Common Drug Review [1]

Submission Status

Product: TBC

Generic Name: darunavir/cobicistat

Manufacturer: Janssen Inc.

Indication: HIV infection

Submission Type: Pre-NOC - Initial

Date Submission Received: 2014-Apr-04 **Date NOC Issued:**

Orginal Targeted CDEC Meeting:

Phase	Target Time (Business Days)	Target Date [2]	Actual CDR Date	Comments
Submission deemed complete	5	2014-Apr-11		- Submission voluntarily withdrawn by the manufacturer on 2014-Apr-08
Patient group input submission received [3]				
Patient group input summary comments received	5			
CDR review reports sent to manufacturer[4]	45			
Comments from manufacturer on CDR review reports received by CADTH	7			
Redaction response from manufacturer on CDR review reports received by CADTH	3			
CDEC meeting				
CDEC recommendation & redacted CDR review reports sent to drug plans and manufacturer	5 to 7			
Embargo period and validation of redacted CDR review reports [5] Manufacturers may make a request for reconsideration and drug plans may make a request for clarification of the recommendation	10			
Final recommendation sent to drug plans and manufacturer (No requests for clarification are made AND no request for reconsideration is made or request for reconsideration is resolved)	5			
CDEC final recommendation posted [6]	Variable			
Final CDR review reports and patient input posted [7]	Variable			
OR				
Clarification and final recommendation sent to drug plans and manufacturer (Clarification requested, no request for reconsideration made)	5			
CDEC final recommendation posted [6]	Variable			
Final CDR review reports and patient input posted [7]	Variable			
OR				
Placed on CDEC agenda for reconsideration (At manufacturer's request)	25 Depends on Meeting Dates			
Final recommendation sent to drug plans and manufacturer	5			
CDEC final recommendation posted [6]	Variable			
Final CDR review reports and patient input posted [7]	Variable			

[1] Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.cadth.ca for more details.

[2] The target dates for this report are based on the CDEC meeting schedule, which is posted on www.cadth.ca.

[3] The deadline for patient group input is 15 business days after CADTH receives the submission or up to 35 business days if advance notice (20 business days maximum) of a submission is received from the manufacturer.

[4] Target time is calculated, based on the date the reviewers receive copies of the manufacturer's submission. Target time does not include the time allocated for receipt of manufacturer's additional electronic copies (5 business days) and time allocated for distribution of electronic copies to reviewers (3 business days).

[5] The Recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of final recommendation.

[6] The target date for posting the CDEC final recommendation depends on several factors including the need for consultation with the manufacturer regarding redaction issues.

[7] The timing of the posting of CDR review reports depends on several factors, including the need for consultation with the manufacturer in case of disagreement with regard to redactions made.

This submission status report reflects status as of Thursday noon.