

Patient Input Template for CADTH CDR and pCODR Programs

Name of the Drug and Indication	Iluvien (fluocinolone acetonide intravitreal implant) Treatment of diabetic macular edema (DME)
Name of the Patient Group	International Federation on Ageing (IFA) Canadian Council of the Blind (CCB) Diabetes Canada (DC) Canadian Association for Retired Persons (CARP)
Author of the Submission	Dr. Jane Barratt (IFA)
Name of the Primary Contact for This Submission	Dr. Jane Barratt
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Telephone Number	(416) 342-1655

1. About Your Patient Group

Founded in 1973, the **International Federation on Ageing (IFA)** is an international non-governmental organization with its headquarters in Toronto, Canada. The organization has general consultative status at the United Nations and its agencies, and a formal working agreement with the World Health Organization (WHO). The vision of the IFA is a world of healthy older people whose rights are both protected and respected and who's aim is to inform good policy and practice, across the life course. The IFA encourages and supports research, policy and practice to advance the management and treatment of those Canadians now and in the future with eye conditions. www.ifa-fiv.org

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. www.ccbnational.net

Diabetes Canada (DC) is a national health charity representing 11 million Canadians living with diabetes or prediabetes. The priorities of our mission are diabetes prevention, care and cure. **Our focus on research and policy initiatives helps us to deliver impact at a population level, and our partnerships broaden our reach in communities across the country.** We drive excellence in disease management by putting practical, evidence-based tools into the hands of health-care providers. We

advocate for environments that make the healthy choice the easy choice. We continue our search for a cure, as well as for better prevention and treatment strategies, by funding the work of innovative scientists. In 1921, Canada changed diabetes for the world with the discovery of insulin. By 2021, we will change the world for those affected by diabetes through healthier communities, exceptional care, and high-impact research. www.diabetes.ca

Canadian Association for Retired Persons (CARP) is Canada's largest advocacy association for older Canadians. CARP is a not-for-profit organization and does not receive government operating funding. Its advocacy mission is funded through membership fees and contributions from its affinity partnerships. Today CARP has more than 320,000 members. As a non-partisan association, CARP is committed to working with all parties in government to advocate for older Canadians. **Its mission is to advocate for better healthcare, financial security, and freedom from ageism.** Many CARP members are active participants in their local chapters who work for local change while supporting national efforts. www.carp.ca

2. Information Gathering

The information was gathered through both an online survey and telephone interviews. All of the data was contributed anonymously.

IFA developed and designed a 10-minute, 22-question online survey that was disseminated in English and French. Recruitment was undertaken by IFA, CCB, DC and CARP through social media and other online platforms. The online survey was open between April 8th and April 19th, 2019. There were 5 respondents in total (3 DME patients and 2 DME caregivers). The respondents were from Canada (4) and Australia (1).

The telephone interviews were all conducted by Dr. Jane Barratt between April 11th and April 23rd, 2019. There were 3 patients and 1 caregiver (on behalf of a patient) interviewed, all of whom had experience on Iluvien. As there were no patients with recent experience on Iluvien in Canada, all of the people interviewed were from the United States.

3. Disease Experience

The respondents reported a wide range of time to a DME diagnosis - from 1 hour to 2 years.

Patients were asked to describe how DME impacts their daily life. Attending medical appointments was rated as the most significant impact at 4.7/5.0, followed by reading (4.3/5.0), driving (4.0/5.0) and housework (3.3/5.0). When the caregivers were asked the same question, the most significant impact was taking their loved one to medical appointments and their employment (both 4.5/5.0), followed by housework and taking care of family (both 3.5/5.0).

Patients were then asked to describe how DME impacts their quality of life. Relying on others and isolation rated as the most significant impacts at 4.3/5.0, followed by independence and enjoyment of family (4.0/5.0), self-worth (3.7/5.0) and contributing to society (3.3/5.0). For caregivers, the most significant impact was mental health (depression, anxiety) and isolation (both at 4.5/5.0), followed by time to self (3.5/5.0).

The survey then asked patients to choose those aspects/symptoms of DME that most concern them. All of the respondents chose each of the four options – blurry vision, floaters, double-vision and blindness/vision loss. When asked to rank those same choices, the results are unsurprising. All of the patients ranked blindness/vision loss as the most important aspect/symptom to control (4.0/4.0), followed by double-vision (2.7/4.0), blurry vision (2.0/4.0) and floaters (1.3/4.0).

“A lack of clear vision and not seeing as well is causing stress and depression.”

4. Experiences With Currently Available Treatments

None of the patients are currently receiving any medications for the treatment of DME. One person had previously received Lucentis and Avastin. One patient is also taking medications for diabetes.

For the individual that had previously taken Lucentis and Avastin, they rated both medications as 'very effective.' More specifically, both Lucentis and Avastin improved visual acuity, helped in retaining independence and maintained their hope. The noted side effect of Lucentis was irritation and for Avastin it was increased intraocular pressure.

When asked about other challenges the one patient and two caregivers faced with treatments (current or previous), two people mentioned travel time/distance to getting treatment, two noted cost of treatment, the two caregivers mentioned time off of work to get treatment and the patient noted treatment administration i.e. swallowing pills.

5. Improved Outcomes

The one patient and two caregivers with current or previous experience with treatments were then asked what improvements they would like to see in a new treatment. All three wanted a halt to vision loss, longer-term vision improvement (i.e. beyond three months) and decreased wait times for procedures. Two respondents also hoped for improvement to their double-vision and blurry vision.

Thinking further about desired improvements, all of the patients were asked how a new treatment option would impact their quality of life. Driving, reading and housework ranked highest at 4.7/5.0, followed by taking care of family and attending medical appointments (both at 4.0/5.0). When the caregivers were asked the same question, the most desired improvement related to their employment at 5.0/5.0, followed equally by taking care of family and housework (both at 4.0/5.0).

All of the patients were then asked how the desired improvements in a new treatment option would impact their quality of life. Relying on others, independence, contributing to society and isolation all averaged a 4.7/5.0 response rate. Self-worth and enjoyment of family came in at 4.3/5.0, followed by mental health (depression, anxiety) at 4.0/5.0. In the case of the two caregivers, mental health (depression, anxiety) averaged 5.0/5.0, followed by isolation and time to self (4.5/5.0) and then physical health (4.0/5.0).

The respondents were asked how important it is to have less frequent injections in a new treatment option for DME; three out of five people ranked this as either 'important' or 'extremely important.' When asked how important it is to have longer-term vision improvement in a new treatment for DME, the results were unanimous – all five individuals ranked this as 'extremely important.'

6. Experience With Drug Under Review

Three patients and one caregiver (speaking on behalf of a patient) who had experience with Iluvien were interviewed by telephone. All are residents of the United States.

The patients are 62, 67, 72 and 76 years old. They were diagnosed with DME 6 years ago, 7 years ago, 5 years ago and 5 years ago respectively.

The 62 year old patient has been on Iluvien since May, 2016 when they received one injection in the left eye. This person has no vision in the right eye, so treatment with Iluvien was especially critical. The 67 year old patient had one injection of Iluvien in each eye in May, 2016 and since then, has had no need for further injections. The 72 year old patient received one injection of Iluvien in one eye in April, 2018, with no further need for injections since that time. The 76 year old patient began Iluvien in 2016 with one injection in the left eye.

One patient received Iluvien through private insurance, while another received it through Veterans Affairs. The third person received Iluvien through a combination of private insurance and a clinical program. The fourth patient (through their caregiver) is unsure how they are getting the drug.

When asked what benefits they have experienced with Iluvien, the patients mentioned the reduction in the number of injections (from every 1-3 months, to every 2-3 years), less worry about infections, elimination of swelling, less time off of work to attend appointments and a decrease in discomfort due to less frequent injections.

When asked how these benefits have impacted their day-to-day activities and quality of life, the patients noted increased independence, more happiness, a greater sense of 'permanency' in their vision, ability to travel, a return to all personal and lifestyle activities and more confidence.

When compared to other treatments for DME, the four patients said:

"Treatment with Iluvien is superior because I can see a lot better and can then be independent to do my own thing."

"Iluvien has been easy, with little or no impact on my lifestyle."

"Iluvien is far superior because of the vision and lifestyle outcomes."

"Iluvien is far better and now (he's) independent. No caring from family is required."

None of the patients mentioned that they experienced any disadvantages with Iluvien. However, when asked about disadvantages with other treatments, one patient noted Lucentis doesn't seem to last as long as Iluvien and requires more frequent appointments. Another person said going for injections every three months meant more burden on their caregiver, concern about infections and anxiety about whether the treatment would even work. The third patient mentioned that with Lucentis, their appointments were more frequent, they were anxious, they missed more work and they could not focus on other aspects of their life. The fourth patient talked about how they were becoming very depressed with the loss of function and independence.

"The countdown to once per month treatment was like having a new set of stitches on a wound which wouldn't heal, whereas Iluvien is positive."

The four patients were then asked about side effects with Iluvien. They ranged from none to minimal ("a few black dots").

Three patients also said that Iluvien was easier to use than previous therapies for DME because there are fewer physician appointments, less travel time, more confidence and a greater focus on other parts of their health and well-being. The other patient was pleased with the current outcomes and status with Iluvien, but said that they could draw no significant comparison with Lucentis.

In closing, when asked to describe how their lives have changed since starting Iluvien, the four individuals said:

"Iluvien has given me the confidence to focus on management of the disease, so my weight has decreased, I exercise more, volunteer part-time and have the incentive to be as well as I can."

"As part of my diabetes management, Iluvien has enabled me to continue my active lifestyle, while monitoring my diet, exercise and medication regimes."

"Iluvien has opened doors again. It's made my life easier, less swelling has meant my vision is a lot better, I am less depressed and optimistic about the future. Iluvien has given me a new life."

“It’s been life-changing. Iluvien has meant less swelling, so (his) vision is a lot better. The independence (he’s) regained is a miracle. (He’s) no longer depressed and is excited with the opportunities to travel and be with friends.”

7. Anything Else?

When asked specifically how important it is that DME patients have the option to access Iluvien in a timely manner (if it is appropriate for them), the majority surveyed ranked that option as ‘extremely important.’ Some of the responses to the question ‘Please tell us in your own words what having access to Iluvien would mean to those affected by DME’ include:

“Improved vision for a longer time with timely access can help increase independence and the ability to partake more in activities that enhance the quality of life.”

“If it would improve my vision even for a limited time, it would be worth it.”

“Anything (or procedure) to improve my vision would be welcome. I am 82, healthy and active, and still have plans for the future.”

Appendix A: Patient Group Conflict of Interest Declaration – International Federation on Ageing

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 Impetus Digital to design, collect and analyze the survey results.

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
Bayer Canada				X
Bayer Global				X
Roche Canada			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: Dr. Jane Barratt

Position: Secretary General

Patient Group: International Federation on Ageing

Date: April 25, 2019

Appendix B: Patient Group Conflict of Interest Declaration – Canadian Council of the Blind

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. Impetus Digital helped to design, collect and analyze the survey results.

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
Bayer Canada				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: Louise Gillis

Position: National President

Patient Group: Canadian Council of the Blind

Date: May 9, 2019

Appendix C: Patient Group Conflict of Interest Declaration – Diabetes Canada

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.

4. 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 jointly contributed to the Iluvien patient input submission with the International Federation on Ageing, the Canadian Council of the Blind and the Canadian Association for Retired Persons.

5. 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.

The International Federation on Ageing engaged with Impetus Digital to design, collect and analyze the survey results.

6. 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

Please find attached a list of organizations who have recently supported Diabetes Canada financially, along with the amounts provided.

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, CDE
 Position: Manager, Research and Policy Analysis
 Patient Group: Diabetes Canada
 Date: May 8, 2019

Financial Contributions to Diabetes Canada (updated 2017)

Constituent/Name	Funder range (\$)
<i>AstraZeneca Canada Inc</i>	350,000+
<i>LifeScan Canada Ltd.</i>	350,000+
<i>Novo Nordisk Canada Inc</i>	350,000+
<i>Sanofi Canada</i>	350,000+
<i>Sun Life Financial</i>	350,000+
<i>Eli Lilly Canada Inc</i>	250,000-349,999
<i>Ascensia Diabetes Care</i>	175,000-249,999
<i>Janssen Inc</i>	175,000-249,999
<i>Medtronic Of Canada Ltd</i>	175,000-249,999
<i>Dairy Farmers Of Canada</i>	100,000-174,999
<i>Merck Canada Inc</i>	100,000-174,999
WEIGHT WATCHERS	100,000-174,999
<i>Abbott Diabetes Care</i>	50,000-99,999
<i>Canola Council Of Canada</i>	50,000-99,999
<i>Insulet Canada Corporation</i>	50,000-99,999
<i>Knight Therapeutics Inc.</i>	50,000-99,999
<i>Manulife Financial</i>	50,000-99,999
<i>Nestle Health Science</i>	50,000-99,999
<i>RBC Foundation</i>	50,000-99,999
<i>The Bank of Nova Scotia</i>	50,000-99,999
<i>Abbott Nutrition</i>	25,000-49,999
<i>BD Medical Diabetes Care</i>	25,000-49,999
<i>Beer Canada</i>	25,000-49,999
<i>Dexcom Canada</i>	25,000-49,999
<i>Dynacare</i>	25,000-49,999
<i>Heartland Food Products Group</i>	25,000-49,999
<i>McNeil Consumer Healthcare</i>	25,000-49,999
<i>Rexall Foundation</i>	25,000-49,999
<i>Roche Diabetes Care</i>	25,000-49,999
<i>SaskCanola</i>	25,000-49,999
<i>Auto Control Medical Inc</i>	5,000-24,999
<i>Bayer Pharmaceuticals</i>	5,000-24,999
<i>Boehringer Ingelheim (Canada) Ltd</i>	5,000-24,999
<i>Canadian Association of Optometrists</i>	5,000-24,999
<i>Canadian Produce Marketing Association</i>	5,000-24,999
CHICKEN FARMERS OF CANADA	5,000-24,999
<i>Edelman Canada</i>	5,000-24,999
<i>EOCI Pharmacomm Ltd.</i>	5,000-24,999
<i>Euro Harvest Bakery Wholesalers</i>	5,000-24,999
<i>Farleyco Marketing Inc</i>	5,000-24,999
<i>ForaCare Technology Canada Inc.</i>	5,000-24,999
<i>Holista Foods</i>	5,000-24,999
<i>InBody Canada</i>	5,000-24,999
<i>Innovative Medicines Canada</i>	5,000-24,999
<i>Ipsen</i>	5,000-24,999
<i>Jays Care Foundation</i>	5,000-24,999
<i>mdBriefCase Group Inc.</i>	5,000-24,999
<i>Montmed</i>	5,000-24,999

<i>Myelin & Associates</i>	5,000-24,999
<i>Novartis Pharmaceuticals Canada Inc</i>	5,000-24,999
<i>Ontario Pork Council</i>	5,000-24,999
<i>Original Energy Sales</i>	5,000-24,999
<i>Paladin Labs Inc</i>	5,000-24,999
<i>Pharmasave Drugs (National) Ltd</i>	5,000-24,999
<i>Prime Strategies Inc.</i>	5,000-24,999
<i>PULSE CANADA</i>	5,000-24,999
<i>Royal College Of Physicians And Surgeons Of Canada</i>	5,000-24,999
<i>Tykess Pharmaceuticals</i>	5,000-24,999
<i>Urban Poling Inc</i>	5,000-24,999
<i>Valeant Canada LP</i>	5,000-24,999
<i>VitalAire Canada Inc</i>	5,000-24,999

Appendix D: Patient Group Conflict of Interest Declaration – Canadian Association of Retired Persons

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.

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

No

8. 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.

No

9. 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
none				

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: Laura Tamblyn Watts
 Position: Chief Public Policy Officer
 Patient Group: Canadian Association of Retired Persons
 Date: May 8, 2019