

## NOTICE FROM THE EXECUTIVE OFFICER: LUCENTIS QUESTIONS AND ANSWERS

April 17, 2008

### Regarding Lucentis listing on the ODB Formulary

- Lucentis is a general benefit product on the ODB formulary which allows physicians to prescribe according to their clinical expertise and judgment. In other words, there are no specific restrictions on prescribers concerning general benefit products.
- The notes listed in the ODB Formulary provide guidance to prescribers on where this product can be used in the most cost effective manner as advised by the ministry's expert advisory committee and an expert in ophthalmology.
- The Ministry does not review or audit physician prescribing practices with respect to notes in the ODB Formulary.

*Q1: Has the Ministry of Health established criteria for who will be eligible to receive Lucentis?*

A1: Following a review by the ministry's expert advisory committee, and a decision by the Executive Officer, Lucentis was listed in the Ontario Drug Benefit Formulary effective March 25, 2008. Lucentis is listed as a General Benefit product for reimbursement for Ontario Drug Benefit (ODB) recipients. A general benefit product on the ODB formulary allows physicians to prescribe according to their clinical expertise and judgment. General Benefit products are reimbursed without specific clinical restrictions to recipients eligible for the ODB program.

The notes listed in the Formulary provide guidance to prescribers on where this product can be used in the most cost effective manner as advised by the ministry's expert advisory committee and an expert in ophthalmology. The Ministry does not review or audit physician prescribing practices with respect to notes in the ODB Formulary.

*Q2: If so, could we get a copy of the criteria?*

A2: There are no specific restrictions on prescribers concerning general benefit products; in other words, physicians are able to prescribe general benefit products at their discretion based on the patient's specific condition. Any Formulary notes provide guidance to the physician. The Formulary notes with respect to Lucentis suggest that the most cost-effective uses of the product are in the following circumstances:

- 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

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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.

*Q3: How much is the Ministry paying the manufacturer for the drug?*

**A3:** Total cost will depend on how many Ontario Drug Benefit program recipients fill a prescription for the drug.

*Q4: How much will it cost for each injection of Lucentis in Ontario?*

**A4:** 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.

*Q5: Are Lucentis prescription claims before March 25, 2008 eligible for reimbursement?*

**A5:** Lucentis became eligible for reimbursement by the Ministry as of March 25, 2008. Prescription claims prior to March 25, 2008 are not eligible for reimbursement.

*Q6: How is Lucentis reimbursed?*

**A6:** Drugs listed in the ODB formulary are reimbursed for ODB eligible recipients pursuant to a prescription from an authorized prescriber and dispensed by a retail pharmacy or a dispensing physician registered according to the ODBA and associated regulations with the Ministry.

*Q7: What is reimbursed for Lucentis treatment?*

**A7:** The ODB program covers the cost of the drug as listed in the ODB formulary and the dispensing fee.