Common Drug Review *

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product:	Prolia
Generic Name:	denosumab
Manufacturer:	Amgen Canada Inc
Indication:	Osteoporosis, postmenopausal
Submission Type:	Initial
Date Submission Received:	2010-Aug-26
Date NOC Issued:	2010-Aug-06
Targeted CEDAC Meeting:	2011-Jan-19
Priority Review Granted:	Not Requested

	Phase	Target Time (Business Days)	Target Date **	Actual CDR Date	Comments
1	Submission deemed complete	5	2010-Sep-02	2010-Sep-02	Submission deemed complete.
2	Patient group input submission received		2010-Sep-17	2010-Sep-17	Patient group input received.
3	CADTH Reviewers' Reports sent to Manufacturer	45	2010-Nov-18	2010-Nov-29	Reviewer's Reports sent to manufacturer on 2010-Nov-29.
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2010-Nov-29	2010-Dec-08	New date for manufacturers comments 2010-Dec-08. Manufacturer comments received on 2010-Dec-08
5	CEDAC Meeting		2011-Jan-19	2011-Jan-19	
6	CEDAC Recommendation *** Sent to Drug Plans, ACP and Manufacturer	5 to 7	2011-Jan-26	2011-Jan-26	
7	Embargo Period **** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2011-Feb-09	2011-Feb-18	2011-Feb-07 - Request for extension to embargo period received. 2011-Feb-10 - Request for extension to embargo period granted. 2011-Feb-18 - New embargo period end date. 2011-Feb-09 - Request for clarification received. 2011-Feb-18 - Request for Reconsideration received. 2011-Feb-28 - Request for Reconsideration granted.
8 (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				
8 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
8 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2011-Mar-23	2011-Mar-23	
9	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2011-Mar-30	2011-Mar-30	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 Formulary 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 Procedure for Common Drug Review, section 8.3.3a, states "…the CEDAC recommendation will be sent to the Manufacturer, ACP and to the drug plans within five (5) to seven (7) business days following the CEDAC meeting…". The original target date is based on five (5) business days.

******** The Recommendation is held in confidence and not acted upon until after CADTH has issued the notice of Final Recommendation.

This submission status report reflects updates as of Thursday noon.