

Common Drug Review

Project Status Report

Brand Name:	Brilinta
Non-proprietary Name:	ticagrelor

Applicant: AstraZeneca Canada Inc.

Indication(s): Prevention of atherothrombotic events with history of myocardial

Project Type: Submission

Date Received: 2016-Feb-18

Date NOC Issued¹: 2016-May-30

Application Fee Schedule²: Schedule B

Key Milestone ³	Target Date	Actual Date	Comments
Application accepted for review	2016-Mar-03	2016-Mar-03	- Review has been initiated 2016-Mar-04
Patient group input received ⁴	2016-Mar-07	2016-Mar-07	- Call for patient input posted on 2016-Jan-15 - Patient group input deadline: 2016-Mar-07 - Patient input submission received
Patient group comments on input summary received	2016-Mar-21	2016-Mar-21	Patient input summary sent for review on 2016-Mar-14 Patient input summary feedback deadline: 2016-Mar-21 Patient input summary feedback received
Draft CDR review report(s) sent to applicant	2016-May-18	2016-Jun-02	- New target date: 2016-May-31 - New target date: 2016-Jun-02
Comments from applicant on draft CDR review report(s) received by CADTH	2016-May-30	2016-Jun-13	- New target date: 2016-Jun-09 - New target date: 2016-Jun-13
Redaction requests from applicant on draft CDR review report(s) received by CADTH	2016-Jun-06	2016-Jun-20	- New target date: 2016-Jun-16 - New target date: 2016-Jun-20
CDR review team's comments on draft CDR review report(s) sent to applicant	2016-Jul-08	2016-Jul-08	
Canadian Drug Expert Committee (CDEC) meeting	2016-Jul-20	2016-Jul-20	
CDEC recommendation & redacted CDR review report(s) sent to drug plans and applicant	2016-Aug-02 to 2016-Aug-04	2016-Aug-04	
Embargo period⁵ and validation of redacted CDR review report(s)	2016-Aug-18	2016-Aug-18	
CDEC Final Recommendation issued to drug plans and applicant if: - no request for clarification is made AND - no request for reconsideration is made AND - no request for resubmission based on a reduced price during embargo period is made	2016-Aug-25	2016-Aug-25	
CDEC Final Recommendation posted ⁶	2016-Aug-26	2016-Aug-26	
Final CDR review report(s) ⁶ and patient input posted		2018-Oct-10	

¹CDR applications for submissions can be filed on a pre-NOC basis. When such a submission is received, this field will indicate 'pending' until the NOC (or NOC/c) is issued by Health Canada.

This CDR Project Status Report is posted every other week, reflecting status as of the end of day Wednesday (4:00 pm ET) of that week.

2018-Oct-10 SR0474-000

² Refer to Appendix 1 of the *Procedure for the CADTH Common Drug Review* (https://www.cadth.ca/media/cdr/process/CDR_Procedure.pdf) for details regarding CDR application fee schedules.

³ Please refer to the *Procedure for the CADTH Common Drug Review* (https://www.cadth.ca/media/cdr/process/CDR_Procedure.pdf) for complete details regarding the CDR process and targeted time frames for key milestones.

⁴The call for patient group input is posted 20 business days inadvance of the applicant's anticipated date of filing the CDR application. Patient groups have a total of 35 business days for preparing and submitting patient input.

⁵ 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*. The applicant may make a request for reconsideration or resubmission based on reduced price during the embargo period, and the drug plans may make a request for clarification, as applicable (see section 8 of the *Procedure for the CADTH Common Drug Review*).

⁶ The timing for posting the CDEC Final Recommendation and CDR review report(s) depends on several factors including the need for consultation with the applicant regarding redaction issues.