

Capecitabine (as a component of the CAPOX regimen for metastatic colorectal cancer)

Product:

CAPECITABINE (Xeloda®)
150mg, 500mg tablets

Class of drugs:

Antineoplastic agent

Indication:

Treatment of metastatic colorectal cancer

Manufacturer:

Hoffmann-La Roche Ltd.

CED Recommendation

The CED recommended that capecitabine (Xeloda) be funded as a component of the CAPOX regimen for the first- and second-line treatment of metastatic colorectal cancer. The CED noted that the CAPOX regimen is similar in efficacy and safety to the FOLFOX regimen also used in this setting. Although the CAPOX regimen is more expensive, some of the additional drug cost is offset by efficiency gains in other parts of the healthcare system, as demonstrated by the cost-effectiveness analysis.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided to fund capecitabine (Xeloda) as a component of the CAPOX regimen for the first- and second-line treatment of metastatic colorectal cancer.

Status

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

Highlights of Recommendation:

- ◆ Capecitabine (Xeloda) is an oral anti-cancer drug used to treat various types of cancer. This particular review considered the funding of capecitabine (Xeloda) as a component of the CAPOX regimen in the treatment of metastatic colorectal cancer.
- ◆ The CAPOX regimen is made up of a combination of anti-cancer drugs that include capecitabine and oxaliplatin. The most relevant comparator for the CAPOX regimen is the FOLFOX regimen, which is a combination of 5-fluorouracil, oxaliplatin and leucovorin. Capecitabine (Xeloda) is preferentially converted to its active form, 5-fluorouracil, in certain types of cancer cells, including colorectal cancer. 5-fluorouracil is available as an intravenous drug, whereas capecitabine (Xeloda) is taken orally. The FOLFOX regimen is currently funded for the first- and second-line treatment of metastatic colorectal cancer.
- ◆ Evidence from clinical studies supports that the CAPOX regimen is similar in efficacy and safety as the FOLFOX regimen.
- ◆ Based solely on drug costs, the CAPOX regimen costs significantly more than FOLFOX regimen. However, because capecitabine (Xeloda) is taken orally and does not require intravenous administration, hospital/clinic resources that would otherwise be utilized could be freed up and reallocated for other intravenous therapies.
- ◆ **Overall, the Committee noted that the CAPOX regimen is similar in efficacy and safety as the FOLFOX regimen in the treatment of metastatic colorectal cancer. Although the CAPOX regimen is more expensive, some of the added drug cost may be offset by efficiency gains in other parts of the healthcare system.**

Background:

Colorectal cancer refers to cancer of the colon (large bowel) and cancer of the rectum. Metastatic colorectal cancer is colorectal cancer that has spread to other parts of the body, such as the liver and lung.

Treatment of metastatic colorectal cancer usually consists of combination chemotherapy. For patients unable to tolerate combination therapy, single drug treatments are also available.

One of the standard combination regimens for metastatic colorectal cancer is the FOLFOX regimen. The FOLFOX regimen is currently funded through Cancer Care Ontario's New Drug Funding Program for the first- and second-line treatment of metastatic colorectal cancer. *(The bulletin outlining the funding decision for the FOLFOX regimen can be found at: http://www.health.gov.on.ca/english/providers/program/drugs/ced/pdf/oxaliplatin_metastatic_colorectal.pdf)*

continued...

Detailed Discussion:

- ◆ The focus of the Committee's review was a large randomized controlled study comparing the CAPOX regimen to the FOLFOX regimen in over 2,000 patients with metastatic colorectal cancer. The study found that the CAPOX regimen is comparable to the FOLFOX regimen in terms of overall survival and progression-free survival.
- ◆ There were four smaller studies in which the CAPOX regimen was compared against the FOLFOX regimen or other regimens similar to FOLFOX. Data from these studies supported that the CAPOX and FOLFOX regimens are similar in efficacy.
- ◆ No major difference in safety between the CAPOX and FOLFOX regimens was noted in the five studies. Compared with the FOLFOX regimen, the CAPOX regimen was associated with less neuropathy (pain, numbness, tingling, and muscle weakness in various parts of the body), neutropenia (low white blood cell count), anemia, hair loss and mouth sores, but had a higher incidence of diarrhea and hand-foot syndrome (a skin reaction that appears on the palms of the hands and/or the soles of the feet).
- ◆ Based on drug acquisition cost alone, the CAPOX regimen is much more expensive than the FOLFOX regimen. Capecitabine (Xeloda) costs approximately \$700 per cycle, while 5-fluorouracil costs less than \$20. Because capecitabine (Xeloda) is taken orally in an outpatient setting, some of the additional drug cost would be partially offset by lower administrative costs. In addition, scarce hospital/clinic resources could be reallocated to other intravenous therapies.
- ◆ Given the above considerations, the Committee recommended that capecitabine (Xeloda) as a component of the CAPOX regimen be funded for the first- and second-line treatment of metastatic colorectal cancer.
- ◆ The CED worked jointly with a subcommittee involving cancer experts to review this cancer drug, as is done for all other cancer drug treatments.

Limited Use Criteria:

The CED recommended that the Limited Use criteria for capecitabine (Xeloda) be expanded to include the following:

As part of the CAPOX regimen for the first-line and second-line treatment of metastatic colorectal cancer.

Cancer Care Ontario Information:

Information on CCO regimens for colorectal cancer may be found at:

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



Ministry of
Health and Long-Term Care
Ontario Public Drug Programs

For more information, please contact:

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Hepburn Block, 9th Floor

80 Grosvenor Street, Queen's Park

Toronto, Ontario M7A 1R3

or click: http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html