CANADIAN COORDINATING OFFICE FOR HEALTH TECHNOLOGY ASSESSMENT

OFFICE CANADIEN DE COORDINATION DE L'ÉVALUATION DES TECHNOLOGIES DE LA SANTÉ

CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

TERIPARATIDE
(Forteo™ --Eli Lilly Canada Inc.)

Description
Teriparatide is a recombinant human parathyroid hormone (1-34) that has been approved by Health Canada for the following indications:

- The treatment of postmenopausal women with severe osteoporosis who are at high risk of fracture or who have failed or are intolerant to previous osteoporosis therapy.
- To increase bone mass in men with primary or hypogonadal severe osteoporosis who have failed or are intolerant to previous osteoporosis therapy.

Recommendation
The Canadian Expert Drug Advisory Committee (CEDAC) recommends that teriparatide not be listed.

Reasons for recommendation

1. One randomized trial compared teriparatide with placebo in postmenopausal women. It showed a decrease in vertebral and non-vertebral (but not hip) fracture rates in teriparatide-treated patients. However, an exclusion criterion for the trial was the use of drugs that alter bone metabolism within the previous 2 to 24 months.

2. CEDAC also considered the results of an unpublished randomized trial, submitted by the manufacturer. The manufacturer has requested that these results remain confidential, pending publication and pursuant to the Confidentiality Guidelines of the Procedures for CDR.

3. No randomized clinical trials, using the Health Canada approved dose, provided evidence that teriparatide decreases fracture rates in men.

4. No evidence is available to support teriparatide's efficacy for patients who continue to fracture due to severe osteoporosis despite adequate anti-resorptive treatment. Given that the cost of teriparatide is approximately 15 to 20 times the cost of anti-resorptive therapy, CEDAC feels that appropriate randomized trials need to be conducted to compare teriparatide to continuation of anti-resorptive therapy in such patients.

5. No evidence was provided to demonstrate that teriparatide is cost-effective in any patient group. Teriparatide costs $9,700 per patient per year and $14,500 per patient per 18 month course (the maximum length of time for which teriparatide treatment is allowed).

6. In rats, teriparatide caused an increase in the incidence of osteosarcoma. This safety concern led the manufacturer to halt some clinical trials earlier than originally planned.

Of Note

1. Two randomized controlled trials showed no impact of teriparatide upon health-related quality of life.

2. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.