Common Drug Review *

Submission Status

Product: Amevive
Generic Name: alefacept
Manufacturer: Astellas Pharma Canada Inc.
Submission Type: Resubmission
Date Submission Received: 2006-Feb-28
Date NOC Issued: 2004-Oct-06
Targeted CEDAC Meeting: 2006-Jun-21
Priority Review Granted: Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2006-Mar-07	2006-Mar-07	
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	2006-May-10	2006-May-26	Additional information requested March 28, 2006. Additional information received March 31, 2006. Additional information received April 3, 2006. Additional information requested April 11, 2006. Additional information received April 13, 2006. Additional information requested April 18, 2006. Additional information received May 3, 2006. Reviewers' reports to manufacturer is delayed pending receipt of additional requirements from the manufacturer. Additional requirements received on May 12, 2006. Manufacturer requested a revised target CEDAC date of July 26, 2006. Revised target CEDAC date granted.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-May-19	2006-Jun-06	Due date for manufacturer's comments June 6, 2006.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-May-31	2006-Jun-14	Due date for reviewers' reply June 15, 2006.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Jul-12	2006-Jul-12	
6	CEDAC Meeting		2006-Jul-26	2006-Jul-26	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Aug-02	2006-Aug-02	
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	2006-Aug-17	2006-Aug-17	Request for Reconsideration received August 17, 2006.
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	2006-Sep-20	2006-Sep-20	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2006-Sep-27	2006-Sep-27	

* 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.