CADTH

Common Drug Review

Submission Status

Product: Soliris

Generic Name: eculizumab

Manufacturer: Alexion Pharma Canada

Indication: Hemolytic Uremic Syndrome, Atypical

Submission Type: Request for Advice

Date Submission Received: 2015-Feb-09

Date NOC Issued: 2013-Mar-01

Original Targeted CDEC Meeting: 2015-May-20

Key Milestone[1]	Target Date	Actual CDR Date	Comments
CADTH request for advice approach detemined	2015-Feb-24	2015-Feb-24	- 2015-Feb-09: Manufacturer informed of request for advice - 2015-Feb-10: Relevant patient groups informed of request for advice - Information or comments due 2015-Feb-24 - Manufacturer's information/comments received: 2015-Feb-24 - Patient groups' information/comments received: 2015 - Mar-05 - Review has been initiated 2015-Feb-25
Draft CDR Request for Advice report sent to manufacturer	2015-Apr-13	2015-Apr-13	
Comments from manufacturer on draft CDR Request for Advice report received by CADTH	2015-Apr-22	2015-Apr-22	
Redaction response from manufacturer on draft CDR Request for Advice report received by CADTH	2015-Apr-29	2015-May-29	
CDEC meeting	2015-May-20	2015-May-20	
If the request for advice does not result in a new or revised CDEC recommendation: CDEC Record of Advice sent to drug plans and manufacturer	2015-May-27	2015-May-29	- New target date: 2015-May-29
CDEC Record of Advice report posted[3]		2015-Jun-02	
OR			
If the request for advice results in a new or revised CDEC recommendation: CDEC recommendation & redacted CDR Request for Advice report sent to drug plans and manufacturer			
Embargo period[2] and validation of redacted CDR Request for Advice report Manufacturer may make a request for reconsideration and drug plans may make a request for clarification of the recommendation			
CDEC Final Recommendation sent to drug plans and manufacturer (No request for clarification is made AND no request for reconsideration is made or request for reconsideration is resolved)			
CDEC Final Recommendation posted [3]			
Final CDR Request for Advice report posted [3]			
OR			
Clarification and final recommendation sent to drug plans and manufacturer (Clarification requested, no request for reconsideration made)[4]			
CDEC Final Recommendation posted [3]			
Final CDR Request for Advice report posted [3]			
OR			
Placed on CDEC agenda for reconsideration (At manufacturer's request)[4]			
CDEC Final Recommendation sent to drug plans and manufacturer			
CDEC Final Recommendation posted [3]			
Final CDR Request for Advice report posted [3]			

[1] Please refer to the *Procedure for the CADTH Common Drug Review* in the Common Drug Review section of www.cadth.ca for complete details regarding the CDR request for advice process and targeted time frames for key milestones.

[2] The recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of final recommendation. A manufacturer may request an extension of up to 20 extra business days solely for the purpose of preparing and filing a request for reconsideration (i.e., a total of 30 business days)

[3] The target date for posting a CDEC Record of Advice, the CDEC Final Recommendation and CDR Request for Advice report depends on several factors including the need for consultation with the manufacturer regarding redaction issues.

[4] The time frame required to address a request for clarification at the drug plans' request or request for reconsideration at the manufacturer's request depends on the amount of work required to address the request and the available dates for CDEC meetings.

This submission status report typically reflects status as of Thursday noon Eastern Time.