

Gemcitabine (for metastatic breast cancer)

Product:

GEMCITABINE (Gemzar®)

Class of drugs:

Antineoplastic agent

Indication:

Treatment of metastatic breast cancer

Manufacturer:

Eli Lilly Canada Inc.

CED Recommendation

The CED recommended not to fund gemcitabine (Gemzar) through Cancer Care Ontario's New Drug Funding Program (NDFP) for the treatment of breast cancer, on the basis that efficacy and value-for-money could not be established with the appropriate drug comparator.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer has decided not to list gemcitabine (Gemzar) for the treatment of metastatic breast cancer.

Status

No funding through Cancer Care Ontario's New Drug Funding Program.

Highlights of Recommendation:

- ◆ Gemcitabine (Gemzar) is used to treat metastatic (advanced) breast cancer.
- ◆ Although a study showed that patients who received gemcitabine (Gemzar) plus paclitaxel survived for three months longer than patients who received paclitaxel alone, the Committee indicated the study results are not relevant to Canadian patients because docetaxel—not paclitaxel—is used as the standard therapy used in Canada.
- ◆ The Committee is concerned that gemcitabine (Gemzar) will be used alone to treat metastatic breast cancer. This indication has not been studied or proven effective.
- ◆ The cost of gemcitabine (Gemzar) therapy in combination with either docetaxel or paclitaxel to treat metastatic breast cancer ranges from \$1,900 to \$2,300 per cycle.
- ◆ **Overall, the Committee noted that because an inappropriate comparison drug was used in the analyses the manufacturer provided, the comparative effectiveness and value-for-money cannot be determined.** As such, the Committee recommended that gemcitabine (Gemzar) not be funded through Cancer Care Ontario's New Drug Funding Program (NDFP) for the treatment of patients with metastatic breast cancer.

Background:

Breast cancer is the most common cancer diagnosed among Canadian women. Despite slight declines in death rates over the past decade for women with breast cancer, one in nine Canadian women will develop breast cancer in their lifetime. Metastatic breast cancer is the most advanced stage of breast cancer. The term "metastatic" describes a cancer that has spread to distant organs from the original tumor site.

Most women in Ontario who develop advanced breast cancer will be treated with either hormonal therapy or single agent chemotherapy. Hormonal therapy is a cancer treatment that blocks the actions of hormones and stops cancer cells from growing. This therapy works if the disease is "hormone-sensitive". Chemotherapy is a cancer treatment that uses drugs to stop the growth of cancer cells.

Women who have not yet been treated with anthracycline (e.g. doxorubicin, epirubicin) chemotherapy are usually offered doxorubicin.

In patients who have previously received anthracyclines, they are usually treated with a taxane (docetaxel or paclitaxel). Docetaxel is the standard treatment in Canada. A recent study has proven that docetaxel is more effective than paclitaxel in treating metastatic breast cancer.

For women who have failed anthracycline therapy and whose disease has progressed rapidly, a quick response to treatment is important in order to obtain control of the disease. Combination chemotherapy (chemotherapy involving more than one cancer medication) may be considered as first-line therapy in these patients.

The side effects of combination chemotherapy are usually greater than that with single-agent treatments. As such, combination therapy should be reserved for women in relatively good health.

The majority of patients in Ontario with metastatic breast cancer are likely to continue to be treated with single agents one after the other, rather than combination therapy.

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Detailed Discussion:

- ◆ The manufacturer, Eli Lilly Canada Inc., asked the Ministry of Health and Long-Term Care to consider listing gemcitabine (Gemzar) on the New Drug Funding Program (NDFP) Formulary.
- ◆ The Committee acknowledged that a pivotal randomized clinical trial reported an approximate three-month overall survival improvement in the gemcitabine/paclitaxel arm, versus paclitaxel alone in metastatic breast cancer patients who have received prior anthracycline therapy. However, paclitaxel is not the standard of care in these patients. The Committee noted that the more relevant comparator in the Canadian context is docetaxel or combination docetaxel/capecitabine.
- ◆ Docetaxel is more widely used in Canada; a recent Phase III trial demonstrated better efficacy with docetaxel monotherapy in comparison to paclitaxel monotherapy. (Jones SE et al., Randomized phase III study of docetaxel compared with paclitaxel in metastatic breast cancer. *J of Clin Onc*, 2005. 23(24):p.5542-51.)
- ◆ The Committee is concerned that gemcitabine (Gemzar) may be used as on its own, which current evidence does not support.
- ◆ The most common side effects of gemcitabine (Gemzar) are increased liver enzyme levels (68%), nausea and vomiting (64%), fever (37%) and rash (25%).
- ◆ The Committee noted that pharmacoeconomic analysis provided was well developed; however, not relevant for the Canadian context as the most appropriate comparator was not used.
- ◆ Overall, the Committee indicated that the clinical study did not use the most appropriate comparator. Docetaxel, rather than paclitaxel, would have been more appropriate in the Canadian context. Similarly, the economic analysis to evaluate cost-effectiveness was not helpful because it used the same comparator.

Cancer Care Ontario (CCO) Information:

Information on CCO chemotherapy regimens for Breast Cancer is available at:

http://www.cancercare.on.ca/index_chemoRegimensbyDisease.htm

The Breast Disease Site Group (DSG) Program in Evidence-based Care (PEBC) guideline for gemcitabine (Gemzar) in the treatment of metastatic breast cancer is available at:

http://www.cancercare.on.ca/index_breastCancerGuidelines.htm



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