Common Drug Review
Patient Group Input Submissions

Aflibercept (Eylea) for Age-related Macular Degeneration

Patient group input submissions were received from the following patient groups. Those with permission to post are included in this document.
Canadian Council of the Blind — permission granted to post.

CADTH received patient group input for this review on or before May 26, 2014

CADTH posts all patient input submissions to the Common Drug Review received on or after February 1, 2014 for which permission has been given by the submitter. This includes patient input received from individual patients and caregivers as part of that pilot project.

The views expressed in each submission are those of the submitting organization or individual; not necessarily the views of CADTH or of other organizations. While CADTH formats the patient input submissions for posting, it does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no personal information is included in the submission. The name of the submitting patient group and all conflict of interest information are included in the posted patient group submission; however, the name of the author, including the name of an individual patient or caregiver submitting the patient input, are not posted.

Canadian Council of the Blind

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Aflibercept (Eylea) for Age-related Macular Degeneration
Name of the patient group	Canadian Council of the Blind (CCB)
Patient group's contact information:	20 James Street, Suite 100, Ottawa, ON K2P 0T6 613 567 0311 Email: [redacted] www.ccbnational.net
Permission is granted to post this submission	Yes

1.1 Submitting organization

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 65 chapters across Canada, and with over 1,500 members, is the largest membership-based organization for the blind.

1.2 Conflict of Interest Declarations

a) *We have the following declaration(s) of conflict of interest in respect of corporate members and joint working, sponsorship, or funding arrangements:*
In 2011 - 2014, CCB received support from the following: VIA Rail, Cannondale, Community Foundation of Ottawa, Lions Club, Keith Communications Inc., Human Resources and Skills Development Canada (HRSDC), and the following pharmaceutical companies - Bayer, Merck Frosst, Novartis, and Pfizer.

b) *We have the following declaration(s) of conflict of interest in respect of those playing a significant role in compiling this submission:*
Nothing to declare. This submission was prepared by CCB staff.

2. Condition and Current Therapy Information

2.1 Information gathering

Information was obtained from printed information on current therapy from drug companies and on-line searches, one-to-one conversations with patients using current therapy, and focus groups.

2.2 Impact of condition on patients

- Available coverage and lack of choice of Health Canada approved drugs for the treatment of eye diseases such as AMD, DME, and RVO are the most important aspects of this condition.
- Quality of life and daily living is severely impacted with impaired vision. Because the patients can no longer drive, they need to find ways to attend medical appointments, shopping and social activities. Assistance is required for what were formally simple tasks such as preparing meals, daily household chores, reading, etc. Patients with AMD & RVO are unable to read regular print (books, newspapers, food labels, menus, greeting cards, etc.) as they have in the past.
- There is a social impact: often when someone develops a condition such as vision loss, friends seem to disappear basically because they don't know how to deal with the situation. People become isolated because they cannot move independently in their former environment.
- The patient has to learn how to deal with new challenges as they arise. Depression can also set in due to the pending loss of independence, potential loss of employment, loss of driving privileges, and the sheer uncertainty of diminished quality of life and of a life with no vision.
- Vision loss can cause patients to fall and injure themselves more frequently.
- There is often an economic impact and higher costs to vision loss due to loss of employment and the cost of treatment.
- Family dynamics change.
- Patients can no longer drive, thread a needle, ID medications, cook/prepare food, and much more.

2.3 Patients' experiences with current therapy

Current therapies include laser therapy, Vitalux, ASA, Lutein, Lucentis and Avastin. Many patients are using currently Health Canada approved injections with good results. This drug may need to be repeated many more times than Eylea would need to be used – i.e. every four weeks after initial regime, where Eylea can be effective for up to 8 weeks after initial 3 month set of treatments.

Some patients are receiving injections of a drug that has not been tested or approved by Health Canada. The long term effects of this drug are not known and could lead to adverse results due to the unknown. Some patients are restricted in choice of treatment due to cost incurred from travel to regional clinics and therefore do not receive the optimal treatment they should be getting. Some provinces only provide a certain amount of money for use of current approved drug therapy.

Patients need to have a choice in approved treatment, currently there is only one medication available. Physicians need to have an alternate treatment should one not be available or may not meet the current needs of their patients. Physicians need to be able to provide approved medications for AMD. Sometimes some patients may have an adverse reaction to an additive in the solution that may not be in Eylea so that they can receive the best care for their condition. Sometimes there may be some irritation which could be avoided with a second choice of medication.

Patients need to receive the best – approved care for AMD (DME & RVO) where ever they live so that the cost factor of travel and medication out-of-pocket expenses prevent them from getting this care.

2.4 Impact on caregivers

With diagnosis of AMD or RVO of a loved one, caregivers have to deal with all the emotional effects of vision loss in someone who had been previously independent, and deal also with their own emotions. Caregivers need to provide a safe environment for the patient. They may need to possibly take time off

work to transport patient to medical appointments, shopping, etc. They may need to do more household chores especially if the patient live alone. They may need to provide comfort and reassurance to the patient.

Caregivers are dealing with an added financial burden due to both patient and caregiver having to take additional time from employment or arranging childcare for other family members as they care for a parent, etc. Due to lack of knowledge or understanding they may not know how to deal with the personal feelings/depression of the patient.

Should a patient not receive proper treatment the caregiver needs to arrange daily living care for the patient – most especially if there is a resulting injury due to decrease in vision.

3. Information about the Drug Being Reviewed

3.1 Information Gathering

Information about Eylea was obtained through computer research, talking with physicians, and one-to-one conversations with patients.

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

a) Based on no experience using the drug:

It is expected that the lives of patients will be improved with Eylea. According to research the macular edema should decrease and therefore improve vision.

The lack of choice as to approved therapy is currently not available. Eylea now would give the patient/physician two drugs to improve eye health.

EYLEA® (aflibercept) Injection is indicated for the treatment of patients with neovascular (Wet) Age-related Macular Degeneration (AMD). The recommended dose for EYLEA is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks, therefore fewer trips to physician and less time for caregivers to miss from work..

EYLEA is indicated for the treatment of patients with Macular Edema following Central Retinal Vein Occlusion (CRVO). The recommended dose for EYLEA is 2 mg administered by intravitreal injection every 4 weeks (monthly). Branch retinal vein occlusion (BRVO) and Central retinal vein occlusion (CRVO) are retinal vascular diseases which are associated with a decrease in vision-related quality of life.

The hemorrhaging that occurs with RVO, along with the macular edema resulting loss of vision causes the patient to become very apprehensive. The need to stop bleeding is most important to prevent further vision loss which would compound the above problems. Also, the increased intraocular pressure – glaucoma - needs to be controlled to decrease the incidence of peripheral vision loss.

An unmet need is that sometimes patients may have an adverse reaction to current therapy and therefore have no second choice of approved medication and therefore continue to lose vision.

It is expected that there will be improvement with this new drug by arresting the progress and possibly regaining sight. There may be a reduction in the number of drops needed in the future, therefore, alleviating adverse reactions or irritations. There will be less macular edema and less bleeding.

If the patient felt they were going to regain sight or prevent further loss, they would often be willing to experience some temporary adverse effects. Patients will indicate that they have nothing to lose if the treatment doesn't work or cause adverse side effects so will be willing to give it a try with the anticipation that they will regain their sight. Regaining sight, controlling bleeding, fewer hospital visits, returning to work, and regaining independence to a greater degree than prior to treatment would be considered adequate improvement and worth the risk of side effects.

Mild irritation for short time is acceptable. Infection is not acceptable but if properly administered and proper patient compliance to post-injection this should not be a problem. With individual dosing as Eylea is prepared, infection would be minimized greatly.

b) *Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:*
EYLEA is the only anti-angiogenic therapy approved for wet age-related macular degeneration (AMD) with a proactive, treat-and-extend dosing approach without the need for interim monitoring**.**

EYLEA has demonstrated efficacy in a proactive, treat-and-extend dosing approach to treatment-naive patients with wet AMD

- Monthly treatment with ranibizumab or bevacizumab produced better efficacy outcomes compared with PRN or scheduled quarterly dosing regimens
- Relative to ranibizumab 0.5 q4 regimens, aflibercept 2q8 requires 5 fewer injections per year and the mode of treatment remains proactive
- Aflibercept 2q8 is also less intensive and less subject to equipment, operator, and interpretive variability

EYLEA®–Demonstrated Efficacy in a Proactive Approach for the Treatment of Wet AMD in Treatment-naive patients

Proven once every 2 months dosing in the first year1Fewer clinic visits

- Treating proactively instead of reactively means patients spend less time at the clinic and less time travelling
- More independence
  With fewer monthly clinic visits, patients have more time for what matters
- Predictability
  A predictable injection schedule offers patients reduced impact of disease management on their personal lives

- Less burden on clinic staff
  Staff no longer needs to spend time coordinating monthly monitoring and unscheduled injections
- Proactive approach
  Ability to proactively extend time between combined monitoring/injection visits based on visual and anatomic response
- Serious adverse reactions related to the injection procedure have occurred in less than 1 in 1,000 intravitreal injections with Eylea and included endophthalmitis, traumatic cataract, and transient increased intraocular pressure.
- The vials are for single use only.
- Long term health is expected to improve greatly as mentioned previously

4. Additional Information

Questions are clear and easy to navigate.

It is important to have patient input when a new drug is being assessed for approval because patients are the ones going to benefit from the treatment. Also, they are the people most aware of the potential results if treatment is not available.