CADTH

Common Drug Review

Submission Status

Product:	Prolia
Generic Name:	denosumab
Manufacturer/Applicant:	Amgen Canada Inc.
Indication(s):	Osteoporosis, men
Submission Type:	Initial
Date NOC Issued:	2012-Nov-21
Date Submission Received:	2015-Mar-10
Application Fee Schedule[1]:	N/A
Original Targeted CDEC Meeting:	2015-Aug-19
Priority Review Status:	Not Requested

Key Milestone[2]	Target Date	Actual Date	Comments
Submission/resubmission accepted for review	2015-Mar-24	2015-Mar-24	- Review has been initiated 2015-Mar-25
Patient group input submission received [3]	2015-Mar-20	2015-Mar-20	- Call for patient input posted on 2015-Jan-29 - Patient group input deadline: 2015-Mar-20 - Patient input submission received
Patient group input summary comments received	2015-Apr-27	2015-Apr-27	- Patient input summary sent for review on 2015-Apr-20 - Patient input summary feedback deadline: 2015-Apr-27 - Patient input summary feedback received
Draft CDR review report(s) sent to manufacturer	2015-Jun-09	2015-Jun-11	- New target date: 2015-Jun-11
Comments from manufacturer on draft CDR review report(s) received by CADTH	2015-Jun-18	2015-Jun-22	- New target date: 2015-Jun-22
Redaction response from manufacturer on draft CDR review report(s) received by CADTH	2015-Jun-25	2015-Jun-29	- New target date: 2015-Jun-29
CDEC meeting	2015-Aug-19	2015-Aug-19	
CDEC recommendation & redacted CDR review report(s) sent to drug plans and manufacturer	2015-Aug-28	2015-Aug-28	
Embargo period[4] and validation of redacted CDR review report(s) Manufacturer may make a request for reconsideration and drug plans may make a request for clarification of the recommendation	2015-Sep-14	2015-Sep-14	
Final recommendation issued to drug plans and manufacturer (No request for clarification is made AND no request for reconsideration is made or request for reconsideration is resolved)	2015-Sep-21	2015-Sep-21	- Notice of final recommendation issued
CDEC Final Recommendation posted [5]		2015-Sep-23	
Final CDR review report(s) and patient input posted [5]		2015-Oct-23	
OR			
Clarification and final recommendation issued to drug plans and manufacturer (Clarification requested, no request for reconsideration made)			
CDEC Final Recommendation posted [5]			
Final CDR review report(s) and patient input posted [5]			
OR			
Placed on CDEC agenda for reconsideration (At manufacturer's request)			
CDEC Final Recommendation issued to drug plans and manufacturer			
CDEC Final Recommendation posted [5]			
Final CDR review report(s) and patient input posted [5]			

[1] Refer to Appendix 1 of the Procedure for the CADTH Common Drug Reviewin the Common Drug Review section of www.cadth.ca for details regarding fee schedules.

[2] 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 process and targeted time frames for key milestones,.

[3] The call for patient group input is posted 20 business days inadvance of the manufacturer's anticipated date of filing the application. Patient groups have a total of 35 business days for prepating and submitting patient input.

[4] The embargoed CDEC recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of *CDEC Final Recommendation* .

[5] The timing for posting the *CDEC Final Recommendation* and CDR review report(s) depends on several factors including the need for consultation with the manufacturer regarding redaction issues.

This submission status report typically reflects status as of each Thursday at noon EasternTime.