

Exemestane (for early breast cancer)

Product:

EXEMESTANE (Aromasin®), 25 mg tablet

Class of drugs:

Aromatase inhibitor; anti-tumour agent

Indication:

Treatment of early breast cancer

Manufacturer:

Pfizer Canada Inc.

CED Recommendation

The CED recommended that exemestane (Aromasin) be listed on the Ontario Drug Benefit (ODB) Formulary as a Limited Use benefit, on the basis that sequential treatment with exemestane (Aromasin) after two to three years of tamoxifen therapy has been demonstrated to provide clinical benefit and value for money.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided to fund exemestane (Aromasin) as a Limited Use benefit on the ODB Formulary.

Status

Funding available through the Ontario Public Drug Programs as a Limited Use benefit.

Highlights of Recommendation:

- ◆ Exemestane (Aromasin) is an oral drug used for the treatment of breast cancer in post-menopausal women.
- ◆ A large clinical study reported that women who switched to exemestane (Aromasin) after 2 to 3 years of tamoxifen (a standard hormone therapy for breast cancer) had a reduced risk of breast cancer recurrence compared to women who continued to receive tamoxifen for the full 5 years.
- ◆ There were no significant differences in rates of common side effects (e.g. hot flashes, weakness, insomnia, sweating, headache) between women who stayed on tamoxifen for 5 years and women who switched to exemestane (Aromasin) after 2 to 3 years of tamoxifen.
- ◆ The cost of exemestane (Aromasin) is approximately \$180 per month. The cost of tamoxifen is \$40-50 per month. Sequential exemestane (Aromasin) treatment after 2 to 3 years of tamoxifen was demonstrated to provide value for money.
- ◆ **Overall, the Committee indicated that sequential treatment with exemestane (Aromasin) has been demonstrated to provide clinical benefit at a reasonable cost.**

Background:

Breast cancer is the most common cancer diagnosed among Canadian women.

Adjuvant therapy is treatment given after surgery, chemotherapy or radiation to prevent or delay the growth and spread of any remaining cancer cells. In most cases, breast cancer relies on estrogen to feed the growth of tumours. Tamoxifen is a standard adjuvant treatment for estrogen receptor-positive breast cancer.

Exemestane (Aromasin) is approved for the sequential treatment of postmenopausal women with estrogen receptor-positive early breast cancer who have received 2 to 3 years of initial adjuvant tamoxifen therapy. Exemestane (Aromasin) works by interfering with the body's ability to make estrogen.

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Detailed Discussion:

- ◆ A randomized controlled trial by Coombes et al (*NEJM* 2004;350(11): 1081-92) enrolled 4742 postmenopausal women with early-stage breast cancer who had completed 2 to 3 years of adjuvant tamoxifen therapy. The study reported that, at three years, the distant disease free survival for patients who switched to exemestane (Aromasin) was 91.5%, compared to 86.8% for patients who remained on tamoxifen for the full 5 years (absolute difference = 4.7%). Overall survival was not different at the time of analysis. However, the Committee noted that distant disease free survival is a good predictor of overall survival.
- ◆ The clinical trial reported no significant differences in rates of hot flashes, asthenia, insomnia, sweating and headache between the two treatment groups.
- ◆ The cost of exemestane (Aromasin) is approximately \$180 per month; the cost of tamoxifen is approximately \$40-50 per month. A pharmacoeconomic analysis demonstrated that sequential therapy with exemestane (Aromasin) provided reasonable value for money.
- ◆ Overall, the Committee agreed that the reported improvement in disease free survival with sequential exemestane (Aromasin) was clinically significant and treatment was cost-effective.
- ◆ The Committee recommended that exemestane (Aromasin) be listed as a Limited Use benefit with the following criteria:
 - For the sequential treatment of postmenopausal women with estrogen receptor-positive early breast cancer who have received 2 to 3 years of initial adjuvant tamoxifen therapy.
 - Authorization Period: Treatment period required to complete a total of 5 years of adjuvant therapy.
- ◆ The CED worked jointly with a subcommittee involving cancer experts to review this cancer drug, as is done for all other cancer drug treatments.

Cancer Care Ontario (CCO) Information:

Information on CCO's chemotherapy regimens for breast cancer is available at:
http://www.cancercare.on.ca/index_chemoRegimensbyDisease.htm

Cancer Care Ontario's Program in Evidence-Based Care Guideline for breast cancer is available at:
http://www.cancercare.on.ca/index_breastCancerGuidelines.htm



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