Common Drug Review
Patient Group Input Submissions

Ranibizumab (Lucentis) for Choroidal Neovascularization in Pathologic Myopia

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.
Canadian National Institute for the Blind — permission not granted to post.

CADTH received patient group input for this review on or before August 28, 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	Ranibizumab (Lucentis) for Choroidal Neovascularization in Pathologic Myopia
Name of the patient group	Canadian Council of the Blind
Patient group's contact information:	20 James St., Suite 100, Ottawa, ON. K2P 0T4 1-613-567-0311 ccbnational@ccbnational.net www.ccbnational.net
Permission is granted to post this submission	Yes

1.1 Submitting organization

Please provide an overview of the organization that is making the submission, including the purpose or aim(s) of the organization and an outline of the type of membership.

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 and one-to-one conversations with patients using current therapy

1. 1.Retina: The Journal of Retinal and Vitreous Diseases - March 2010 - Volume 30 - Issue 3 - pp 399-406 - doi: 10.1097/IAE.0b013e3181bcef24;
2. 2.Neelam K et al. Choroidal neovascularization in pathological myopia. Prog Retin Eye Res 2012;31:495-525.
3. Rose K et al. Quality of life in myopia. Br J Ophthalmol 2000;84:1031-1034.
4. Yoshida T et al. Myopic choroidal neovascularization: a 10-year follow-up. Ophthalmology 2003;110:1297-1305.
5. Wolf S et al. Ranibizumab vs verteporfin PDT for choroidal neovascularization secondary to pathologic myopia: a Phase III study. Asia Pacific Academy of Ophthalmology 2013.

2.2 Impact of condition on patients

Choroidal neovascularization is a common cause of vision loss in patients with pathologic myopia, often resulting in irreversible central vision loss. This is particularly important because choroidal neovascularization secondary to pathologic myopia affects many people of working age.

Whereas Choroidal neovascularization in pathological myopia (CNV), usually affects persons between mean ages of 40-50 years of age, there can be a major impact on the persons career, independence, family responsibilities, etc. 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.

- 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, read newspapers/books, watch TV, thread a needle, ID medications, cook/prepare food, and much more.

CNV can have a severe impact on career expectations and financial status. This is an important issue for younger patients who may be supporting themselves and their families.

2.3 Patients' experiences with current therapy

Current therapies include laser photocoagulation, photodynamic therapy with verteporfin, surgery, and off label drugs. Currently, verteporfin photodynamic therapy (vPDT) is the only pharmacologic approved treatment for myopic subfoveal CNV. vPDT generally stabilizes, but does not improve, visual acuity.

Despite its widespread use for many years, the amount of benefit achieved with photocoagulation and the possibility that it is maintained over the years remains unknown. Furthermore, studies suggest that the enlargement of the laser scar could be a potentially vision-threatening long-term complication after two years, since it may cause the gradual occurrence of a blind spot in the centre of the visual field due to progressive atrophy of the retina.

(As a person who has received photocoagulation therapy in the past can attest to the major impact of laser scars that has taken my vision as well as atrophy of the retina).

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.

Patients need to have a choice in approved treatment. Also, patients need to receive the best – approved care for CNV where ever they live. Cost factors of travel and medication are often out-of-pocket expenses that can prevent them from getting the care they need to allow them to continue employment and caring for their families.

Patients need to be able to receive the best care available to ensure a good quality of life. Loosing central vision from laser scaring does not meet this major need of maintaining independence, employment and self-esteem.

2.4 Impact on caregivers

With diagnosis of CNV of a loved one, caregivers have to deal with all the emotional effects of vision loss in someone who had been previously independent, a breadwinner, a driver, or a care-giver themselves and deal also with their own emotions. Caregivers need to provide a safe environment for the person. They may need to possibly take time off work to transport the family member to medical appointments, shopping, etc. They may need to do more household chores especially if the person lives alone. They may need to provide comfort and reassurance to the loved one.

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 loved one.

The caregiver must modify the home so that the danger of falls or injuries is reduced for the person with reduced vision.

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 Ranibizumab – Lucentis for Choroidal Neovascularization in Pathologic Myopia 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:

- Is it expected that the lives of patients will be improved by this new drug, and how?
- Yes. This drug has been beneficial in improving the lives of patients with other Retinal conditions such as AMD, DME, and RVO. Many of those treated that I have spoken with have been able to regain lines on the Snellen Chart and regain driving privileges.

- Is there a particular gap or unmet patient need in current therapy that this drug will help alleviate?
- 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.

- Would patients be willing to experience serious adverse effects with the new therapy if they experienced other benefits from the drug?
- 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.

- How much improvement in the condition would be considered adequate? What other benefits might this drug have — for example, fewer hospital visits or less time off work?
- Any improvement that would allow a person to regain sight. Return to work, drive a car, and provide for the family and fewer visits to medical appointments would be benefits.

b) Based on patients' experiences with the new drug as part of a clinical trial or through a manufacturer's compassionate supply:

- What positive and negative effects does the new drug have on the condition?
- Literature shows that Ranibizumab has better effects in treating CNV than current treatments. Lucentis (ranibizumab) offers BCVA gains of up to 14 letters at Month 12

- Which symptoms does the new drug manage better than the existing therapy and which ones does it manage less effectively?
- There is minimal chance of scar tissue with this new drug over the current photocoagulation therapy.

- Does the new drug cause adverse effects?
- Regardless of treatment there is always a chance of adverse effects and according to literature these are minimal with Ranibizumab.

- Which adverse effects are acceptable and which ones are not?
- 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, infection would be minimized greatly.

- Is the new drug easier to use?
- Yes. The number of treatments can be as few as one.

- How is the new drug expected to change a patient's long-term health and well-being?
- Long term health is expected to improve greatly as mentioned previously.

4. Additional Information

Myopic CNV is the most common vision-threatening complication of PM, the leading cause of CNV second only to Age-related Macular Degeneration (AMD), characterized by the occurrence of newly formed abnormal blood vessels. These blood vessels can rupture, leaking blood and fluid around the retina, which can result in irreversible deterioration of central vision.

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.

Questions are clear and easy to navigate.

Canadian National Institute for the Blind

1. General Information

Name of the drug CADTH is reviewing and indication(s) of interest	Ranibizumab (Lucentis) for Choroidal Neovascularization in Pathologic Myopia
Name of the patient group	Canadian National Institute for the Blind
Patient group's contact information:	1929 Bayview Avenue, Toronto, Ontario M4G 3E8 416-486-2500 Ext 7689 www.cnib.ca
Permission is granted to post this submission	No permission is granted
Date of submission	September 9, 2014

The patient group has not granted permission to post its patient input submission. When permission is not granted, CADTH will post on its website that a patient submission was received, but it was not posted at the request of the submitter.

The patient input that was provided in this submission, along with all other patient input received for this drug, is included in the summary of patient input that is contained in the posted *CDR Clinical Review Report*.