Common Drug Review *

Submission Status

Product: Levemir

Generic Name: insulin detemir

Manufacturer: Novo Nordisk Canada Inc.

Submission Type: Resubmission #2

Date Submission Received: 2009-Mar-10 **Date NOC Issued:** 2005-Sep-29

Targeted CEDAC Meeting: 2009-Sep-16 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission deemed complete	5	2009-Mar-10	2009-Mar-10	ACP Requested Review
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-Jun-09	2009-Jun-02	Additional information requested March 25, 2009. Additional information received April 2, 2009. Additional information requested April 6, 2009. Additional information received April 6, 2009. Additional information received April 9, 2009. Additional information requested May 5, 2009. Additional information received May 11, 2009.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2009-Jun-18	2009-Jun-12	Due date for manufacturer's comments June 11, 2009.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2009-Jun-29	2009-Jun-23	Due date for reviewers' reply June 23, 2009.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2009-Jun-30	2009-Jun-30	
6	CEDAC Meeting		2009-Jul-15	2009-Jul-15	CEDAC meeting date changed from September 16, 2009 to July 15, 2009. Additional information requested July 8, 2009. Additional information received July 13, 2009.
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2009-Jul-22	2009-Jul-22	
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	2009-Aug-06	2009-Aug-20	Request for extension of Embargo period received on July 31, 2009. Extension granted, new end date for Embargo period is August 20, 2009.
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	2009-Aug-20	2009-Aug-20	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.