



Canadian Agency for
Drugs and Technologies
in Health

COMMON DRUG REVIEW

Canadian Expert Drug Advisory Committee Final Recommendation and Reasons for Recommendation Plain Language Version

Ranibizumab (Lucentis® – Novartis Pharmaceuticals Canada Inc.) Indication – Age-related Macular Degeneration

The information contained within this plain language version of the Canadian Expert Drug Advisory Committee (CEDAC) Final Recommendation and Reasons for Recommendation about this drug is based on the information found within the corresponding technical version of the CEDAC Final Recommendation and Reasons for Recommendation. Health care professionals and those requiring more detailed information are advised to refer to the technical version available in the [CDR Drug Database](http://www.cadth.ca) on the CADTH web site (www.cadth.ca).

Drug

Ranibizumab, commonly known as Lucentis®, is approved to treat a condition of the eyes called age-related macular degeneration usually referred to as AMD. AMD is a disease of the eye that causes loss of the ability to see and may make it more difficult to read, drive, or perform other daily activities. Lucentis prevents unusual blood vessels from forming in the eye which break, causing blood and fluid to leak into the eye – the cause of many of the problems in a type of AMD known as “wet” AMD.

Dose

Lucentis is available in vials that contain 3.0 mg of medication in 0.3 mL of solution. The recommended dose of Lucentis is 0.5 mg injected into the eye once a month for three months – after which time the injections may be given from once every month to once every three months, depending on the patient’s response and if monthly injections are not possible.

CEDAC Recommendation

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that Lucentis be listed for coverage by Canada’s publicly funded drug plans under the following conditions: drug plans should limit coverage to a maximum of 15 vials for each patient; Lucentis should be used to treat the better-seeing eye affected by AMD; Lucentis should not be covered in combination with Visudyne® —another drug used to treat AMD.

Reasons for the Recommendation

- Lucentis has been shown to be more effective in treating AMD than other available treatments. Treatment with Lucentis has been shown to slow down vision loss and in some cases improves vision.

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- Each injection of Lucentis costs \$1,575 and some patients will likely be treated for a long period of time. The manufacturer did an economic study of the cost of Lucentis compared to other treatments that also looked at how much these treatments improve the quality of life of patients with AMD. The costs depend on the type of AMD patients have and how long they are treated for. It is possible that the cost estimated by the manufacturer will be higher especially if patients are treated for a long period of time.
- The manufacturer of Lucentis also proposed a “Product Listing Agreement” whereby the manufacturer would cover the costs of the drug if patients require more than 9 injections in the first year of treatment and more than 6 injections each year after. Since the manufacturer’s economic study only looked at patients being treated for a maximum of two years to estimate how much Lucentis would cost drug plans, CEDAC recommended that drug plans only cover up to 15 vials for each patient (the equivalent of 9 vials in the first year and 6 in the second year of treatment).

Summary of Committee Considerations

- CEDAC considered three studies with a total of 1,323 adult patients with AMD.
- One study compared Lucentis with Visudyne which is used together with photodynamic therapy (PDT) – another treatment option for AMD. After a year of treatment, more patients treated with Lucentis had improved vision and less vision loss than those patients treated with Visudyne PDT. Patients treated with Lucentis also reported an improvement in their quality of life compared to those treated with Visudyne PDT. These improvements appeared to continue up to two years of treatment.
- The other two studies compared Lucentis to no active drug – called a “sham”. In the first study, patients were treated with monthly injections. After a year of treatment patients treated with Lucentis had improved vision and less vision loss than those patients treated with the sham procedure. Patients treated with Lucentis also reported an improvement in their quality of life compared to those treated with the sham procedure. Similar results were seen during the second year of treatment as well. In the second study patients were treated with monthly injections for three months followed by injections once every three months. After a year of treatment the patients treated with Lucentis had less vision loss, but did not improve their vision or report an improved quality of life when compared to patients treated with the sham procedure.
- Serious side effects related to Lucentis being injected into the eye occurred in less than 1 out of 1000 patients. They included infection of the eye, cataracts and problems with the retina (the back of the eye). Because of how Lucentis works in the body, there is a chance of a blood clot forming in a blood vessel.

Of Note

- CEDAC was aware that patients with AMD are being treated in Canada with Avastin[®] a drug approved to treat colon cancer. Avastin is not approved for the treatment of AMD. Although Avastin has a similar effect on blood vessels, there is not much information about how well Avastin works and how safe it is in treating AMD. Avastin is much less costly than Lucentis. This led the Committee to question whether Lucentis offers good value in the treatment of AMD. In making its recommendation, CEDAC considered a request by the manufacturer of

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Lucentis to reconsider the drug for coverage as well as information from the publicly funded drug plans that they could not cover Avastin for the treatment of AMD.

- The recommendation that Lucentis be covered by Canada's publicly funded drug plans should be reviewed when information becomes available about how Lucentis compares to Avastin in the treatment of AMD.
- Lucentis is supplied in vials that can only be used once but they contain much more drug than the recommended dose. This will result in wastage of Lucentis. The manufacturer of Lucentis together with the drug plans should explore whether there is a way to reduce this waste.

Background on CEDAC

CEDAC is a committee of the Canadian Agency for Drugs and Technologies in Health (CADTH). The committee is made up of drug evaluation experts and public members. CEDAC provides recommendations about whether or not drugs should be listed for coverage through the participating publicly funded drug plans; however, the individual drug plans make their own decision about whether or not to cover a drug.

In making its recommendations, CEDAC decides if the drug under review ought to be covered by the participating public drug plans based on an evidence-informed review of the medication's effectiveness and safety, and based on an assessment of its cost-effectiveness in comparison with other available treatments.

The CEDAC Final Recommendation and Reasons for Recommendation neither takes the place of a medical professional providing care to a particular patient, nor is it intended to replace professional advice. CADTH is not legally responsible for any damages arising from the use or misuse of any information contained or implied by the contents of this document.

The statements, conclusions, and views expressed herein do not necessarily represent the view of Health Canada, the federal government, any provincial or territorial government, or the pharmaceutical manufacturer.

The manufacturer has reviewed this document and has not requested the deletion of any confidential information.

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