

Capecitabine (for gastric cancer)

Product:

CAPECITABINE (Xeloda®), 150 mg, 500 mg tablet

Class of drugs:

Antineoplastic agent

Indication:

Treatment of gastric cancer

Manufacturer:

Hoffman-La Roche Limited

CED Recommendation

The CED recommended that capecitabine (Xeloda) for the treatment of gastric cancer not be funded on the basis that efficacy and value for money are unconfirmed.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to fund capecitabine (Xeloda) for the treatment of gastric cancer.

Status

No funding through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Capecitabine (Xeloda) is an oral chemotherapy used to treat various types of cancer. This particular review evaluated the use of capecitabine (Xeloda) for the treatment of advanced gastric (stomach) cancer.
- ◆ The use of capecitabine (Xeloda) for the treatment of gastric cancer is not an approved indication in Canada.
- ◆ Capecitabine (Xeloda) is converted in the body to its active form, 5-fluorouracil (5-FU). 5-FU is available as an intravenous drug. Some doctors may wish to use capecitabine (Xeloda) as a substitute for intravenous 5-FU due to the convenience of an oral medication.
- ◆ The Committee noted that patients with gastric cancer may have problems swallowing oral medications; hence, capecitabine (Xeloda) may not be suitable for some patients.
- ◆ Preliminary evidence suggests that capecitabine (Xeloda) may be as effective as intravenous 5-FU in the treatment of advanced gastric cancer. However, the final results from a key study are required to confirm the efficacy of capecitabine (Xeloda) in this indication.
- ◆ Based solely on drug costs, capecitabine (Xeloda) is significantly more expensive than intravenous 5-FU. A comprehensive economic comparison between the two drugs is not available; therefore, it is unknown whether capecitabine (Xeloda) provides value of money when other costs associated with drug administration and monitoring are taken into consideration.
- ◆ **Overall, the Committee indicated that capecitabine (Xeloda) for gastric cancer should not be funded until its efficacy and value for money have been confirmed.**

Background:

Gastric cancer is the second leading cause of death from cancer worldwide. While it is more common in Asia, the incidence of gastric cancer in Ontario is low.

Surgery provides the only potential cure. Chemotherapy, radiation and best supportive care are the options available for treating advanced gastric cancer that cannot be surgically removed.

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Detailed Discussion:

- ◆ The Committee considered the funding of capecitabine (Xeloda) as part of a combination chemotherapy regimen for the treatment of advanced gastric cancer.
 - ◆ The Committee reviewed two studies evaluating the use of capecitabine (Xeloda) in gastric cancer. Both were non-inferiority studies (i.e. clinical trials designed to show that a new treatment is not clinically worse than the comparator).
 - ◆ One study (*Kang et al. 2006 ASCO Annual Meeting Proceedings. J Clin Oncol 2006; 24(18S):LBA4018*) compared capecitabine (Xeloda)/cisplatin versus 5-FU/cisplatin in patients with previously untreated, advanced gastric cancer. Interim data reported that the capecitabine/cisplatin combination was non-inferior to the combination of 5-FU/cisplatin in terms of progression-free survival. Final results of this trial have not been published.
 - ◆ A second study, the REAL2 trial (*Cunningham et al. 2006 ASCO Annual Meeting Proceedings. J Clin Oncol 2006; 24(18S):LBA4017*), compared four combination chemotherapy regimens in patients with gastric and esophageal cancers. Preliminary results suggested that capecitabine (Xeloda) was non-inferior to intravenous 5-FU in terms of response rates and toxicity. The efficacy results could not be separated for gastric cancer versus esophageal cancer.
 - ◆ Common side effects with capecitabine (Xeloda) include hand-foot syndrome, stomatitis, diarrhea, and hyperbilirubinemia.
 - ◆ The drug cost for capecitabine (Xeloda) is significantly more than that for intravenous 5-FU. The Committee recognized that there may be cost-savings associated with an oral treatment. However, relevant pharmacoeconomic data, such as a comparison between capecitabine (Xeloda) and 5-FU that incorporates administrative costs, were not available to fully assess the cost-effectiveness of capecitabine (Xeloda) in this setting.
- ◆ Overall, the Committee noted that the current evidence for the use of capecitabine (Xeloda) in advanced gastric cancer is based on preliminary data. Moreover, pertinent pharmacoeconomic information is unavailable to determine value for money.
 - ◆ 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 Information:

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

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) has not reviewed the use of capecitabine for the treatment of gastric cancer.



Ministry of
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