Common Drug Review *

Submission Status

Product: Soliris

Generic Name: eculizumab

Manufacturer: Alexion Pharmaceuticals Inc.

Submission Type: New

Date Submission Received: 2009-Sep-18 **Date NOC Issued:** 2009-Jan-28

Targeted CEDAC Meeting: 2010-Mar-24 **Priority Review Granted:** Granted

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Assessment	5	2009-Sep-25	2009-Sep-25	Category 1 requirements deemed incomplete.
	Submission deemed complete			2009-Oct-09	Submission deemed complete. Priority Review granted. Manufacturer has elected to provide comments on the CDR Reviewer's Report within three business days, therefore CEDAC date changed from March 24, 2010 to February 17, 2010.
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	2009-Dec-24	2009-Dec-10	Additional information requested September 25, 2009. Additional information received October 8, 2009. Additional information requested October 20, 2009. Additional information received November 2, 2009. Additional information requested November 5, 2009. Additional information received November 11, 2009. Additional information requested November 17, 2009.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2010-Jan-12	2009-Dec-15	Due date for manufacturer comments December 15, 2009.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2010-Jan-20	2009-Dec-18	Due date for reviewers' reply December 18, 2009.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2010-Feb-03	2010-Jan-06	Additional information requested January 17, 2010. Additional information received January 20, 2010.
6	CEDAC Meeting		2010-Jan-20	2010-Jan-20	CEDAC meeting changed from February 17, 2010 to January 20, 2010.
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2010-Jan-27	2010-Jan-27	
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	2010-Feb-10	2010-Feb-10	
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	2010-Feb-18	2010-Feb-18	Notice of Final Recommendation issued.
	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			
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5			

* 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.