WWW.CCOHTA.CA

Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

# Common Drug Review *

## Submission Status

**Product:** Amevive

**Generic Name:** Alefacept

**Manufacturer:** Biogen Idec Canada Inc.

**Submission Type:** NEW

**Date Submission Received:** 2004-Nov-16

**Date NOC Issued:** 2004-Oct-06

**Targeted CEDAC Meeting:** 2005-Mar-16

**Priority Review Granted:** Not Requested

| | Phase | Target Time (Business Days) | Target Date** | Actual CDR Date | Comments |
|---|---|---|---|---|---|
| 1 | Submission Deemed Complete | 5 | 2004-Nov-23 | 2004-Nov-24 | |
| 2 | CDR Reviewers' Reports Completed<br>• Reviewers selected and contracted<br>• Literature search and selection completed<br>• Systematic review of clinical data completed<br>• Critical appraisal of pharmacoeconomic (PE) data completed<br>• Clinical and PE reports written<br>• Reports edited and finalized<br>• Reviewers' reports sent to manufacturer | 45 | 2005-Feb-01 | 2005-Feb-02 | Additional information requested December 17,2004.<br>Additional information received December 20, 2004.<br>Additional information requested January 18, 2005.<br>Additional information received January 31, 2005. |
| 3 | Comments from Manufacturer on Reviewers' Reports Received by CDR | 7 | 2005-Feb-10 | 2005-Feb-11 | Due date for manufacturer's comments February 11, 2005. |
| 4 | Reviewers' Reply to Manufacturer's Comments Completed | 7 | 2005-Feb-21 | 2005-Feb-18 | |
| 5 | CEDAC Brief Completed and Sent to CEDAC Members | 5 | 2005-Feb-28 | 2005-Mar-03 | |
| 6 | CEDAC Meeting | | 2005-Mar-16 | 2005-Mar-16 | |
| 7 | CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer | 5 | 2005-Mar-23 | 2005-Mar-23 | |
| 8 | Embargo Period***<br>Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation and Reasons for Recommendation | 10 | 2005-Apr-07 | 2005-Apr-07 | Request for reconsideration received April 7, 2005. |
| 9 (a) | Final Recommendation sent to Drug Plans, ACP, and Manufacturer<br>(No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved) | 5 | | | |
| | **OR** | | | | |
| 9 (b) | Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer<br>(Clarification Requested, no Request for Reconsideration made) | 5 | | | |
| | **OR** | | | | |
| 9 (c) | Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request) | 25<br>Depends on Meeting Dates | 2005-May-18 | 2005-May-18 | |
| 10 | Final Recommendation sent to Drug Plans, ACP, and Manufacturer | 5 | 2005-May-26 | 2005-May-26 | Notice of Final Recommendation Issued. |

* Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.ccohta.ca for more details.

** The CDR review process is initiated AFTER a submission is deemed complete. The target dates for this report are based on the CEDAC meeting schedule, which is posted on www.ccohta.ca.

*** The Recommendation and Reasons for Recommendation are to be held in confidence and not acted upon until after the CDR Directorate has issued the notice of Final Recommendation.