Common Drug Review *

Submission Status

Product: Orencia

Generic Name: abatacept

Manufacturer: Bristol-Myers Squibb Canada

Submission Type: New Indication

Date Submission Received: 2008-Aug-29 **Date NOC Issued:** 2008-Jul-11

Targeted CEDAC Meeting: 2009-Jan-21 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Assessment	5	2008-Sep-08	2008-Sep-08	Category 1 Submission requirements deemed incomplete September 8, 2008.
	Submission deemed complete			2008-Sep-09	Submission deemed complete.
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	2008-Nov-24	2008-Nov-27	Additional information requested September 26, 2008. Additional information received September 29, 2008. Additional information requested October 10, 2008. Additional information received October 15, 2008. Additional information requested October 28, 2008. Additional information received October 30, 2008. Additional information requested November 3, 2008. Additional information received November 7, 2008.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2008-Dec-03	2008-Dec-08	Due date for manufacturer's comments December 8, 2008.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2008-Dec-12	2008-Dec-17	Due date for reviewer's reply December 17, 2008. Additional information requested December 11, 2008. Additional information received December 15, 2008. Additional information received December 23, 2008.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2009-Jan-07	2009-Jan-07	Additional information received January 12, 2009. Additional information received January 16, 2009.
6	CEDAC Meeting		2009-Jan-21	2009-Jan-21	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2009-Jan-28	2009-Jan-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	2009-Feb-11	2009-Feb-11	Request for Reconsideration received February 10, 2009. Additional information received February 17, 2009. Additional information requested February 19, 2009.
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	2009-Apr-15	2009-Apr-15	Reconsideration CEDAC date moved from March 18, 2009 to April 15, 2009. Pending receipt of additional information. Additional information received March 24, 2009. Additional information requested April 8, 2009. Additional information received April 13, 2009.
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2009-Apr-22	2009-Apr-22	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.