

Insulin glargine (Basaglar) for diabetes mellitus, type 1 & 2

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

Canadian Diabetes Association and the Consumer Advocare Network—permission granted to post.

CADTH received patient group input for this review on or before October 27, 2015.

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Canadian Diabetes Association and the Consumer Advocare Network

Section 1 — Information About the Submission Patient Group

Name of the drug	Basaglar (insulin glargine SEB)		
Indication of interest	Type 1 and type 2 diabetes		
Name of the patient group	Canadian Diabetes Association and the Consumer Advocare Network		
Name of the primary contact for this submission:			
Position or title with patient group			
Email			
Telephone number(s)			
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Patient group's contact information: Email			
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Website	www.diabetes.ca		
Permission is granted for CADTH to post this submission	Yes		

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.

The Consumer Advocare Network is a registered not-for-profit organization set up in 1999 to provide education and support to patient groups to promote engagement in healthcare policy and decision-making. Advocare provides regular training and produces education materials for use by patient groups and also provides input to health policy makers and healthcare providers. In 2012, Advocare created the Canadian Expert Patients in Health Technology, a network of individuals committed to promoting informed patient engagement at all levels of health policy and decision-making.

1.2 Conflict of Interest Declarations

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. The CDA did not have any conflicts of interest in the preparation of this submission. The full list of organizations that made donations to the CDA in 2014 is appended.

With reference to this submission, the Consumer Advocare Network has received unrestricted educational grants over the past 5 years to develop materials and workshops on subsequent-entry biologics from BIOTECanada, Janssen-Ortho, Amgen, Sanofi, and Wyatt Health Management, as well as funding support from Health Canada to participate in workshops and consultations on SEBs. Durhane Wong-Rieger is a volunteer with the Consumer Advocare Network; she is paid by the Canadian Organization for Rare Disorders and the Institute for Optimizing Health Outcomes, both of which also receive unrestricted funding from these entities for other programmes. She has no conflict of interest to declare in the preparation of this submission.

Section 2 — Condition and Current Therapy Information

2.1 Information Gathering

The Canadian Diabetes Association (the CDA) solicits patient input through surveys distributed through social media and email blasts. Content of this submission is derived from an online survey available to Canadians with diabetes and caregivers for approximately 10 days in October 2015. It gathered information from 367 Canadians with type 1 or 2 diabetes and 61 caregivers for people with diabetes, about the impact of diabetes, experience with Lantus (insulin glargine) and with Basaglar (insulin glargine SEB) as well as barriers to accessing long-acting insulin analogues.

Impact of diabetes: Diabetes is a chronic and progressive disease. Type 1 diabetes occurs when the body does not produce insulin or produces very little insulin. Type 2 diabetes occurs when the pancreas does not produce enough insulin or when the body does not effectively use the insulin that is produced. 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 activities and opportunities including travel and career. Some felt that diabetes "dictates" their lives, that they are "held captive by diabetes," and that diabetes is "overwhelmingly debilitating." Diabetes management is "constant struggle" and "a 24 hour, 7 days a week job." Many are frustrated that they cannot lead a "normal life" due to diabetes. Some lost their driver's privilege, employment, independence and spontaneity in daily life in general. It is also challenging when a person needs to manage diabetes as well as other co-existing conditions. Direct quotes below further describe the general impact of diabetes on respondents:

- "Diabetes ended my career with the Canadian Forces after 8 years. it was extremely expensive (approx 500/month) in 2008 to purchase as I did not have a drug care plan at the time, and has seriously affected me in a negative way."
- "[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 dialesis [sic] I had to spend most of my life's savings. Being sick can be very very expensive"
- "You give up a lot of control in your life to your diabetes... Following your dreams and choosing a career path, traveling, playing sports- those are all seriously shadowed by the question- will I have enough supplies, will my numbers be good enough to do this?

Many respondents indicated they are experiencing complications as a result of diabetes, including neuropathy, foot complications, heart problems, eye problems/loss of vision, kidney problems (that resulted in kidney transplant and dialysis), skin ulcers, erectile dysfunction, amputation and depression. Other impact includes fatigue and lack of energy. There was also a frequent emphasis on the psychological and emotional impact of diabetes on the lives of respondents as well as those their family members, as a result of 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 particularly difficult. Direct quotes below describe the stress diabetes has caused to individuals and their family members:

- "having type 1 as a parent and a caregiver to aging parents means my health and safety effects 10 family members directly"
- "[diabetes has affected me] In a great way, with drastic mood and weight changes, and the missunderstanding of my family members who do not have Diabetes"
- "have to always think about and worry about the lows happening at work, overnight and whether I can afford to have a low by keeping blood sugars so well controlled to reduce risk of lows or do I let sugars be higher so that I don't have to take the time to treat a low... my family worries and doesn't realize sometimes how awful I feel when my blood sugars are over 10 or too low"
- "The years since my diagnosis have been a roller coaster of learning, compromising, accepting, fighting, etc... it is a full time battle to keep things under control..."
- "I have been living with type 1 diabetes for 55 years. Supply cost has always been an issue when raising a family on a limited income."

Many respondents did note that diabetes has made them more aware of their diet and physical activity, and "more conscious of my health habits." Some have quit smoking and drinking as a result of their diabetes diagnosis.

Many survey respondents indicated they are currently experiencing the following <u>symptoms/conditions</u>. Between 351-372 individuals answered this question.

- Hypoglycemia (sometimes for 56%, and often for 11%)
- High blood pressure (moderate for 37% and severe for 12%)
- High cholesterol (moderate for 33% and severe for 9%)
- Mental health problems (moderate for 18% and severe for 6%)
- Kidney problems (moderate for 12% and severe for 6%)
- Foot problems (moderate for 27% and severe for 9%)
- Eye problems (moderate for 29% and severe for 9%)

- Nerve damage (moderate for 21% and severe for 11%)
- Damage to blood vessels, heart or brain (moderate for 13% and severe for 5%)
- Liver disease (moderate for 6% and severe for 1%)
- Endocrine disorder (moderate for 15% and severe for 7%)

2.2 Patients' Experiences With Current Therapy

A total of 255 respondents have experience with the reference drug Lantus (insulin glargine). As Basaglar is a new drug not yet on the market, only two respondents have experience with Basaglar (insulin glargine SEB). Among people who have used the reference drug Lantus, 47% were diagnosed more than 20 years ago, 24% diagnosed 11-20 years ago, 17% diagnosed between 6-10 years ago, and 11% diagnosed 3-5 years ago. Four respondents are newly diagnosed (1-2 years).

Respondents noted the **effectiveness of Lantus** (insulin glargine) to maintain blood glucose control, often in combination with Humalog:

- "I take Lantus and Humalog. Test twice daily, inject both in the morning, Humalog noon and evening. A1C around 7.6 (been as low as 7.2) considering I have been a diabetic for over 25 yrs it really can't get much better."
- "With glargine insulin, I was finally able to have stable blood sugars throughout the day and night,
 without hypoglycemic blood sugar levels, or rebounded hyperglycemic blood sugar levels. Later, my
 child was diagnosed with type 1 diabetes, and was put on Glargine insulin immediately."
- "When I was on NPH, I frequently had night lows and it was necessary to wake at 3am every night to test and often treat. When I was switched to Lantus, this problem disappeared."
- "Before Lantus my son had to take two doses of Lente or NPH insulin for basal coverage. With those
 insulins he had many hypoglycaemic episodes. Since he has been using nightly injections of Lantus
 his episodes of hypoglycaemia have lessened greatly. He also stated that the Lantus made him feel
 much better."

Some respondents noted the effects of Lantus did not last long enough to control their blood glucose: "sometimes its effects didn't last long enough, causing blood sugar to spike at inopportune moments; however, it was a reliable method for treating my blood sugars." Others mentioned side effects such as weight gain, hunger, allergic reaction, hives, overnight/morning hypoglycemia, burning sensation and pain with Lantus injections. One individual noted lipodystrophy at injection sites.

There are **unmet needs** with the treatment of diabetes and with Lantus (insulin glargine). Respondents would like to gain better control of their blood glucose levels, such as fasting blood glucose and A1C. One individual noted: "the pattern of blood sugar has been ongoing - low to normal at breakfast, good or 7-10 at noon, higher at supper. I would like to see this level out over the day." Some respondents would like to have improvement in the administration of insulins so they can reduce the number of injections needed to maintain blood glucose control. For example, one respondent noted: "My lantus pen cannot dial up to the 90 units that I need so, I have to take two injections every night rather than one injection." Other respondents would like to be able to combine different insulins they are currently taking into one single injection — "I want my current regimen to be introduced in single dose"; "Ability to mix short acting humalog with long acting lantus in the same syringe. Currently requires two separate injections." One respondent would like a "slowly releasing long acting treatment taken at least weekly." Finally, drug shortages resulting in decreased availability of Lantus was an issue for some respondents: "It would seem that pharmacy's run out of Lantus every time I need to purchase a vial."

The majority of respondents did not have concerns with accessing long-acting insulins. For some people with diabetes, however, the cost of long-acting insulins was cited as a challenge or barrier to accessing the treatment. Approximately 17% of survey respondents who answered the question (n=239) indicated they are experiencing, or experienced in the past, difficulty in accessing the treatment due to cost. Currently some patients find it financially challenging to receive the treatment, due to lack of insurance (such as employer insurance, following retirement or job loss, for example) or that the insulin is not covered by public or private insurance. Those who have experienced difficulty in the past attributed the eventual ease of financial burden with this insulin being listed on the public drug plan ("when I did not have drug coverage the costs for Lantus was difficult to manage") or are completely relying on their employer insurance to cover the cost of the treatment. Shortage of supply and administrative process were also cited as barriers to accessing the treatment; one individual stated that it "requires annual approval from Provincial board" while another from the Territories indicated "it is not covered by the Territorial health insurance without special referral." Some expressed frustration over additional administrative burden and specific rules of insurance companies to access the treatment: "I had to have my endocrinologist complete a limited use form in order to have my insurance plan cover the cost. They did eventually cover it"; "certain private insurance groups want to know that you have tried NPH before Lantus"; "it is ridiculous that people will need to have hypoglycemia overnight with Humulin N or Novolin NPH before an MD can apply for Lantus coverage in MB."

Below are additional direct quotes from respondents that highlight the various challenges including cost to receiving the needed treatment for their diabetes:

- "I had to retire from full-time employment and live on a low income-fixed pension that does not cover my medical needs nor my Alberta Blue Cross non-group coverage for medications."
- "The availability of Lantus in Canada was delayed due to a shortage of supply...meant that my child needed to continue to use a long acting insulin that did not meet my child's needs. There were two instances of seizures that resulted from the difficulty of regulating the correct insulin dosage. Since the use of Lantus, basal insulin dosage has been vastly improved."
- "Having low income, plus premium medical coverage (BC), and fair Pharmacare having such high
 deductibles, (\$700, and then \$500) for prescriptions, it is impossible to get expensive medications
 when the amount I have to spend per month is about \$20. Even special authority medications are
 not accessible without paying a deductible to Fair Pharmacare first."

One caregiver for an individual with diabetes indicated that the cost of long-acting insulins even influenced their health care provider's prescribing decisions: "When first diagnosed he was not given a long-acting insulin and would be high all the time. The reason was the doctor said we couldn't afford it even though it was covered under my work plan. Changed doctors, received lantus and more stable levels within one week of the change." A few respondents noted the cost of treatment is impacting their adherence: "Because of the cost of insulin, especially lantus, sometimes I find that I put myself on a limit of units I take because of the price."

Respondents indicated concern about not being able to get coverage when the job situation changes in the future: "in near future as my husband is changing jobs in pre-existing conditions may be hard to get coverage."

The lack of and varied coverage of long-acting insulins across jurisdictions makes it challenging for people with diabetes to manage their disease, as one respondent pointed out: "I can't afford my treatment which includes testing supplies. I don't have good third party insurance, provincial coverage is

not great, coverage for diabetes management should be the same across Canada and not dependent on provincial coverage."

2.3 Impact on Caregivers

45 respondents shared their experience of caring for a family member with diabetes. Parents of children with diabetes have described diabetes management as a "24 hour a day, 7 days a week concern" which requires "constant vigilance" about "BG numbers...testing and adjusting, counting all carbs and calculating insulin requirements." As children with type 1 diabetes go through different stages in life, diabetes continues to affect the entire family: "When he was younger (Under 12) his A1C was very good. Since then he has wanted his independence from us but he does not maintain good control of his blood sugar and this is a source of strife." Many parents indicated feeling financial strain due to additional costs to "provide proper diet" and medications. Below are some direct quotes from respondents that highlight the stress and anxiety felt by caregivers:

- "[Diabetes] causes stress, burn out, family disruption in vacation and family time, sibling rivalry, school disruption, learning difficulties, added medical concerns ie dental, yeast infections, bedwetting"
- "2 sons diagnosed at 6yrs and 18 months with Type 1 ... The past 16 years our lives have revolved around testing, insulin doses, food requirements, carb counting, balancing excercise[sic] and activity with insulin on board, sleepless nights up testing to catch lows, not to begin to mention the added stress of caring for a child with the flu who has type 1. However, despite all this try and ensure that your child has as close to a 'normal' childhood as their peers."
- "currently stresses because we don't know how our son will get insulin when off our work
 insurance plan in less than a year. He has been unable to find work and has difficulty controlling
 highs and lows in areas that require high activity"
- "It is a very expensive disease and no treatment means death so other things have to be set aside to pay for medications."

Section 3 — Information about the Drug Being Reviewed

3.1 What Are Patients' Expectations for the SEB?

Respondents who have experience with the reference drug Lantus (insulin glargine) would like to see that the SEB Basaglar to be more effective than, or at least as effective as, the reference drug, and at a reduced cost or with the cost fully covered. Others hope for longer coverage in terms of the effect of drug: "Length of coverage should be a full 24 hrs/ Want it to last the full 24 hours, not 18 - 20 as sometimes occurs with lantus". One respondent would like to see the SEB address the unmet needs from the use of Lantus such as burning sensation, and "allergic reaction such as itchy hives or really bad hypoglycemia reactions." Generally, respondents would like to see that the SEB "have few side effects; it should protect not damage other parts of the body; not cause weight gain; be easy to administer; be effective in lowering and keeping [blood sugar] levels stable; be available to all; be cost effective and covered under [government plans such as] OHIP."

The availability of insulin glargine was raised as an issue; respondents hope that Basaglar would be more readily available and help fill the gap of any shortages. There is concern over the quality of the SEB: "Always afraid that similars are not the same quality as the originals."

In terms of <u>perceived effectiveness and side effects</u>, while the majority reserved opinion on this question, between 30-36% of respondents who have experience with Lantus think Basaglar would be

the same as Lantus in reducing hypoglycemia, reduce fatigue, and slow progression of complications; 17% think it will cost about the same. About 30% think the side effects would be about the same.

Among those who have experience with Lantus, 52% would be willing to try Basaglar if it cost less, 31% would be willing to try if it cost the same. About 14% would not be willing to switch to Basaglar regardless of the cost. The distress caused by a change to a stable treatment regimen was described by a respondent: "The quality of control out weighs the lowering of cost. That's what I believe. I have had diabetes for almost 50 years.... Why put me through this anxiety and stress. My chronic disease is under control with the insulin I was put on by my Endo who is very aware when it comes to insulin and how each person will respond to different manufacturers products."

Section 4 — Additional Information

4.1 Key Messages

- Diabetes and its complications pose tremendous emotional and financial strain on those with the disease and their family. A high proportion of respondents have developed various comorbidities/complications.
- The majority of respondents did not have concerns about accessing long acting insulins. However, the cost of long-acting insulins can be a significant challenge for a proportion of people with diabetes who can afford the treatment only if it is covered through public or private (such as employer) insurance plans. The financial burden impacts adherence to treatment and contributes to the stress of diabetes management as well adverse health outcomes. Respondents described the unfairness of not being able to access life saving treatment due to cost and the variability across Canada.
- Respondents attested to the effectiveness of the originator drug Lantus (insulin glargine) in controlling blood glucose levels, in combination with a rapid-acting insulin analogue.
- The majority of respondents would like to see Basaglar (insulin glargine SEB) be more effective, or as effective as, the originator drug, and at a reduced cost more than half would like to try Basaglar if it cost less.
- Some have experienced a shortage of Lantus supply and hope Basalgar would address this need.

4.2 Comments on Potential Ways SEBs Can be Used

We asked Canadians with diabetes whether they agree with the following ways that the Basaglar, insulin glargine SEB, could be used. Approximately half of respondents who have used the reference drug Lantus agree that the Basaglar could be used as an alternative to the reference drug Lantus, with physician approvals, but not switched back and forth:

- 1. 51% of respondents (of 200 who have Lantus experience) agree that Basaglar (insulin glargine SEB) can replace the original product Lantus (insulin glargine SEB) once a patient has been on Lantus for a period of time, i.e. a one time switch, with physician approval.
- 2. 52% of respondents (of 198 with Lantus experience) agree that Basaglar (insulin glargine SEB) can be used instead of the original product Lantus (insulin glargine) when starting treatment with insulin glargine, with physician approval.
- 3. 25% of respondents (of 198 with Lantus experience) agree that Basaglar and Lantus can be exchanged back and forth, while about 20% disagree.

In general, respondents would consult their doctors and/or diabetes teams concerning any decision to change medications, some would leave such decisions totally to their doctors: "someone's doctor would

be in the best position to determine which insulin (or alternatives) would be appropriate for their patient... If both insulins are essentially the same then I don't see why there would be a huge concern to use one over the other. However, I am not a doctor and sometimes other factors affect drug efficacy and safety (even if the drugs are in a similar class)." Many would like to get more information about these two drugs and discuss with their physician.

Most people felt uneasy about switching insulin glargine/insulin glargine SEB back and forth. While some are more confident about the similarities between these two drugs ("If it works exactly the same with the same required units, then it should be interchangeable without physician approval"), others are cautious as to whether these two drugs are the same: "My understanding is that these drugs would be similar but not the same. As such, they shouldn't be taken interchangeably;" "Drug substitutions can have severe impacts on other organs etc so need to be monitored and approved;" "You should not keep switching between one and the [other;] Even though they are supposed to be the same there are always differences". Many chose to reserve their opinion because they are not familiar with the SEB Basaglar or have not used it. Some have managed well with the reference insulin glargine and prefer to stay with the same drug: "If not equivalent, should not be able to switch. My highs and lows are hard enough to control. Better to stay on what I know for safety;" "Often have found that changing insulin types is difficult for people. Do not see a need to change insulin if Lantus is keeping blood sugars controlled."

In summary, diabetes has a serious and life changing impact on those affect by the condition. Treatment with insulin glargine has offered control of blood glucose for many individuals. As the prevalence of people with diabetes in Canada continues to increase, the need for affordable, safe and effective treatment is critically important. The most appropriate treatment for a patient will depend on the individual's clinical profile, responses to previous treatment as well as their own preferences. The availability of insulin glargine SEB provides an important option for patients living with diabetes.

Appendix: Organizations and foundations that made donations to the Canadian Diabetes Association in 2014 (up to December 31, 2014)

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Source: CDA 2014 Annual Report, available at http://www.diabetes.ca/getmedia/d4beee80-01c5-46a1- b2f6-37cbb49e9c61/2014-cda-annual-report.pdf.aspx