CADTH

# Common Drug Review

## Project Status Report

**Brand Name:** Xgeva

**Non-proprietary Name:** denosumab

**Applicant:** CDR-participating drug plans

**Indication(s):** Prevention of skeletal-related events due to bone metastases from breast cancer

**Project Type:** Submission

**Date Received:** 2015-Jul-31

**Date NOC Issued[1]:** 2011-May-10

**Application Fee Schedule[2]:** N/A

| Key Milestone[3] | Target Date | Actual Date | Comments |
|---|---|---|---|
| Application accepted for review | 2015-Aug-17 | 2015-Aug-17 | - Review has been initiated 2015-Aug-18 |
| Patient group input received[4] | 2015-Jun-16 | 2015-Jun-16 | - Call for patient input posted on 2015-Apr-27<br>- Patient group input deadline: 2015-Jun-16<br>- Patient input submission received |
| Patient group comments on input summary received | 2015-Sep-08 | 2015-Sep-08 | - Patient input summary sent for review on 2015-Aug-31<br>- Patient input summary feedback deadline: 2015-Sep-08<br>- Patient input summary feedback received |
| Draft CDR review report(s) sent to applicant | 2015-Nov-02 | 2015-Nov-10 | - New target date: 2015-Nov-10 |
| Comments from applicant on draft CDR review report(s) received by CADTH | 2015-Nov-11 | 2015-Nov-19 | - New target date: 2015-Nov-19 |
| Redaction requests from applicant on draft CDR review report(s) received by CADTH | 2015-Nov-18 | 2015-Nov-26 | - New target date: 2015-Nov-26 |
| Canadian Drug Expert Committee (CDEC) meeting | 2016-Jan-20 | 2016-Jan-20 | |
| CDEC recommendation & redacted CDR review report(s) sent to drug plans and applicant | 2016-Jan-27 to 2016-Jan-29 | 2016-Jan-27 | |
| Embargo period[5] and validation of redacted CDR review report(s) | 2016-Feb-10 | 2016-Feb-10 | |
| *CDEC Final Recommendation* issued to drug plans and applicant if:<br>- no request for clarification is made AND<br>- no request for reconsideration is made AND<br>- no request for resubmission based on a reduced price during embargo period is made | 2016-Feb-18 | 2016-Feb-25 | - New target date: 2016-Feb-25<br>- Notice of final recommendation issued |
| *CDEC Final Recommendation* posted[6] | 2016-Mar-01 | 2016-Mar-01 | |
| Final CDR review report(s)[6] and patient input posted | | 2018-Sep-07 | |

[1] CDR 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.

[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.

[4] The 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.

**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.**