# Common Drug Review *

**Submission Status**

**Product:** Forteo  
**Generic Name:** teriparatide (rDNA origin) injection  
**Manufacturer:** Eli Lilly Canada Inc.  
**Submission Type:** New Indication  

<table>
<thead>
<tr>
<th>Date Submission Received:</th>
<th>2008-Dec-18</th>
<th>Date NOC Issued:</th>
<th>2008-Jul-07</th>
<th>Targeted CEDAC Meeting:</th>
<th>2009-May-20</th>
<th>Priority Review Granted:</th>
<th>Not Requested</th>
</tr>
</thead>
</table>

## Phase 

<table>
<thead>
<tr>
<th>Phase</th>
<th>Target Time (Business Days)</th>
<th>Target Date**</th>
<th>Actual CDR Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Submission Assessment</td>
<td>5</td>
<td>2009-Jan-02</td>
<td>Submission deemed complete.</td>
</tr>
</tbody>
</table>

### Submission deemed complete

#### Additional information requested January 20, 2009.

#### Additional information received January 23, 2009.

#### Additional information received January 28, 2009.

#### Additional information requested January 30, 2009.

#### Additional information requested February 4, 2009.

#### Additional information requested February 9, 2009.

#### Additional information received February 12, 2009.

#### Additional information received February 17, 2009.

#### Additional information received February 19, 2009.

#### Additional information requested February 20, 2009.

#### Additional information received March 5, 2009.

### 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

**Target Date:** 2009-Mar-19  
**Actual CDR Date:** 2009-Mar-19

### 3 Comments from Manufacturer on Reviewers' Reports Received by CDR

**Target Date:** 2009-Mar-30  
**Actual CDR Date:** 2009-Mar-30

### 4 Reviewers' Reply to Manufacturer's Comments Completed

**Target Date:** 2009-Apr-08  
**Actual CDR Date:** 2009-Apr-08

### 5 CEDAC Brief Completed and Sent to CEDAC Members

**Target Date:** 2009-May-05  
**Actual CDR Date:** 2009-May-05

### 6 CEDAC Meeting

**Target Date:** 2009-May-20  
**Actual CDR Date:** 2009-May-20

### 7 CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer

**Target Date:** 2009-May-27  
**Actual CDR Date:** 2009-May-27

### 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

**Target Date:** 2009-Jun-10  
**Actual CDR Date:** 2009-Jun-10

### 9 Final Recommendation sent to Drug Plans, ACP, and Manufacturer

(No Requests for Clarification are made AND no Request for Reconsideration is made)

**Target Date:** 2009-Jul-22  
**Actual CDR Date:** 2009-Jul-22

### 9 (a) Final Recommendation sent to Drug Plans, ACP, and Manufacturer

(No Requests for Clarification are made AND no Request for Reconsideration is Resolved)

**Target Date:** 2009-Jul-22  
**Actual CDR Date:** 2009-Jul-22

### 9 (b) Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer

(Clarification Requested, no Request for Reconsideration made)

**Target Date:** 2009-Jul-22  
**Actual CDR Date:** 2009-Jul-22

### 9 (c) Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)

**Target Date:** 2009-Jul-15  
**Actual CDR Date:** 2009-Jul-15

### 10 Final Recommendation sent to Drug Plans, ACP, and Manufacturer

**Target Date:** 2009-Jul-22  
**Actual CDR Date:** 2009-Jul-22

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* 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.

July 24, 2009