

## CADTH COMMON DRUG REVIEW

# Patient Input

## **DEXAMETHASONE (OZURDEX)**

(Allergan Inc.)

Indication: Diabetic Macular Edema (DME)

CADTH received patient input from:

**Canadian Council of the Blind (CCB)**

**Canadian National Institute for the Blind (CNIB)**

**The Foundation for Fighting Blindness (FFB)**

October 17, 2017

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## Patient Group

Canadian Council of the Blind (CCB)  
Canadian National Institute for the Blind (CNIB)  
The Foundation for Fighting Blindness (FFB)

### 1. About Your Group

**The Canadian Council of the Blind (CCB)** was founded in 1944 by blind war veterans and graduates from schools of the blind. All officers and directors are blind or visually impaired, which gives a unique sensitivity to the needs of the blind community. The CCB is a registered charity pursuant to the provisions of the Income Tax Act (Canada); charity number is: 11921 8899 RR0001. The CCB has over 70 chapters across Canada, and with over 1,500 members, is the largest membership-based organization for the blind. **The purpose of the CCB is to give people with vision loss a distinctive and unique perspective before governments.** The CCB deals with the ongoing effects of vision loss by encouraging active living and rehabilitation through peer support and social and recreational activities. CCB promotes measures to conserve sight, create a close relationship with the sighted community and provide employment opportunities. For the 21st century, the CCB is committed to an integrated proactive health approach for early detection to improve the quality of life for all Canadians. <http://ccbnational.net/fresco/>.

**The Canadian National Institute for the Blind (CNIB) is committed to creating an inclusive, accessible, barrier-free society that provides the tools blind or partially sighted Canadians require to live safe, fulfilling and independent lives.** CNIB believes in making communities accessible, caring and inclusive. We believe that people living with vision loss should have no limitations placed on their ability to succeed and we work hand-in-hand with Canadians who are blind or partially sighted to advocate for a barrier-free society. As Canada's main provider of post-vision loss rehabilitation therapy, CNIB ensures its clients are able to receive the support they need throughout their journey through vision loss. Whether it be safety and mobility training, assistance with remaining gainfully employed, or gaining access to alternative formats of published works, CNIB operates across Canada providing these services to the best of the organization's ability and funded almost entirely by charitable donations received from the public. [www.cnib.ca](http://www.cnib.ca)

**The Foundation Fighting Blindness** is Canada's leading charitable funder of sight-saving research. Our Charitable Registration Number is: 11912 9369 RR0001. **The mission of the Foundation Fighting Blindness is to lead the fight against blindness by advancing retinal disease research, education and public awareness.** We work with Canadian families affected by retinal diseases and with vision scientists at hospitals and universities across Canada. Over the past 43 years, the Foundation has contributed over \$32 million to sight-saving research. We have a rigorous process of peer review, and the systems and processes in place to support and monitor complex research projects. We do not charge membership fees and consider our community of various stakeholders (donors, educational event participants, researchers, etc.) to be our general members. [www.ffb.ca](http://www.ffb.ca)

Together we are co-signatories on the Canadian Patient Charter for Vision Care (<http://www.cnib.ca/en/get-involved/join-an-event/Vision-Health-Month/Documents/CHARTER-12x18-ENG.pdf>), which illustrates our commitment to ensuring that patients have access to the highest standard of vision care across Canada. We do not recommend specific treatments because we believe that these decisions are between the patient and her/his doctor. We advocate for the best care.

## 2. Information Gathering

At the Foundation Fighting Blindness (FFB), we offer in-person educational events for people who are living with blinding eye diseases. In 2017, two of the FFB's education events were focused on diabetes-related vision loss. These events were held in Sudbury and Timmins, Ontario. During these sessions, we had the opportunity to meet with different people living with diabetes-related vision loss. In addition, the FFB designed and conducted a 10-minute online survey that was completed by 64 patients between March 24 and June 13, 2017. Individuals were recruited from a database of diabetes patients and were screened to ensure that they have diabetic macular edema (DME). The average age of the sample is 49; 56% of the patients from the sample live in Ontario; 59% are male and 41% are female; 84% are from rural and suburban locations and 16% are rural.

## 3. Disease Experience

What stands out clearly in the collected survey data is that DME has a significant impact on the daily lives of those living with the disease, with nearly half of the surveyed patients reporting that their lives are affected in some way by the condition, often in the form of a high impact on their ability to participate in work and school activities. Patients also reported that their DME impacts them nearly as much as other chronic and costly conditions such as COPD, cancer, and depression.

In addition to living with DME, 6 out of 10 patients indicated that they had at least one other eye problem diagnosed as a result of their diabetic retinopathy (e.g. cataracts, glaucoma, dry eyes, etc.). Because of the many comorbidities that occur with diabetes, the patients that we surveyed were also seeing a variety of different health care professionals and attending an average of 38 different appointments each year. Patients most frequently saw their family doctor, followed by their endocrinologist and ophthalmologist (averaging 3 times/year with appointments lasting a minimum of 30 mins each).

Among patients that are receiving injections for their DME and also working, four in ten take half a day off while more than one third take the full day to receive their injection.

The data also indicates a shared burden for both the patients and their loved ones, since family members and friends often accompany the patient to the hospital and other health centres—77% of the group indicated that they receive assistance, usually from family members, when they go for injections. In some cases, social workers provide this assistance. The most common help needed is to travel and wait with the patient, though care is also needed after their injection. 44% of the patients we surveyed reported that they required help with everyday tasks after the injection and 39% required emotional support.

Patients indicated that the disease presents a considerable psychological burden as well. 69% of the group indicated that the seriousness of their diseases is either "very serious" (36%) or "fairly serious" (33%), totalling 69% of the sample. 39% of the sample indicated that they think about the disease "very often" (at least once a day), while 30% out of the same group think about their DME "often" (at least once a week). The combined average of patients who think about the disease "very often" or "often"—69% of the sample—jumps to 86% when the sample is reduced to the patients who indicated that their DME is "very serious" or "fairly serious." As one would expect, the psychological burden of the disease increases in parallel with the disease's seriousness.

## 4. Experiences with Currently Available Treatments

Contemporary approaches to treating DME take the form of 1) laser treatments (typically "focal" or "scatter" lasers) and 2) injections of anti-VEGF drugs such as Lucentis, Eylea, and Avastin.

Older patients are more likely to have had injections, which is in all probability a result of the progression of the disease with age. Being in an urban setting appears to increase one's access to injections, with many in rural/suburban settings not receiving any treatment. Income has a clear impact on treatment as well, with many low income individuals not receiving any. At the same time, patients receiving laser treatment are more likely to be covered by public insurance.

Among injection patients, Lucentis and Eylea are the most commonly used drugs (32% in both cases), followed by Avastin (18%) and Ozurdex (5%). 14% of the surveyed group were not sure which drug was in the injection they received.

Patients receiving injections were recommended frequent injections by their doctors. Almost all were told they needed injections at least every 2 to 4 months, with half told once a month. While most of the injection patients are compliant with the injection frequency recommended to them, 1 in 10 of those who are recommended treatment every month are not receiving monthly treatments. Missed injections are by no means an uncommon experience, with 27% of the sample indicating that they missed appointments in the past. The leading reason for a missed appointment was weather conditions (33% out of those who missed appointments), a factor that is likely increased for those living in rural parts of Canada. Patients also reported other reasons for missing appointments, including: length of travel time; anxiety about the injection; unable to get time off work/school; cost of transportation; illness.

It is particularly noteworthy that among patients who were not compliant, 50% reported that the reason for missing appointments was that they could not afford them. Another 50% indicated the wait time to see a specialist was too long.

In terms of coverage, half of the injection patients received some form of private coverage, with 41% being completely covered. 23% of the sample pay at least some expense out of pocket. On average, it cost an injection patient a total of \$136 to travel back and forth from injection appointments in the past year.

32% of the sample group indicated that their appointments last more than 30 minutes. Among those who are working, 42% take a half day off and 33% take a full day, demonstrating a high impact on the productivity of those living with the disease. On average, a surveyed injection patient takes 24 hours off of work in a year.

## 5. Improved Outcomes

According to our data, decreasing the frequency of injections is the most important factor in improving patient experience: 27% of the group indicated that this is the case (having to have fewer injections to get the same results), 23% listed it as the second most important factor, and 14% listed it as the third. It is safe to conclude that fewer injections could be a key factor in leading to improved compliance and overall better quality of life for DME patients.

At the same time, decreased wait times for procedures, more time with the doctor, and paid transportation are also desirable outcomes for significant portions of the group: 18% indicated that decreased wait times are most important, 14% indicated more time with the doctor, and 14% indicated paid transportation.

Optimized treatment options for patients, especially options that reduce the frequency of injections, appear to have the ability to improve the patient's experience, especially for those who are living outside of urban centres. Since adherence to the prescribed injection schedule is an issue for some patients, it is also possible that optimization could have a beneficial effect on health outcomes.

## 6. Experience with Drug Under Review

5% of the injection patients indicated that they have received injections of Ozurdex. Though the study was not designed to measure the specific outcomes of that drug compared to others, the data emerging from survey responses should be taken into consideration, we think, when considering the unfolding Diabetes epidemic and any potential new treatments.

Efficacy and safety are essential criteria, surely, but a patient's quality of life (both during and after treatment) should not be ignored. The study was designed to assess and quantify, where possible, the burden—social, financial, psychological, and otherwise—of DME on a patient's life. We believe the data provides insights into factors that are indispensable vis-à-vis the review of relevant drugs.

## 7. Biosimilar

Ozurdex is not a biosimilar. On the topic of biosimilars, however, it is worth reiterating that the study data is not drug specific. If a new treatment—either original/innovative or biosimilar—emerges with the potential to lessen the disease’s burden, that drug is worth considering.

Accessibility factors are also important: the “best drug” should be safe, effective, and appropriate; it should demonstrate a clear ability to improve the patient’s quality of life; and its availability should be equitable and barrier-free within the context of Canada’s regulatory and policy frameworks—that is, it should be accessible to Canadians regardless of geography, employment, culture, and so forth.

## 8. Anything Else?

Researchers, health practitioners, policy experts, and others agree that diabetes is a growing and evolving epidemic, both globally and in Canada. As the incidence of diabetes grows, DME will grow as well. A patient’s life is impacted by the disease through a range of factors: life changes, loss of productivity, missed work/school hours, and more. As our data shows, DME is also a disease that constantly weighs on a patient’s mind, suggesting a strong psychological burden. Caregivers are impacted by the disease as well, and in complex ways that are not always easy to measure or quantify.

DME has these impacts, surely, but its impacts and associated burdens are more pronounced among vulnerable populations and those living outside of Canada’s urban centres. As the number of diabetes patients in Canada increases, more patients in rural communities will need options that are effective, that help them comply with treatment programs, and that reduce the psychological toll of the disease.

## Appendix 1: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH CDR and pCODR programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

No

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.

Yes, we worked with Environics Research to design, deploy, and analyze the survey data. We also consulted with members of Diabetes Action Canada, which is a Strategic Patient Oriented Research (SPOR) Network in Diabetes and its Related Complications ([www.diabetesaction.ca](http://www.diabetesaction.ca)). Specifically, we worked with members of the Diabetic Retinopathy Screening – National Tele-Ophthalmology program and the Knowledge Translation program to design the survey. The FFB is a partner on this SPOR network that aims to understand the growing diabetes epidemic so that we can take action to ensure better health outcomes for patients living with diabetes across Canada.

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

Company	Check Appropriate Dollar Range			
	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Allergan				X

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

**Name/Position/Group:** Louise Gillis (National President, CCB), Diane Bergeron (Executive Director, Strategic Relations and Engagement (CNIB), Chad Andres (Manager, Research & Education, FFB)

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