# Common Drug Review *

## Submission Status

**Product:** Tysabri
**Generic Name:** natalizumab
**Manufacturer:** Biogen Idec Canada Inc.
**Submission Type:** Resubmission #1
**Date Submission Received:** 2008-May-06
**Date NOC Issued:** 2006-Sep-28
**Targeted CEDAC Meeting:** 2008-Oct-15
**Priority Review Granted:** Not Requested

| | Phase | Target Time (Business Days) | Target Date** | Actual CDR Date | Comments |
|---|---|---|---|---|---|
| 1 | Submission Assessment | 10 | 2008-May-21 | 2008-May-21 | |
| | Submission deemed complete | | | 2008-May-21 | Resubmission deemed complete. |
| 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 | 2008-Aug-06 | 2008-Aug-26 | Additional information requested June 16, 2008.<br>Additional information requested June 18, 2008.<br>Additional information requested June 19, 2008.<br>Additional information received June 27, 2008.<br>Additional information received July 3, 2008.<br>Additional information received July 15, 2008.<br>Additional information received July 16, 2008.<br>Revised information received July 28, 2008, CDR assessing review timelines.<br>Additional information requested August 1, 2008.<br>Revised information received August 7, 2008, CDR assessing review timelines.<br>Additional information received August 14, 2008. |
| 3 | Comments from Manufacturer on Reviewers' Reports Received by CDR | 7 | 2008-Aug-15 | 2008-Sep-04 | Due date for manufacturer comments September 5, 2008. |
| 4 | Reviewers' Reply to Manufacturer's Comments Completed | 7 | 2008-Aug-26 | 2008-Sep-15 | Due date for reviewers' reply September 15, 2008.<br>Additional information requested September 10, 2008.<br>Additional information received September 11, 2008. |
| 5 | CEDAC Brief Completed and Sent to CEDAC Members | 5 | 2008-Sep-30 | 2008-Sep-30 | |
| 6 | CEDAC Meeting | | 2008-Oct-15 | 2008-Oct-15 | |
| 7 | CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer | 5 | 2008-Oct-22 | 2008-Oct-22 | |
| 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 | 2008-Nov-05 | 2008-Nov-05 | Request for Reconsideration received November 5, 2008. |
| 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<br>(At Manufacturer's request) | 25<br>Depends on Meeting Dates | 2009-Feb-18 | 2009-Feb-18 | Additional information requested January 7, 2009.<br>Additional information received January 8, 2009.<br>Additional information requested January 13, 2009.<br>Additional information received January 13, 2009.<br>Discussed at January 21, 2009 CEDAC meeting.<br>Recommendation deferred pending further discussion.<br>Additional information requested February 10, 2009.<br>Additional information received February 11, 2009.<br>Additional information requested February 17, 2009.<br>Additional information received February 17 & 18, 2009.<br>Discussed at February 18, 2009 CEDAC meeting. |
| 10 | Final Recommendation sent to Drug Plans, ACP, and Manufacturer | 5 | 2009-Feb-25 | 2009-Feb-25 | Notice of Final Recommendation issued. |

* Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.cadth.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.cadth.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.
Reflects updates as of Thursday noon.