Common Drug Review *

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product: Kuvan

Generic Name: sapropterin dihydrochloride

Manufacturer: BioMarin Pharmaceutical (Canada) Inc.

Indication: Phenylketonuria (PKU)

Submission Type: Initial

Date Submission Received: 2010-Jul-08 **Date NOC Issued:** 2010-Apr-30

Targeted CEDAC Meeting: 2010-Nov-17 **Priority Review Granted:** Granted

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission deemed complete	5	2010-Jul-15	2010-Jul-15	Submission deemed complete. Priority review granted on 2010-Aug-26
2	Patient group input submission received		2010-Jul-29	2010-Jul-29	Patient group input received.
3	CADTH Reviewers' Reports sent to Manufacturer	45	2010-Sep-30	2010-Oct-01	Reviewer's Reports Sent on 2010-Oct-01.
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2010-Oct-12	2010-Oct-13	New due date for Manufacturer's Comments 2010-Oct-13. Manufacturer's Comments received on 2010-Oct-13.
5	CEDAC Meeting		2010-Nov-17	2010-Nov-17	
6	CEDAC Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2010-Nov-24	2010-Nov-24	
7	Embargo Period*** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2010-Dec-08	2010-Dec-08	Manufacturer requested reconsideration on 2010-Dec-08 Reconsideration granted on 2010-Dec-14
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-Jan-19	2011-Jan-19	
9	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2011-Jan-26	2011-Jan-26	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 Recommendation is held in confidence and not acted upon until after CADTH has issued the notice of Final Recommendation.

Reflects updates as of Thursday noon.