Common Drug Review *

Submission Status

Product: Tysabri
Generic Name: natalizumab
Manufacturer: Biogen Idec Canada Inc.
Submission Type: New
Date Submission Received: 2006-Oct-26
Date NOC Issued: 2006-Sep-28
Targeted CEDAC Meeting: 2007-Feb-21
Priority Review Granted: Denied

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2006-Nov-02	2006-Nov-02	Priority review requested. Priority review denied November 8, 2006.
2	CDR Reviewers' Reports Completed • Reviewers selected and contracted • Literature search and selection completed • Systematic review of clinical data completed • Critical appraisal of pharmacoeconomic (PE) data completed • Clinical and PE reports written • Reports edited and finalized • Reviewers' reports sent to manufacturer	45	2007-Jan-11	2007-Jan-11	Additional information requested November 8, 2006. Additional information received November 13, 2006. Additional information requested November 16, 2006. Additional information received November 17, 2006. Additional information requested December 13, 2006. Additional information received December 14, 2006. Additional information requested December 19, 2006. Additional information received December 22, 2006. Additional information received January 2, 2007.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2007-Jan 22	2007-Jan-22	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2007-Jan-31	2007-Jan-31	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2007-Feb-07	2007-Feb-07	Additional information requested February 14, 2007. Additional information received February 16, 2007.
6	CEDAC Meeting		2007-Feb-21	2007-Feb-21	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2007-Feb-28	2007-Feb-28	
8	Embargo Period*** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation and Reasons for Recommendation	10	2007-Mar-14	2007-Mar-22	Request for extension of Embargo Period received on March 7, 2007. Extension granted, new date for receipt of Request for Reconsideration is March 22, 2007. Request for Reconsideration received March 22, 2007.
9 (a)	Final Recommendation sent to Drug Plans, ACP, and Manufacturer (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 (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
9 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2007-Apr-18	2007-Apr-18	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2007-Apr-25	2007-Apr-26	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.