



## Common Drug Review *Patient Group Input Submissions*

### **dulaglutide (Trulicity) for Type 2 diabetes**

**Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.**

**Canadian Diabetes Association** — permission granted to post.

#### **CADTH received patient group input for this review on or before January 13, 2016.**

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# Canadian Diabetes Association

## Section 1 — General Information

<b>Name of the drug CADTH is reviewing and indication(s) of interest</b>	dulaglutide (Trulicity) Type 2 diabetes
<b>Name of patient group</b>	Canadian Diabetes Association
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### 1.1 Submitting Organization

The Canadian Diabetes Association (the CDA) leads the fight against diabetes by helping people with diabetes live healthy lives while we work to find 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. The CDA 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 with diabetes, supporting research, and translating research into practical applications, the CDA is delivering on its mission.

### 1.2 Conflict of Interest Declarations

The Canadian Diabetes Association (the CDA) solicits and receives unrestricted educational grants from multiple manufacturers/vendors of pharmaceuticals, supplies and devices for diabetes and its complications. These funds help the CDA to support community programs and services for people with diabetes, fund research and advocacy, across Canada. Sponsors were not involved in developing this submission. A list of organizations and foundations that made donations to the CDA in 2014 can be found in the appendix. The CDA did not have any conflicts of interest in the preparation of this submission.

## Section 2 — Condition and Current Therapy Information

### 2.1 Information Gathering

The Canadian Diabetes Association (the CDA) solicited patient input through surveys distributed through social media and email blasts. Content of this submission is derived from 2 surveys. The first survey, conducted in October 2015 for 10 days, gathered information from 212 Canadians with type 2 diabetes and 61 caregivers for people with diabetes about the impacts of diabetes. The second survey, conducted in December 2015 for 4 weeks, gathered information from Canadians with type 2 diabetes (n= 352) and their caregivers (n=34) about current drug therapies and experience with dulaglutide and/or other GLP-1 agonists, as well as aspects of diabetes they would like medications to address.

### 2.2 Impact of Condition on Patients

Type 2 diabetes is a chronic (progressive) condition that occurs when the pancreas does not produce enough insulin or when the body does not effectively use the insulin that is produced. Insulin is a hormone that controls the amount of glucose in the blood. Common symptoms of diabetes include fatigue, thirst and weight change. High blood glucose levels can cause long-term complications such as blindness, heart disease, kidney problems, nerve damage and erectile dysfunction. The goal of diabetes management is to keep glucose levels within the target range to minimize symptoms and avoid or delay the complications.

Diabetes requires considerable self-management, including healthy eating, regular physical activity, healthy body weight, taking diabetes medications (oral and/or injection) as prescribed, monitoring blood glucose and stress management. Poor glucose control can result in acute crises, and serious long-term complications.

Respondents were asked to describe the daily impact of diabetes. For the majority of respondents, diabetes has negatively impacted all aspects of their lives and limited daily activities. Some indicated that they were “held captive by diabetes” and that diabetes was “overwhelmingly debilitating.” Diabetes management is a “constant struggle” involving meal planning, testing blood glucose, taking medication and ensuing stress. Many are frustrated that they cannot lead a “normal life” due to diabetes. Other impacts include fatigue and lack of energy. It is also challenging when a person needs to manage diabetes as well as other co-existing conditions/diabetes-related complications. Many respondents reported complications as a result of their diabetes, including neuropathy, foot complications, heart problems, strokes, eye problems/loss of vision, kidney problems (leading to kidney transplant and dialysis), pancreatitis, skin ulcers, erectile dysfunction, amputation and depression.

There was a frequent emphasis on the psychological and emotional impact of diabetes on the lives of respondents and their family members, due to the need to adjust to changes in diet and lifestyle, stress and anxiety about hypoglycemia, daily medication and treatment management, strain on relationships with family, and financial burden. For individuals who have to manage diabetes and care for other members of the family, it is also very difficult.

Direct quotes below further describe the general impact of diabetes on respondents:

*“I need to be careful with what I eat and how much I eat, especially carbohydrates. Also need to balance out a snack, insulin needs and exercise to ensure I don't have a hypoglycemic episode while exercising. I also need to monitor my insulin needs while doing errands, again to avoid a hypoglycemic episode.”*

*– person living with type 2 diabetes*

*“[Diabetes has] affected my family also due to my being not able to work while I was waiting for a kidney transplant , which was given to me by ... my son . Because of being on dialysis [sic] I had to spend most of my life's savings. Being sick can be very very expensive.” – person living with type 2 diabetes*

*“It is difficult to lead a normal life when you always need to be taking meds or checking your [blood sugar] levels and reading labels on all your food while your [blood sugar] levels change with or without food intake. The impact of diabetes on all your other organs is another huge problem and when you treat one you harm another. Most difficult disease to manage.” – person living with type 2 diabetes*

Respondents to the December 2015 survey reported the following **conditions/symptoms**. A large proportion of respondents reported high blood pressure (59%), high cholesterol (55%), foot problems (47%), hypoglycemia (42%), eye problems (40%) and nerve damage (34%). The percentages are based on 308–337 people with type 2 diabetes and caregivers who responded to the question about symptoms/conditions they were experiencing (Table 1).

**Table 1: Conditions experienced by surveyed respondents, by degree of severity**

Condition	Moderate/sometimes	Severe/often	Total
Hypoglycemia	40%	2%	42%
High blood pressure	47%	12%	59%
High cholesterol	46%	9%	55%
Mental health problems	10%	3%	13%
Kidney problems	14%	4%	18%
Foot problems	36%	10%	47%
Eye problems	33%	7%	40%
Nerve damage	26%	8%	34%
Damage to blood vessels, heart or brain	11%	4%	15%
Liver disease	6%	2%	8%
Endocrine disorder	7%	2%	9%

In addition, four respondents reported thyroid problems and one reported erectile dysfunction.

The two tables below show the conditions experienced by surveyed respondents, by age groups. Whereas the percentages are similar across age groups for the majority of conditions, apparent differences are observed in some conditions: hypoglycemia, high blood pressure, mental health problems and foot problems (Table 2). Table 3 describes aspects of diabetes that respondents believed were “quite important” or “very important” that medications should address, by age groups.

**Table 2: Conditions experienced by respondents, by age group (percentage)**

Condition (moderate/severe)	Under 55 (n=46)	55-69 (n=128)	70 and older (n=105)
Hypoglycemia	38%	49%	36%
High blood pressure	56%	57%	66%
High cholesterol	56%	55%	54%
Mental health problems	27%	14%	15%
Kidney problems	14%	18%	16%
Foot problems	43%	40%	55%
Eye problems	47%	43%	41%
Nerve damage	31%	35%	38%
Damage to blood vessels, heart or brain	14%	14%	18%
Liver disease	5%	9%	8%
Endocrine disorder	7%	11%	10%

**Table 3: Aspects of diabetes that are important for medications to address, by age group (percentage)**

Aspect	Under 55 (n=46)	55-69 (n=128)	70 and older (n=105)
Blood glucose kept at satisfactory level during the day or after meals	91%	96%	93%
Blood glucose kept at satisfactory level in the morning or after fasting	95%	95%	97%
Avoid low blood sugar during the day	91%	92%	85%
Avoid low blood sugar overnight	93%	89%	86%
Avoid weight gain/reduce weight	93%	91%	86%
Reduce high blood pressure	72%	89%	89%
Avoid stomach side effects	84%	84%	73%
Avoid urinary tract infection or yeast infection	74%	83%	78%
Avoid fluid retention	85%	86%	79%

### 2.3 Patients' Experiences With Current Therapy

Many people with type 2 diabetes have difficulty achieving optimal glycemic control and are therefore at risk for both acute and chronic diabetes complications. The initial therapy they receive is most often metformin, but over time, most people will require the addition of a second or third agent to reach glycemic targets. Many of the currently available second-line therapies cause significant weight gain while their ability to achieve optimal glycemic control may be limited by hypoglycemia.

A total of 386 Canadians with diabetes and caregivers indicated experience taking diabetes medications. The majority of respondents (59% of 301) indicated that they were “satisfied” or “very satisfied” with their current therapies whereas 20% indicated dissatisfaction. When asked about specific symptoms before and after treatment, over half of respondents indicated current therapies resulted in “better” or “much better” blood glucose and A1C control: 65%, 55%, and 56% reported better control for fasting,

after eating and upon waking blood glucose levels, respectively. For target A1C levels, 55% indicated better results with treatment.

Approximately 63% of respondents indicated that weight gain had not improved or gotten worse with the current treatment compared with 32% who reported improvement (n= 279 responses); for GI effects 64% reported “the same,” “worse” or “much worse” compared with 21% who reported improvement(n= 272 responses). Describing current therapies, 62% reported same or worse results for dehydration (compared to 19% who saw improvement) and 52% indicated same or worse for urinary tract/yeast infection (compared to 22% who saw improvement). Approximately half of respondents (47%) reported improvement in hypoglycemia with current therapy.

Overall, respondents were more satisfied than dissatisfied with their medications in terms of the ability to manage their blood sugar and A1C levels. However, there were considerable issues with side effects.

Surveyed patients were asked to rate the **importance of benefits/side effects when choosing diabetes medications**, using a five-point scale from “not at all important” to “very important.”

Over/close to 90% of respondents indicated the following benefits of therapy were “quite important” or “very important”:

- blood sugars kept at satisfactory levels in the morning/after fasting (96%)
- blood sugars kept at satisfactory levels during the day/after meals (94%)
- avoiding weight gain (90%)
- avoiding low blood sugar during the day/overnight (89%)

The following aspects are also considered important by the vast majority:

- reducing high blood pressure (87%)
- avoiding fluid retention (84%)
- avoiding GI effects (80%)
- avoiding urinary tract infection (80%)

The medications currently taken by people we surveyed include metformin (168), insulin (120), sulfonylureas (68), DPP-4 inhibitors (42), SGLT2 inhibitors (38), combination D-PP4 inhibitors +metformin (36), meglitinides (9), TZDs (8), rosiglitazone+metformin (3), and acarbose (4).

## Section 3 — Information about the Drug Being Reviewed

### 3.1 Information Gathering

The Canadian Diabetes Association (the CDA) solicited patient input on the drug being review, through a survey distributed through social media and email blasts. Conducted in December 2015 for 4 weeks, the survey gathered information from Canadians with type 2 diabetes (n=352) and their caregivers (n=34) about experience with dulaglutide and/or other GLP-1 agonists, and the most important aspects of diabetes they would like new medications to address.

### 3.2 What Are the Expectations for the New Drug or What Experiences Have Patients Had With the New Drug?

The availability of dulaglutide to offer an alternative treatment option for stabilizing blood glucose is important to patients. Dulaglutide, a once-weekly type 2 diabetes medication, belongs to a class of injectable drugs known as glucagon-like peptide 1 (GLP-1) receptor agonists, which lower blood glucose

by mimicking the functions of natural incretin hormones; these hormones stimulate the release of insulin after eating, inhibit the release of glucagon, and slow glucose absorption into the bloodstream.

### **Experience with dulaglutide/other GLP-1 agonists**

As dulaglutide is not yet on the Canadian market and very few respondents have taken it, the survey asked about experience taking other drugs of the same class (GLP-1 receptors agonists). A total of 71 respondents reported having taken liraglutide (Victoza), 5 have taken exenatide (Byetta) and 4 have taken dulaglutide (Trulicity). Most of the respondents were over age 55 (about 53% were between 55-69 years old, 13% over 70 years old) and about 25% were between 40-54 years old. Among them, 42% have had diabetes for 11-20 years, 25% over 20 years, and 20% between 6-10 years. About 65% reported currently using metformin, 51% currently using insulin, 28% currently on a SGLT2 inhibitor, 24% currently on a sulfonylurea, 10% currently using a DPP-4 inhibitor, two are currently using sitagliptin+metformin, rosiglitazone+metformin, or meglitinide, and one person is using acarbose.

Overall, 65% of those who reported experience with a GLP-1 agonist (mostly in combination with other medications) indicated satisfaction with the current therapy, primarily as a result of better blood glucose control (fasting, upon waking) and A1C control (70%). Better post-prandial blood glucose was reported by 66%. About 50% indicated better or much better weight control versus 47% who reported “same” or “worse” results. Approximately 46% indicated that their hypoglycemia improved with current therapy, compared to 46% who saw no improvement; 67% reported same or worse GI effects (versus 23% who saw improvement), 66% reported same or worse for dehydration (versus 16% who saw improvement), and 53% reported same or worse urinary tract/yeast infection (versus 20% who saw improvement).

One respondent taking dulaglutide reported that it was “very effective in weight loss and blood sugar control”. People who have taken any GLP-1 agonists consistently reported better control of blood glucose levels and A1C, and better results with side effects, notably avoiding weight gain. Below are some direct quotes from respondents using GLP-1 agonists:

*“My quality of life and day-to-day feelings of wellness have dramatically improved since being on this drug...since I started .... I have felt much, much better. I don't have severe feelings of hunger every four hours and I have feelings of fullness during eating so it is easier to prevent over eating.”*  
– person with type 2 diabetes

*“I have never used dulaglutide but I know my experience with [other GLP-1 agonist] has been very good. It has helped to drastically reduce my blood glucose test results and brought my A1C down significantly from 10.0 to 7.9 in just a few months.”* – person with type 2 diabetes

*“The GLP-1 drug that I have been taking was very life changing: better numbers, better A1C, lost weight, feel better generally except for occasional nausea[sic] and acid reflux.”* – person with type 2 diabetes

*“[GLP-1 agonist] enabled me to reduce my weight and keep it off.”* - person with type 2 diabetes

*“Using [GLP-1 agonist] has greatly improved my quality of life as a type 2 diabetic(after initial nausea and vomiting)as it is unnecessary for me to carry .... pens with me in my daily life and I avoid low blood sugars when giving a too-high a dose of insulin....better control”* – person with type 2 diabetes

*“I would like an effective medication that can help eliminate the problems with older drugs. My mother suffered horrible diarrhea with metformin and was miserable. [GLP-1 agonist] was a lifesaver! She*

*managed to lose over 50 lbs and was off ALL meds. When she lost drug coverage she had to stop (province doesn't cover), has put on the wait[sic] and is back on a host of medications.” – caregiver for person with type 2 diabetes*

One individual reported “extremely negative experience with [GLP-1 agonist].” While GLP-1 agonists work well for many, some find its **cost** a barrier, especially for seniors. One individual using a GLP-1 agonist as part of a clinical trial remarked: “I hope [it] will be covered under my drug program, it's helping with my blood sugar and I feel much better since trials began.” A retiree noted: “I use [GLP-1 agonist] now and am on retirement income. I would like to see it covered by my health insurance or have another drug that is as effective that is covered.” Another senior expressed a similar wish: “include [my GLP-1 agonist] (and those relate drugs that are actually effective) in the list of drugs covered by the Seniors Drug Plan.”

About 45% of respondents (based on 282 responses) believed it is important or very important that dulaglutide be made available to Canadians with type 2 diabetes. One individual noted that “it is important that people have options because different medications seem to vary in their effectiveness with different people.” Another noted that “if [a drug] works successfully for patients with type 2 diabetes, then it should be available and at a reasonable price.” Some (who have taken liraglutide) believed that dulaglutide could also “lower need for more insulin which can lead to weight loss and will improve quality of life for diabetics i.e. weight loss leading to improved blood pressure and A1C.” A number of respondents viewed the less frequent injections as an advantage: “If Trulicity is as effective .... once a week injection would be better”; “If you can inject once to manage blood glucose for 1 week then it makes it easier to control.” An individual currently on metformin and insulin noted: “Save me from taking 4 injections daily [which] complicates life. I've read a lot about Trulicity... Can't wait for it in Canada.” As the price of drugs is a barrier for some people, respondents hoped for dulaglutide to be made available, at an affordable cost.

### **Expectations of new medications**

Respondents hope that new medications would be able to offer the following benefits:

- Affordability, accessibility for all people with diabetes
- Better control
- Minimal or no side effects; reduced risk of hypoglycemia; better control of high blood pressure and cholesterol
- Do not increase the risk of diabetes complications
- Improve life and life expectancy
- Works well for the majority of patients
- Taking less medication
- Less testing
- Easier administration (i.e. without a needle)
- Weight loss/prevent weight gain
- A cure

For people who are dependent on insulin and/or injectable medications, many voiced the hope for reduced or elimination of injections: “Anything that will avoid pricking the fingers would be a huge bonus”; “Make it possible to stop taking insulin and other injectables, i.e., be able to take the meds orally.” An individual who is currently taking another GLP-1 agonist, an SGLT2 inhibitor and insulin



noted: “The combination of medications I am currently on seems to be working well for me. If I have one hope, it would be to reduce the number of injections I have to have each day.”

### **Summary**

Type 2 diabetes requires intensive self-management and can be challenging; as one respondent put it: “Managing diabetes is very stressful because you take lots of medication and in spite of your best efforts, maintaining target ranges is difficult.” To achieve optimal blood glucose levels, individualization of therapy is essential, including selecting the drug or combination of drugs, route of administration (oral or injection), how frequently the patient monitors blood glucose and adjusts dosage, the benefits and risks that the patient experiences and/or tolerates, and the lifestyle changes the patient is willing or able to make.

There are clear expectations that new drugs should offer better blood glucose control to prevent hyper- and hypoglycemia, as well as longer term control, with minimal side effects (particularly weight gain), at affordable costs, reduced dependency on other drugs and insulin, as well as less frequent injections required to maintain blood glucose control. Many surveyed respondents who have not had experience with dulaglutide hoped that the medication would provide good control while reducing the number of injections, medications and testing. While cost remains a barrier, based on the experience of respondents, many of these expectations were met by GLP-1 agonists in providing better control of blood glucose levels and of diabetes in general.

At least one person did not have a positive experience/did not experience improvement with GLP-1 agonist treatment, which reinforces the understanding that different people with type 2 diabetes require different options in terms of medications to help effectively manage their disease. Their clinical profile, preference and tolerance of therapy can direct physicians to the most appropriate drug therapy. The availability of dulaglutide thus provides an important option for patients with type 2 diabetes.

**Appendix: Organizations and foundations that made donations to the Canadian Diabetes Association in 2014 (up to December 31, 2014).** Source: CDA 2014 Annual Report, available at <http://www.diabetes.ca/getmedia/d4beee80-01c5-46a1-b2f6-37cbb49e9c61/2014-cda-annual-report.pdf.aspx>

593123 Alberta Ltd.	Community Foundation of Ottawa	Jackson Family Fund	Orville & Alvera Woolacott Foundation	Subway
A. E. (Ted) & Deanna M. Turton Charitable Foundation	Community Initiatives Fund	Janssen Inc.	Panasonic Canada Inc.	Sudbury Rocks Running Club
Abbott Diabetes Care	Connect Marketing Group	Jays Care Foundation	Pfizer Canada Inc.	Sunrise Soya Foods
Abbott Laboratories Ltd.	Co-operators/CUMIS	Jewish Community Foundation	Pharmasave Central	Sure Flow Equipment Inc.
Adi Development Group	Crabtree Foundation	Johnson & Johnson	Point Edward Ex-Servicemen's Association	TD Securities
Agway Metals Inc.	Deloitte LLP	Kal Tire	PriceWaterhouse-Coopers LLP	Teck Resources
Aqueduct Foundation	Dr. Charles & Margaret Brown Foundation	Kinsmen Club of Kingston	Private Giving Foundation	TELUS Cares
AstraZeneca Canada Inc.	EECOL Electric	Kinsmen Club of Saskatoon	Raymond James Canada Foundation	The Airlie Foundation
Aubrey & Marsha Baillie Family Fund	Egg Farmers of Canada	Kiwanis Club of Vancouver	RBC Foundation	The Alice & Murray Maitland Foundation
Bayer HealthCare – Diabetes Care	Eli Lilly Canada Inc.	Knights Templar Charitable Foundation of Canada	Regina Queen City Kinsmen	The Arthur J. E. Child Foundation
Bayer Inc.	Eli Lilly Canada Inc./Boehringer Ingelheim Alliance	KPMG	Relic Riders	The Barrett Family Foundation
BD Medical – Diabetes Care	Enterprise Holdings Inc.	Lagniappe Foundation	Rexall Foundation	The Birks Family Foundation
BHP Billiton	Ernest I. Silverberg, Morris Silverberg, David Silverberg, Maier Silverberg & Antzi Silverberg Fund	Lawson Foundation	Roche Diagnostics Canada	The Brian & Susan Thomas Foundation
Blistex Corporation	File Hills Qu'Appelle Tribal Council	Leland Industries Inc.	Rotary Club of Bolton	The Charles Norcliffe Baker & Thelma Scott Baker Foundation
Brandt Group of Companies	Fleming Foundation	Leon's Furniture Ltd.	Royal Bank of Canada	The Co-operators
Brandt Tractor	G. Murray & Edna Forbes Foundation	Leslie & Irene Dube Foundation	Rubicon	The Edwards Charitable Foundation
Britton Smith Foundation	Gamma-Dynacare Medical Laboratories	LifeScan Canada Ltd.	Sanofi	The Gill Family Charitable Trust
Brokerteam Holdings	General Mills Canada Corporation	Lions Clubs of Canada	Saskatchewan Association of Optometrists	The Guelph Community Foundation
Build-A-Bear Workshop Bear Hugs Foundation	Gerald C. Baines Foundation	Loblaw Companies Ltd.	Saskatchewan Community Initiatives Fund	The J. P. Bickell Foundation
Burrows Colden Family Foundation	Gerrie Electric Wholesale Ltd.	Longo's Family Charitable Foundation	Saskatchewan Indian Gaming Authority	The Jewish Foundation of Manitoba
Cameco	GlaxoSmithKline Inc.	Manitoba Association of Healthcare Professionals	Saskatoon Community Foundation	The Kitchener & Waterloo Community Foundation
Canadian National Railway Company	Glenn's Helping Hand Foundation Inc.	May Court of Oakville Foundation	Scotia Private Client Group	The Lawrason Foundation
Canola Council of Canada	Government of British Columbia	McNeil Consumer Healthcare	Scotiabank	The Leflar Foundation
Capital Cosmo	Groupe SEB	Medavie Blue Cross	Sherry & Sean Bourne Family Charitable Foundation	The Lorne & Evelyn Johnson Foundation
Carmen's Group	Halifax Protestant Infants' Foundation	MEDEC	Shiff Family Charitable Foundation	The M & N Foundation
Carolyn Sifton Foundation	Halifax Youth Foundation	Medtronic of Canada Ltd.	SIGA	The Manchee Foundation
CCR Building & Remodeling	Husky Energy Inc.	Merck Canada Inc.	South Saskatchewan Community Foundation Inc.	The Mariano Elia Foundation
Cenovus Employee Foundation	Icecaps Care Foundation	Nestlé Health Science	Sticklings Bakery	The May Court Club of Oakville
Chartwell Retirement Residences	Inga & Anna Storgaard Fund	Newman's Own Foundation	Strategic Charitable Giving Foundation	The Murray & Audrey Neufeld Charitable Foundation Inc.
		Northland Properties Corp.		
		Novartis Pharmaceuticals Canada Inc.		
		Novo Nordisk Canada Inc.		
		NWM Private Giving Foundation		

The Toronto Star  
Fresh Air Fund  
The Walker  
Lynch Foundation  
The WB Family Foundation  
The Windsor Foundation  
The Winnipeg Foundation  
The Worrall Family Fund  
United Way of  
Lower Mainland  
Vale  
Vancouver Foundation  
Victoria Foundation  
Wellington  
Laboratories Inc.  
Zechariah Perlman &  
Doris Perlman Fund