Clarification to the Notice from the Executive Officer Re: Lucentis – Change in Status to Limited Use (April 1, 2011)

Qs & As

Q1: What is the status of Lucentis, and is it reimbursed under the ODB Program?

A1: As of May 19, 2011 Lucentis had its listing status changed to a Limited Use (LU) product in the ODB formulary, which means that patients must meet the established Limited Use criteria for Lucentis in order to receive coverage under the ODB program.

If a patient is an ODB-eligible recipient and the physician determines that the patient meets all the Limited Use criteria for Lucentis, then Lucentis would be covered for that patient under the ODB program.

As such, as of May 19, 2011, if a patient new to Lucentis therapy meets the LU criteria, the prescription should include the appropriate LU code. For patients currently receiving Lucentis through General Benefit, confirmation that they meet the LU criteria is required and the LU code should be documented on the next prescription or refill.

Please note that if the prescriber has determined that the patient meets the Limited Use criteria for Lucentis, then the patient should not be asked to pay anything other than their normal co-payment/deductible under the ODB program for filling the prescription for Lucentis at a pharmacy that is registered and authorized to submit electronic claims on the ministry's Health Network System.

Patients who do not meet the LU criteria will not be reimbursed through Ontario Public Drug Programs. Claims submitted for patients that do not meet the LU requirement will be subject to recovery.

Q2: Has the Ministry of Health established criteria for who will be eligible to receive Lucentis?

A2: Yes. Lucentis is listed as a Limited Use product for reimbursement for Ontario Drug Benefit (ODB) recipients, effective May 19, 2011. A listing as a Limited Use product in the ODB formulary means that prescribers may prescribe according to their clinical expertise and judgment, but that only patients who meet the Limited Use criteria (and whose prescriptions include the appropriate LU code) will be eligible for reimbursement under the ODB.

Q3: What are the Limited Use criteria?

A3: The Limited Use (LU) criteria for Lucentis are consistent with the previous therapeutic notes, and are as follows:

- For the treatment of patients with new onset (< 3 months) neovascular (wet) age-related macular degeneration (AMD) in a verteporfin PDT (Visudyne)-naïve eye.

- Initial diagnosis should be confirmed by an appropriate diagnostic procedure and administration should be done by a qualified ophthalmologist experienced in Intravitreal injections.
- Patients receiving concurrent administration of verteporfin PDT (Visudyne) are not eligible for reimbursement.
- Treatment should be initiated with a loading phase of one injection per month for three consecutive months, followed by a maintenance phase.
- During the maintenance phase, patients should be monitored for best corrected visual acuity or continued disease activity. If there is clinical or diagnostic evidence of disease activity such as a loss of greater than 5 letters in visual acuity (Early Treatment Diabetic Retinopathy Score (ETDRS) chart or one Snellen line equivalent), Lucentis may be administered. The interval between two doses should not be shorter than one month.

Limited Use authorization is valid for one year. This means that the prescriber must confirm the patient's eligibility, according to the LU criteria, every year.

Please note that the "new onset (<3 months)" criterion refers to the patient's condition at the time when they were first diagnosed and treated. This means that patients who were previously receiving Lucentis for the treatment of neovascular (wet) age-related macular degeneration (AMD) will remain eligible for coverage under the new Limited Use criteria.

Q4: *A patient has been receiving Lucentis for the last year and is scheduled to receive the next needle in a month. The patient would like to know if they are covered by the ODB program for their future needles?*

A4: Patients will continue to be covered by the ODB program if they meet the Limited Use criteria for Lucentis. The prescriber must confirm each patient's eligibility each year by including the Limited Use code on the patient's prescription. Refer also to A1 and A3.

Q5: *How is Lucentis reimbursed?*

A5: Drugs listed in the ODB formulary are reimbursed for ODB eligible recipients when they are prescribed by an authorized prescriber, and dispensed (according to legislation/regulations governing the program), at a pharmacy that is registered and authorized to submit electronic claims on the ministry's Health Network System.

Q6: *What is reimbursed for Lucentis treatment?*

A6: The ODB program covers the cost of the drug as listed in the ODB formulary and the dispensing fee.

Q7: How much will it cost for each injection of Lucentis in Ontario?

A7: Lucentis is listed in the Formulary at $1575.0000 per 0.3mL vial package. The total cost of treatment will depend on the number of injections a patient receives.