

Topotecan (for small cell lung cancer)

Product:

TOPOTECAN (Hycamtin®)

Class of drugs:

Antineoplastic agent

Indication:

Treatment of small cell lung cancer

Manufacturer:

GlaxoSmithKline Inc.

CED Recommendation

The CED recommended that topotecan (Hycamtin) not be funded through Cancer Care Ontario's New Drug Funding Program (NDFP) for the treatment of small cell lung cancer, on the basis that there are insufficient data to establish clinical benefit and value for money.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to fund topotecan (Hycamtin) for the treatment of small cell lung cancer.

Status

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

Highlights of Recommendation:

- ◆ Topotecan (Hycamtin) can be used to treat various types of cancer. In this review, the Committee considered the use of topotecan (Hycamtin) in the treatment of small cell lung cancer (SCLC) in patients who have failed initial or first-line chemotherapy (i.e. in second-line treatment).
- ◆ Evidence for the use of topotecan (Hycamtin) in the treatment of SCLC is limited.
- ◆ Preliminary results from one study comparing topotecan (Hycamtin) to *no drug treatment* showed that topotecan (Hycamtin) improved survival.
- ◆ A second study comparing topotecan (Hycamtin) to the current standard combination of CAV, (cyclophosphamide, doxorubicin, vincristine), reported that both therapies demonstrated similar benefits in terms of tumour response and survival. However, in terms of side effects, the number of patients who required blood transfusions was ten times higher in the group who received topotecan (Hycamtin).
- ◆ The most common side effect with topotecan (Hycamtin) is myelosuppression (i.e. suppression of the bone marrow leading to low levels of red blood cells, white blood cells and platelets). Other side effects include hair loss, fatigue, diarrhea, nausea and vomiting.
- ◆ Topotecan (Hycamtin) costs approximately \$1,800 per treatment cycle. Value for money could not be determined because the manufacturer did not provide an economic model.
- ◆ **Overall, the Committee concluded that there is insufficient data to establish the clinical benefit and cost-effectiveness of topotecan (Hycamtin) in the second-line treatment of SCLC.**

Background:

Lung cancer is the most common cause of cancer-related deaths in Canada. Small cell lung cancer (SCLC) accounts for about 15-20% of all lung cancer. It generally grows faster and is more aggressive than non-small cell lung cancer.

Chemotherapy is the most common treatment for all stages of small cell lung cancer. Although the disease initially responds to first-line drug therapy, almost all patients eventually relapse. Patients with small cell lung cancer who relapse or progress after first-line chemotherapy have a poor prognosis. Second-line chemotherapy may cause tumours to regress, but the response is usually short-lived for most patients.

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Detailed Discussion:

- ◆ There is currently no standard second-line chemotherapy regimen for SCLC in patients who have failed to respond or have relapsed shortly after first-line therapy. Clinical trials are needed to determine the optimal treatment regimen.
- ◆ Preliminary results from a phase III trial (O'Brien M. et al *Lung Cancer*. 2005;49 Suppl 2:S54) showed a statistically significant difference in overall survival ($p=0.0104$) favouring topotecan (Hycamtin) over best supportive care.
- ◆ The von Pawel study (*J Clin Oncol*. 1999;17(2):658-67) found no statistically significant difference in tumour response rates or median survival between topotecan (Hycamtin) and the CAV regimen (cyclophosphamide, doxorubicin and vincristine). An improvement in symptom management favouring topotecan (Hycamtin) was reported; however, the scoring system for this measure was not validated. The transfusion rate in patients who received topotecan (Hycamtin) was ten times higher than in patients who received the CAV regimen.
- ◆ Common side effects of topotecan (Hycamtin) include myelosuppression, hair loss, fatigue and gastrointestinal disturbances, such as diarrhea, nausea and vomiting.
- ◆ Topotecan (Hycamtin) costs approximately \$1,800 per treatment cycle. A Canadian pharmacoeconomic model evaluating the use of topotecan (Hycamtin) in SCLC has not been conducted; therefore, value for money cannot be determined.
- ◆ Overall, the Committee concluded that topotecan (Hycamtin) should not be funded for the second-line treatment of SCLC, given the limited evidence of clinical benefit and the lack of data on cost-effectiveness.
- ◆ 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 chemotherapy regimens for small cell lung cancer can be found at:

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

The Lung Cancer Disease Site Group (DSG) Program in Evidence-based Care (PEBC) guideline for the use of chemotherapy in relapsed small cell lung cancer is available at:

<http://www.cancercare.on.ca/english/toolbox/qualityguidelines/diseasesite/lung-ebs/>



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