursement is being requested specifically for people within this grouping who are also living with prediabetes. Prediabetes is often 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, prediabetes significantly increases the risk for type 2 diabetes. In fact, Public Health Agency of Canada data suggest that more than half of the people with prediabetes will develop type 2 diabetes within eight to 10 years. For people living with overweight or obesity and prediabetes, various weight management approaches can help reduce likelihood of progression to diabetes.

Diabetes is a disease characterized by elevated levels of glucose in the blood. Common symptoms of diabetes include extreme fatigue, unusual thirst, frequent urination and weight gain or loss. Diabetes necessitates considerable daily self-management. Treatment regimens differ between individuals, but most include eating in a balanced manner, engaging in regular physical activity, taking medications (oral and/or injectable) as prescribed, monitoring blood glucose and managing stress.

About 90 to 95 percent of those diagnosed with diabetes live with type 2. Type 2 diabetes occurs when the pancreas does not produce enough insulin, or the body does not effectively use the insulin that is produced. Among other things, treatment may include exogenous insulin, in addition to other therapies, like oral and/or other injectable medications. Typically, type 1 diabetes presents in children and adolescents, while type 2 develops in adulthood, though either type of diabetes can be diagnosed at any age. Those of advancing age, with a genetic predisposition, who are part of a high-risk population (African, Arab, Asian, Hispanic, Indigenous or South Asian descent, low socioeconomic status) and/or who are living with comorbid conditions, including obesity, are at increased risk of type 2 diabetes.

It can be quite serious and problematic for people with diabetes when blood glucose levels are not at target. Low blood sugar can precipitate an acute crisis, such as confusion, coma, and/or seizure that, in addition to being dangerous, may also contribute to a motor vehicle, school/workplace or other type of accident, causing harm. High blood glucose can cause weakness, nausea, vomiting, abdominal pain and other symptoms. Over time, glucose levels above target can irreversibly damage blood vessels and nerves, resulting in issues like blindness, heart disease, kidney dysfunction, foot ulcers and lower limb amputations. One of the goals of diabetes management is to keep glucose levels within a target range to minimize symptoms and decrease the risk of complications and consequences.

Most respondents indicated that living with prediabetes or type 2 diabetes is preoccupying, inconvenient and burdensome. Management is constant, with the condition requiring a great deal of foresight and planning to deal with. While some suggested the impact to everyday life is minimal, the vast majority of respondents spoke negatively of their experience with prediabetes or diabetes and expressed feelings of guilt, shame, frustration and discouragement associated with their condition.

Survey respondents shared the ways in which prediabetes and type 2 diabetes impacts their daily life and overall quality of life. They provided the following insights:

“Slows me down. No energy.”

“I have to watch my diet so that takes all the pleasure out of food and going out to dinner. My doc keeps preaching doom and gloom.”

“Need for exercise and mindful eating, medical appointments and prescriptions.”

“Guilt, mental exhaustion.”

“Experience extreme fatigue. Not able to do intensive exercise, or exercise properly due to body weight. Sugar fluctuation causing blurred vision sometimes. Not able to reduce weight in spite of dieting. Unable to participate in outdoor activities.”

“I feel awful most of the time and I feel very trapped by what food I must eat.”

“I’ve essentially been living my entire adult life as diabetic. Chronic stress, fatigue and shame. Daily injections, medications and carb counting. Diabetes is involved in every activity of my day.”

“It restricts so many things I used to do. Now I get fatigued and headaches especially when my blood sugar is high (it’s always on the higher side). It’s frustrating!”

“Feel sluggish when my blood sugar is not balance [sic], feel insecure.”

“Affects my overall health.”

When asked specific questions about medical history, respondents (n=21) disclosed the following (in addition to prediabetes or type 2 diabetes):

- 52% have high blood pressure (n=11)
- 33% have abnormal cholesterol levels (n=7)
- 5% have a heart condition or heart disease (n=1)
- 10% have kidney issues or kidney disease (n=2)
- 48% have mental health concerns (n=10)
- 76% have weight management issues (n=16)
- 19% have eye problems (n=4)
- 5% have foot problems (n=1)

Additional conditions people experience include fatty liver, Sjogren's syndrome, asthma, osteoarthritis, brain inflammation, gall bladder issues, psoriasis, food sensitivities, environmental sensitivities, medication allergies and polycystic ovary syndrome.

Respondents also shared the ways in which overweight or obesity has impacted their daily life and overall quality of life. A few people commented that weight doesn't significantly affect their day-to-day activities or general way of living, but many respondents felt otherwise. They said:

"I find it hard to do anything."

"[I am] less active than before overweight. Lower self esteem. Want to avoid doctor because always reminded I need to lose weight."

"Makes it harder to be physically active, I feel less attractive, more tired."

"Weight affects everything I do, walking, housework, sitting, exercise."

"[I experience] insecurities, discomfort, fatigue."

"It causes joint pain and makes me feel depressed."

"These days it affects my self worth and mental health more than my activity level. But it's taken a lot to get there. Causes increased stress and increased likelihood for other health concerns."

"[I experience] terrible self esteem, [it is] hard to navigate a size 0 world in a size 20 body. The world is not made for those suffering with obesity."

"[I have been] getting tired easily. Panting when walking, and weight prevents me from using staircase as my legs pain. Feel that I am getting left out from get-togethers. Need to buy clothes often. Not able to stand for long hours and do housework including cooking. Overweight has caused knee problems. Quality of life has been affected. I feel body shamed. Doctors don't feel comfortable in treating obese person. Obesity has caused sleep apnea for me. In short, being overweight has caused me whole lot of problems mentally, physically and financially."

"Obesity is a terrible disease both physically [and] mentally. Buying plus sized clothing is more expensive, fitting in vehicles, furniture... there are so many negative factors. The stereotype is that fat people can/should just diet or quit eating 'bad' food. Obesity is so much more than fat."

These comments provide a glimpse at the lived reality of people experiencing overweight and obesity, demonstrate that the condition challenges physical and mental health, and illustrate the bias, stigma and discrimination people regularly face as they navigate the healthcare system and the world more generally.

4. Experiences With Currently Available Treatments

Of those who responded to the question (n=21), 3 people (14%) reported taking or having taken medication for weight management. When asked about likes and dislikes associated with these

medications, one respondent said “I feel like it helps me towards my goals”. Another said “[I] love being off insulin. The swings still happen but I don’t feel panicky with them”.

The following criteria were considered to be “very important” or “important” in selecting a medication for weight management:

- minimizes other side effects (100% of respondents)
- affordability (94% of respondents)
- ease – can be obtained without having to apply for special access authorization (88% of respondents)
- long-term effectiveness – helps maintain weight loss (88% of respondents)
- minimizes gastrointestinal side effects, e.g., diarrhea, nausea, vomiting, abdominal pain (88% of respondents)
- timeliness – can be obtained immediately (82% of respondents)
- short-term effectiveness – helps promote weight loss (76% of respondents)
- medication can be taken in pill form by mouth rather than injection (71% of respondents)

Respondents also said that physician support, local availability, information about long-term side effects of the medication and the damage they may cause, effectiveness and limited interaction with other medications are also important considerations in choosing a weight management medication.

Other weight management methods previously tried or currently engaged in were reported by respondents as follows:

- 95% are eating healthy (n=18)
- 74% are engaging in physical activity (n=14)
- 16% are taking herbal remedies or over-the-counter supplements (n=3)
- 11% are using a commercial weight loss program (e.g., WW, Jenny Craig, Herbal Magic, etc.) (n=2)
- 11% are following a medically-supervised obesity management program (n=2)
- 11% are considering or have undergone bariatric surgery (n=2)

Respondents provided feedback on how manageable and successful they feel these approaches are:

“Not successful. They require extreme organization, dedication, and a strong mental mind. Motivation is moot as it can’t overcome the other mental and physical barriers.”

“They have worked in past but I need to be determined.”

“I try to eat healthy but crave sweets.”

“I’ve been a consistently active person and have sometimes struggled with eating but mostly normally. In combination with medication I believe they are key. In my case adding medication helped me know what full felt like for the first time.”

“I can only succeed when I have the mental mindset to do so.”

“Successful but always end up gaining the weight back.”

“It’s a struggle.”

“Non sustainable [sic], on will power alone.”

Some respondents felt these strategies were effective (to varying degrees and under specific circumstances), but others expressed significant challenges with weight management. Of those who provided feedback on this question (n=7), 43% of people (n=3) said they were “very satisfied” or “satisfied” with the medications they take for weight management, while 29% (n=2) said they were “dissatisfied”; 29% (n=2) said they were neither “satisfied nor dissatisfied”.

With respect to antihyperglycemic treatment, 91% (n=19) of all respondents to this question (n=21) reported taking medication for their prediabetes or diabetes. Those being taken at the time of survey completion included insulin (glargine U300/other long-acting, short-acting, rapid-acting and premixed), GLP-1 receptor agonists, DPP-4 inhibitors, DPP-4 inhibitor/metformin combination, SGLT2 inhibitors and metformin. Additionally, respondents reported experience with insulin glargine, intermediate-acting insulin, TZDs and sulfonylureas. Of the 18 people who answered this question, 61% (n=11) said they were “very satisfied” or “satisfied” with their medication. Another 17% of people (n=3) expressed being “dissatisfied” or “very dissatisfied” with their medication, while 22% (n=4) were “neither satisfied nor dissatisfied”. Reported side effects of the medications included nausea, loss of appetite, atopic dyshidrosis, eczema, cheiropompholyx, constipation, diarrhea, bloating, fatigue, increased urination and yeast infections and weight gain.

Over 50% of respondents commented that their current medications were “much better” or “better” than previous treatments at meeting target fasting blood glucose levels, target levels upon waking, after meal targets and target hemoglobin A1c. The majority of respondents (50% or more) said their current medications were neither better nor worse when it came to gastrointestinal side effects (diarrhea, nausea, vomiting, abdominal pain), incidence of extreme thirst/dehydration, incidence/severity of yeast infections and incidence/severity of urinary tract infections. When it comes to weight management, 39% of respondents (n=7) said their current medications were “much better” or “better” at helping them to maintain or lose weight than previous therapies, 44% (n=8) said they were “about the same” and 17% (n=3) said they were “worse” or “much worse”.

When choosing a prediabetes or diabetes medication, respondents said it was important that the medication be affordable, discreet, without any major side effects, that it help meet hemoglobin A1c targets and prevent complications, and that it be immediately available.

People shared the following comments about what they like and dislike about their medications for prediabetes or diabetes:

“Controls appetite, hard on the stomach.”

“Helps blood sugar levels, sometimes tastes fishy.”

“I don’t like medicines because I get bowel problems.”

“Doesn’t make much difference to me. It seems to regulate my sugars slightly.”

“Adding [an SGLT2] and [a GLP-1] decreased the required insulin. And helped me feel full and like my body was healing faster. When I added those meds it honestly felt like my body was functioning again for the first time in a long time. The increased urination and the increased yeast infections not great but worth it.”

“It’s affordable.”

“It’s convenient. Easy to remember.”

“I don’t like or dislike.”

Some respondents said they don’t experience any issues or barriers to accessing their medications, but others shared that they find it difficult to procure medications and adhere to their prescribed regimen because their treatments are expensive, they don’t have insurance coverage to offset the cost, they don’t have a regular doctor to manage their care, they need a specific brand of medication, they are confused by the number of medications they are taking and they have to get special authorization for coverage, which was described as a “struggle”.

5. Improved Outcomes

Here is input from respondents on what they desire in new treatments for prediabetes, diabetes and weight management, and improvements they’d like to see to current therapies:

“Lower cost.”

“Reversing diabetes and reversing fatty liver disease, reversing high blood pressure, reversing gastrointestinal issues.”

“Make it accessible to all obese persons.”

“Better universal screening.”

“No needles – there has to be an easier way.”

“Less injections and more oral meds. Something that doesn’t increase damage to other organs. AFFORDABILITY!!!”

“Coverage, seeing extra weight as a chronic health condition, which, when controlled prevents other health issues, saving healthcare money.”

“A cure.”

If new treatments provided the desired improvements, respondents shared how daily life and overall quality of life would be improved:

“It would have a great effect.”

“Improved overall health, physically and mentally. Prevention of potential future health issues.”

“Weight reduction helps in overall quality of life – ability to walk and exercise, easing joint problems, heart is not over burdened [sic], fatty liver can be reverses. Confidence to move in social circles.”

“Overall quality of life is improved because your body feels like it’s functioning again. Losing weights [sic] biggest impact is the social and mental well being [sic] it improves.”

“More energy and more feeling better.”

6. Experience With Drug Under Review

Of those who responded to the question (n=18), 1 person reported currently taking Wegovy (semaglutide injection) 2.4 mg, along with other medications. There was also 1 person who used to take it before, but not anymore. The medication was obtained through manufacturer’s sample for 2 respondents. Both people who reported experience with the drug under review said their ability to maintain or lose weight, meet target hemoglobin A1c levels and meet target blood sugar levels was “much better” on Wegovy (semaglutide injection) 2.4 mg than before. There was 1 respondent who said gastrointestinal issues (diarrhea, nausea, vomiting, abdominal pain) were “much better” on Wegovy (semaglutide injection) 2.4 mg compared to before and 1 respondent who said they were “much worse”. The respondents shared that Wegovy (semaglutide injection) 2.4 mg generally “helped a lot”, caused fewer cravings, resulted in weight loss (which was highly valued) and removed the need for insulin. One respondent said “not being on insulin is huge for me as I don’t feel like I’m on a roller coaster”.

7. Companion Diagnostic Test

Wegovy (semaglutide injection) 2.4 mg does not have a companion diagnostic.

8. Anything Else?

Overweight, obesity, prediabetes and diabetes are conditions that require intensive 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 in a timely manner and with good result to help them lead a normal life. Wegovy (semaglutide injection) 2.4 mg 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, Wegovy (semaglutide injection) 2.4 mg should be an option for people living with obesity and prediabetes.

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

“There should be more help with the cost of drugs.”

“[There ought to be increased] funding for a cure or a more sustainable treatment.”

“[It is] frustrating that [treatments for other medication conditions are] covered, but not the newest and most effective medical [sic] for diabetes.”

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.

Diabetes Canada had no outside assistance to collect or analyze data used in this submission.

3. List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review.

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.

Table 1: Financial Disclosures

Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
PLEASE SEE ATTACHED				

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, RD

Position: Manager, Research and Public Policy

Patient Group: Diabetes Canada

Date: April 1, 2022

Diabetes Canada Financial Contributors Last updated: February 2021

\$400,000+



\$150,000 - \$399,999



\$50,000 - \$149,999



\$20,000 - \$49,999

Abbott Nutrition, All Bran, Boehringer Ingelheim (Canada) Ltd, Dexcom Canada, Heartland Food Groups, Lifescan Canada Ltd., Lifestyle Hearing, Nestle Health Science, Sanofi Pasteur, Takeda Canada Inc, TD Insurance