

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

DEXAMETHASONE INTRAVITREAL IMPLANT (Ozurdex)
(Allergan, an AbbVie Company)

Indication: For the treatment of adult patients with diabetic macular edema (DME) who are pseudophakic.

December 1, 2022

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CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0739
Name of the drug and Indication(s)	Dexamethasone Intravitreal Implant (Ozurdex) for adult patients with diabetic macular edema
Organization Providing Feedback	FWG

1. Recommendation revisions		
Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	Major revisions: A change in recommendation category or patient population is requested	<input type="checkbox"/>
	Minor revisions: A change in reimbursement conditions is requested	<input type="checkbox"/>
No Request for Reconsideration	Editorial revisions: Clarifications in recommendation text are requested	<input type="checkbox"/>
	No requested revisions	<input checked="" type="checkbox"/>

2. Change in recommendation category or conditions
Complete this section if major or minor revisions are requested
Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation
Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification.
b) Reimbursement conditions and related reasons
Please provide details regarding the information that requires clarification.
c) Implementation guidance
Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

CADTH Reimbursement Review Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	SR0739	
Brand name (generic)	Ozurdex (dexamethasone intravitreal implant)	
Indication(s)	Diabetic macular edema	
Organization	Canadian Council of the Blind	
Contact information ^a	Name: Keith D. Gordon Ph.D., Senior Research Officer	
Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<p>Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.</p> <p>We were extremely disappointed by the decision made by CADTH for a medication that we believe has a role to play for the treatment of diabetic macular edema, when nothing else works.</p> <p>There has been a lot of discussion recently about the importance of taking Real World Experience (RWE) into account when evaluating submissions on the value of new medications. However, the specific requirements of the RWE data have not been spelled out by CADTH. CCB and the other patient groups believe that we submitted credible RWE data based on a 67-patient survey. However, CADTH's response was that Quality-of-Life assessments were not included in the clinical studies and appeared to ignore our data. As has been noted by CADTH, clinical studies do not represent RWE and should be considered in combination with other data from the real world. It doesn't appear that this has been done in this case.</p> <p>While we agree with CADTH concerns re safety of Ozurdex, we also believe that there is a small group of patients for whom Ozurdex will be effective and safe and that the safety can be effectively monitored by the prescribing ophthalmologist.</p> <p>The positive impact of Ozurdex is best described by the following experience of one patient, reported in White Cane Magazineⁱ. The steroid referred to was Ozurdex.</p> <p>"I started losing my vision 15 years ago, and went through a three-year period of one eye surgery and treatment after the next. I stopped driving, had to leave the job that I loved, and dealt with mental health challenges as a result. It all started with my diagnosis of type 2 diabetes in 1992 – although I didn't realize the connection at the time. In fact, I wasn't made aware that vision loss was a complication of diabetes until the damage had been done. In 2005, I developed a cataract in one eye. The cataract surgery didn't go well. When I went to the doctor a couple weeks later for a check-up, he told me that my eye was hemorrhaging (bleeding) and referred</p>		

me to a retina specialist. My visit to this specialist was a rude awakening. He told me that all the trouble I was having with my eye had begun with my diabetic retinopathy (DR). I had no idea what he was talking about. 'You've known that you had DR for a couple years, right?' he asked. Not only did I not know, but I'd never even heard the term before. The specialist was stunned, as was I. My DR – which I'd just learned I had – had progressed to diabetic macular edema. Despite multiple surgeries and 16 rounds of laser surgery, the treatment didn't work. I also had a cataract in my other eye. I started taking anti-VEGFs and they worked for a short time, but I had to go from an eye injection every six weeks to every three and a half weeks eventually, to reduce and manage the bleeding and edema in my eye. Throughout my journey, I've had many bad experiences with health care practitioners. I was very fortunate to connect with Dr. Geoff Williams about 14 years ago. When my anti-VEGF treatments stopped working, he put me on a steroid treatment that has dramatically improved the bleeding in my eye. Unfortunately, it's not covered by Alberta's drug benefit program – it's only partially funded in Quebec. For years, I was able to take advantage of my partner's private plan, which covered a portion of the medication, but eventually the relationship ended, and so did my access to treatment. Despite the cost, fortunately, today I'm miraculously stable due to the longevity of this drug, but I make sacrifices to save the vision I have left. I continue to lean on my faith, and on the experience and leadership of Dr. Williams. I've had to surrender much to diabetes and to the vision loss especially, but I remain hopeful that stakeholders will convey the understanding to elected officials for critical funding!"

We hope that CADTH will reconsider its recommendation and recommend the reimbursement of Ozurdex for the very few patients whose condition is similar to that described by the above patient.

¹ Cupello F. Knowledge, Awareness, and Early Diagnosis of Diabetes-Related Vision Complications Are Critical. White Cane Magazine. March 2022. P 32. Available at: [file:///C:/Users/kgord/Downloads/WC-2022-MAGAZINE-FINAL-withHyperlinks-2-VD%20\(2\).pdf](file:///C:/Users/kgord/Downloads/WC-2022-MAGAZINE-FINAL-withHyperlinks-2-VD%20(2).pdf)

Expert committee consideration of the stakeholder input

2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If not, what aspects are missing from the draft recommendation?

Clarity of the draft recommendation

3. Are the reasons for the recommendation clearly stated?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If not, please provide details regarding the information that requires clarification.

^a CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the [Procedures for CADTH Drug Reimbursement Reviews](#) for further details.

A. Patient Group Information					
Name	<i>Please state full name</i>				
Position	<i>Please state currently held position</i>				
Date	<i>Please add the date form was completed (DD-MM-YYYY)</i>				
<input type="checkbox"/>	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.				
B. Assistance with Providing Feedback					
1. Did you receive help from outside your patient group to complete your feedback?				No	<input type="checkbox"/>
				Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.					
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?				No	<input type="checkbox"/>
				Yes	<input type="checkbox"/>
If yes, please detail the help and who provided it.					
C. Previously Disclosed Conflict of Interest					
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.				No	<input type="checkbox"/>
				Yes	<input type="checkbox"/>
D. New or Updated Conflict of Interest Declaration					
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	
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Add company name</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<i>Add or remove rows as required</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

ⁱ Cupello F. Knowledge, Awareness, and Early Diagnosis of Diabetes-Related Vision Complications Are Critical. White Cane Magazine. March 2022. P 32. Available at: [file:///C:/Users/kgord/Downloads/WC-2022-MAGAZINE-FINAL-withHyperlinks-2-VD%20\(2\).pdf](file:///C:/Users/kgord/Downloads/WC-2022-MAGAZINE-FINAL-withHyperlinks-2-VD%20(2).pdf)