### Common Drug Review

**Submission Status**

**Product:** Lucentis  
**Generic Name:** ranibizumab injection  
**Manufacturer:** Novartis Pharmaceuticals Canada Inc.  
**Indication:** Macular edema, secondary to retinal vein occlusion

<table>
<thead>
<tr>
<th>Phase</th>
<th>Target Time (Business Days)</th>
<th>Target Date ³</th>
<th>Actual CDR Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Submission deemed complete</td>
<td>5</td>
<td>2012-May-02</td>
<td>2012-May-02</td>
</tr>
</tbody>
</table>
| 2     | Patient group input submission received ³ | 2012-May-16 | 2012-May-16 | Call for patient input posted on 2012-Apr-11  
Patient group input deadline: 2012-May-16  
Patient group input submission received |
| 3     | CADTH Reviewers' Reports sent to Manufacturer ⁴ | 45            | 2012-Jul-18     | 2012-Jul-23 | New Target date: 2012-Jul-23 |
| 4     | Comments from Manufacturer on Reviewers' Reports Received by CADTH | 7             | 2012-Jul-27     | 2012-Aug-01 | New Target date: 2012-Aug-01 |
| 5     | CDEC Meeting                 |                | 2012-Sep-19     | 2012-Sep-19 |
| 6     | CDEC Recommendation Sent to Drug Plans and Manufacturer | 5 to 7        | 2012-Sep-26     | 2012-Sep-26 |
| 7     | Embargo Period ⁵             | 10             | 2012-Oct-11     | 2012-Oct-11 |
| 8 (a) | Final Recommendation sent to Drug Plans and Manufacturer  
(No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved) | 5             | 2012-Oct-18     | 2012-Oct-18 | Notice of Final Recommendation issued |
| 8 (b) | Clarification and Final Recommendation sent to Drug Plans and Manufacturer  
(Clarification Requested, no Request for Reconsideration made) | 5             |                |            |
| 8 (c) | Placed on CDEC Agenda For Reconsideration  
(At Manufacturer's request) | 25             | Depends on Meeting Dates | |
| 9     | Final Recommendation sent to Drug Plans and Manufacturer | 5             |                |            |

### Notes

- **Phase 1:** Submission deemed complete  
**Target Time:** 5 business days  
**Target Date:** 2012-May-02  
**Actual CDR Date:** 2012-May-02

- **Phase 2:** Patient group input submission received  
**Target Time:** 2012-May-16  
**Target Date:** 2012-May-16  
**Actual CDR Date:** 2012-May-16  
- Call for patient input posted on 2012-Apr-11  
- Patient group input deadline: 2012-May-16  
- Patient group input submission received

- **Phase 3:** CADTH Reviewers' Reports sent to Manufacturer  
**Target Time:** 45 business days  
**Target Date:** 2012-Jul-18  
**Actual CDR Date:** 2012-Jul-23  
New Target date: 2012-Jul-23

- **Phase 4:** Comments from Manufacturer on Reviewers' Reports Received by CADTH  
**Target Time:** 7 business days  
**Target Date:** 2012-Jul-27  
**Actual CDR Date:** 2012-Aug-01  
New Target date: 2012-Aug-01

- **Phase 5:** CDEC Meeting  
**Target Date:** 2012-Sep-19  
**Actual CDR Date:** 2012-Sep-19

- **Phase 6:** CDEC Recommendation Sent to Drug Plans and Manufacturer  
**Target Time:** 5 to 7 business days  
**Target Date:** 2012-Sep-26  
**Actual CDR Date:** 2012-Sep-26

- **Phase 7:** Embargo Period  
**Target Time:** 10 business days  
**Target Date:** 2012-Oct-11  
**Actual CDR Date:** 2012-Oct-11

- **Phase 8 (a):** Final Recommendation sent to Drug Plans and Manufacturer  
(No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved)  
**Target Time:** 5 business days  
**Target Date:** 2012-Oct-18  
**Actual CDR Date:** 2012-Oct-18  
Notice of Final Recommendation issued

- **Phase 8 (b):** Clarification and Final Recommendation sent to Drug Plans and Manufacturer  
(Clarification Requested, no Request for Reconsideration made)  
**Target Time:** 5 business days  
**Target Date:**

- **Phase 8 (c):** Placed on CDEC Agenda For Reconsideration  
(At Manufacturer's request)  
**Target Time:** 25 business days  
**Target Date:** Depends on Meeting Dates

- **Phase 9:** Final Recommendation sent to Drug Plans and Manufacturer  
**Target Time:** 5 business days  
**Target Date:**

2. The target dates for this report are based on the CDEC meeting schedule, which is posted on www.cadth.ca.  
3. The deadline for Patient Group Input is 15 business days after CADTH receives the Submission or up to 25 business days if advance notice of a Submission is received from the Manufacturer.  
4. Target time is calculated, based on the date the Reviewers receive copies of the Manufacturer’s Submission. Target time does not include the time allocated for receipt of Manufacturer’s binders (5 business days) and time allocated for distribution of binders to reviewers (3 business days).  
5. The Recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of Final Recommendation. This Submission Status Report reflects status as of Thursday noon.