



CADTH REIMBURSEMENT REVIEW

Patient and Clinician Group Input

insulin icodec (Awiqli)
(Novo Nordisk Canada Inc.)

Indication: The once-weekly treatment of adults with diabetes mellitus to improve glycemic control.

October 30, 2023

This document compiles the input submitted by patient groups and clinician groups for the file under review. The information is used by CADTH in all phases of the review, including the appraisal of evidence and interpretation of the results. The input submitted for each review is also included in the briefing materials that are sent to expert committee members prior to committee meetings.

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Patient Group Input

Patient Input

- Name of Drug: Insulin Icodec
- Indication: Diabetes Mellitus, type 2
- Name of Patient Group: Diabetes Canada
- Author of Submission: [REDACTED]

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 from October 2nd to 23rd, 2023. The survey was open to people across Canada and consisted of a self-administered questionnaire. The survey was directed at people living with type 2 diabetes and caregivers of people living with type 2 diabetes. The survey inquired about respondents' lived experience with diabetes and diabetes medications, and expectations for new drug therapies in Canada. Further, the survey posed several questions specifically about the drug under review, insulin icodec. Awareness about the survey was generated through Diabetes Canada's social media channels (Twitter, LinkedIn and Facebook), e-blast to Diabetes Canada digital subscribers, and via a health-care providers' online forum (Diabetes Canada's Professional Section).

A total of 21 people responded to the October 2023 survey – of those who responded to the general information section of the survey, 13 identified as living with type 2 diabetes while only one respondent identified as a caregiver to somebody with type 2 diabetes. Of those who responded to questions about age and time since diagnosis (n = 14), 93% were over the age of 55, with the largest number of respondents (35%, n = 5) in the 75–84-year-old category, and 71% having lived with diabetes for over 10 years (29% of this group reported having diabetes for over 20 years).

The majority of respondents live in Ontario (n = 4) and British Columbia (n = 4), with one respondent from Prince Edward Island, Quebec, Manitoba and Alberta, two respondents identified as living in Nova Scotia. 78% of respondents indicated that they live in an urban or suburban region (n = 11), with 14% indicating that they live in a rural area (n = 2). 9 respondents identified as male and 5 identified as female. 79% of respondents identified as White Caucasian (n = 11), while only one respondent identified as being either South Asian, Southeast Asian or Chinese.

3. Disease Experience

Insulin icodec is a once-weekly basal insulin that is designed to achieve a long half-life by changing the human insulin molecule. Reimbursement is being requested specifically for adults living with type 2 diabetes consistent with a subset of the Health Canada indication, for the once-weekly treatment of adult patients with type 2 diabetes mellitus to improve glycemic management.

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 diabetes. 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 position), and/or who are living with comorbid conditions, including obesity, are at increased risk of developing 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 non-traumatic 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 survey respondents indicated that living with type 2 diabetes is preoccupying, inconvenient, and burdensome. Management is constant, with the condition requiring a great deal of foresight and planning. The majority of respondents spoke of the challenges of managing their blood glucose in relation to their diet and food choices, and the constant pressure of diabetes management. Survey respondents shared the ways in which type 2 diabetes impacts their daily life and overall quality of life. They provided the following insights:

4. Experiences With Currently Available Treatments

Respondents were asked how often they (or the person they care for) experience hyperglycemia (high blood sugar) and hypoglycemia (low blood sugar). Percentages and totals are presented in the table below. Of note for this submission is that of respondents report high blood sugar more than once a day.

	Not at all	Less than 1/month	2-4 times/month	More than 1/week	More than 1/day	In the past, but not now	Don't know
Hyperglycemia (n = 20)	5% (n = 1)	14% (n = 3)	33% (n = 7)	10% (n = 2)	24% (n = 5)	5% (n = 1)	5% (n = 1)
Hypoglycemia (n = 20)	38% (n = 8)	29% (n = 6)	10% (n = 2)	14% (n = 3)	0% (n=0)	5% (n = 1)	0% (n=0)

With respect to antihyperglycemic treatment, all respondents (n = 19) to this question reported taking medication for their diabetes. Those being taken at the time of survey completion included insulin (glargine U300/other long-acting, short-acting, and rapid-acting), insulin icodec, daily/weekly GLP-1 receptor agonists and GLP-1 receptor agonists/metformin combination, DPP-4 inhibitor/metformin combination, SGLT2 inhibitors and SGLT2 inhibitors/metformin combination, TZD/metformin combination, sulfonylureas, and metformin. Additionally, respondents reported experience with insulin glargine, short-acting insulin, rapid-acting insulin, DPP-4 inhibitors, DPP-4 inhibitors/metformin combination, TZD/metformin combination, sulfonylureas, metformin, and meglitinide.

18 respondents also indicated utilizing non-medication interventions to manage their diabetes:

50% reported healthy eating (n = 9)

17% reported engaging in physical activity (n = 3)

28% reported taking herbal remedies or over-the-counter supplements (n = 5)

6% reported that they have considered or done bariatric surgery (n = 1)

Of the 18 people who answered this question, 61% (n = 11) said they were “very satisfied” or “satisfied” with their medication. No respondents expressed being “dissatisfied” or “very dissatisfied” with their medication, while 28% (n = 5) were “neither satisfied nor dissatisfied”. 11% (n = 2) indicated that they do not take any medication.

Over 70% of respondents commented that their current medications were “much better” or “better” than previous treatments at meeting target fasting blood glucose levels, after meal targets, and maintaining or losing weight. Between 25 and 44% of respondents reported that their current medications were “much better” or “better” at avoiding high and low blood sugar, and meeting target hemoglobin A1C levels. At least one quarter of respondents (24% or more) said their current medications were neither better nor worse when it came to meeting target blood sugar levels upon waking, avoiding high and low blood sugar, and meeting target hemoglobin A1C levels. Over 45% of respondents indicated that their current medications were “much better” or “better” than previous treatments at maintaining or losing body weight and preventing vascular complications.

The table below represents how current medications being used by respondents (n = 16) impact medication objectives and potential side effects.

	Better/much better than before	Same as before	Worse/Much worse than before
Meeting target A1C blood sugar levels	71% (n = 12)	24% (n = 4)	0% (n=0)
Meeting target fasting blood sugar levels	69% (n = 11)	19% (n = 3)	6% (n = 1)
Meeting target blood sugar levels upon waking	53% (n = 8)	24% (n = 4)	0% (n=0)
Meeting target blood sugar levels after meals	50% (n = 8)	38% (n = 6)	0% (n=0)
Avoiding hypoglycemia (low blood sugar)	44% (n = 7)	38% (n = 6)	13% (n = 2)
Avoiding hyperglycemia (high blood sugar)	56% (n = 9)	31% (n = 5)	6% (n = 1)
Maintaining or losing weight	56% (n = 10)	33% (n = 6)	11% (n = 2)
Organ damage (pancreas, liver, kidney, heart)	25% (n = 4)	69% (n = 11)	6% (n = 1)
Preventing vascular complications (heart attacks, strokes, peripheral vascular disease)	47% (n = 7)	53% (n = 8)	0% (n=0)
Thirst and/or dehydration	31% (n = 5)	56% (n = 9)	27% (n = 4)
Gastrointestinal side effects (diarrhea, nausea, vomiting, abdominal pain)	13% (n = 2)	69% (n = 1)	6% (n = 1)
Yeast infections and/or Urinary tract infections	25% (n = 4)	44% (n = 7)	6% (n = 1)

Reported side effects of the medications included gastrointestinal issues (nausea, constipation, diarrhea), weight gain, and kidney pain.

When asked what they liked about their diabetes medications, respondents indicated that their medications were easy to use, had no side effects, and helped lower their A1C. Factors that respondents disliked about their medication included quantity and/or timing of dosing different medications (e.g., too many pills/needles; some are taken daily while others are taken weekly), fluctuations to blood glucose levels, that they need the medication at all, and the cost associated with the medications.

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

“Enables me to generally have morning blood sugar levels below or well below 7.5.”

“It works, not great, but it works.”

“Covered in Insurance ... later in the age no idea.”

“Easy to use.”

“A1C finally in range.”

5. Improved Outcomes

Respondents shared how important the following considerations are in choosing medications for diabetes management:

Avoid high blood sugar at any time (100%, n = 10)

Reduce the risk of heart problems (100%, n = 11)

Blood sugar kept at satisfactory level upon waking, during the day, after fasting, or after meals (100%, n = 11)

Avoid low blood sugar during the day or overnight (92%, n = 12)

Avoid yeast infections or urinary tract infections (100%, n = 11)

Avoid fluid retention (100%, n = 11)

Avoid weight gain/reduce weight gain (90%, n = 10)

Reduce high blood pressure (90%, n = 10)

Respondents also highlighted the affordability of prescription medications and the financial burden it places on them as a consideration in choosing treatments. Four respondents indicated that ease of use and effectiveness were important to them in choosing medications for diabetes management.

Respondents were asked what improvements they'd like to see in a new treatment that is not achieved in currently available treatments for type 2 diabetes. Here is their input:

“Less side effects and reasonable cost.”

“Weight control.”

“Blood flow improvement to extremities.”

“I Weight loss and better A1C results.”

A handful of respondents also provided detail on how their daily life and overall quality of life would be different if a new treatment provided their desired improvements:

“Life will be much better with less stress and worry about my health.”

“Gratitude for any help to stay healthy.”

“Super and better result of maintaining my blood sugar level.”

“Reduce the number of medications required.”

“Reduce insulin, increase weight loss as well as better nutrition counseling and improve mental health.”

6. Experience With Drug Under Review

Of those who responded to the question (n = 18), five respondents reported currently taking insulin icodec, along with other medications. The medication was obtained through private insurance.

The table below represents how insulin icodec being used by respondents (n = 5) impact medication objectives and potential side effects.

	Better/much better than before	Same as before	Worse/Much worse than before
Meeting target A1C blood sugar levels	83% (n = 4)	17% (n = 1)	0% (n=0)
Meeting target fasting blood sugar levels	83% (n = 4)	17% (n = 1)	0% (n=0)
Meeting target blood sugar levels upon waking	83% (n = 4)	17% (n = 1)	0% (n=0)
Meeting target blood sugar levels after meals	83% (n = 4)	17% (n = 1)	0% (n=0)
Avoiding hypoglycemia (low blood sugar)	60% (n = 3)	40% (n = 2)	0% (n=0)
Avoiding hyperglycemia (high blood sugar)	83% (n = 4)	17% (n = 1)	0% (n=0)
Maintaining or losing weight	60% (n = 3)	40% (n = 2)	0% (n=0)
Organ damage (pancreas, liver, kidney, heart)	25% (n = 1)	75% (n = 3)	0% (n=0)
Thirst and/or dehydration	40% (n = 2)	60% (n = 3)	0% (n=0)
Gastrointestinal side effects (diarrhea, nausea, vomiting, abdominal pain)	40% (n = 2)	40% (n = 2)	20% (n = 1)
Yeast infections and/or Urinary tract infections	40% (n = 2)	60% (n = 3)	0% (n=0)

For respondents who have used or are currently using insulin icodec, they shared the following comments about what they liked about medication and how insulin icodec has impacted their life:

“Better a1c.”

“Once a week.”

“Can lower my blood sugar within the target level.”

“Lowered my A1C's to be within range for the first time in 10 years and in less than 3 months.”

“Brought sugar levels under control.”

For respondents who have used or are currently using insulin icodec, they shared the following comments about what they disliked about medication:

“Cost.”

“Injection.”

7. Companion Diagnostic Test

Insulin icodec does not have a companion diagnostic, therefore this question is not applicable to our submission.

8. Anything Else?

Diabetes is a disease that requires intensive self-management. Diabetes Canada's 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada highlight the importance of personalized care when it comes to 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, people living with diabetes and their caregivers hope for additional affordable agents that they can access in a timely manner and with good result to help them lead a normal life. Insulin icodec may help improve glucose management, thereby reducing the risk of diabetes-related complications, improving lives, and saving millions in direct health-care costs. For this reason, insulin icodec should be an option for people living with type 2 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.

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

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

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

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

Table 1: Financial Disclosures

Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Novo Nordisk				X
AstraZeneca	X			
Janssen			X	
Sanofi	X			
Bayer	X			

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

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: [REDACTED]

Position: [REDACTED]

Patient Group: Diabetes Canada

Date: October 26, 2023

Clinician Group Input

No clinician group input was received by the deadline of the call for input.