Topotecan (for recurrent ovarian cancer)

Product:
TOPOTECAN (Hycamtin®)

Class of drugs:
Antineoplastic agent

Indication:
Treatment of platinum-sensitive recurrent ovarian cancer

Manufacturer:
GlaxoSmithKline Inc.

CED Recommendation

The CED recommended that topotecan (Hycamtin) be funded for the single-agent treatment of platinum-sensitive recurrent ovarian cancer under Cancer Care Ontario's New Drug Funding Program, on the basis that patients who cannot tolerate platinum should have access to this drug used as a single agent.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided to list topotecan (Hycamtin) for the treatment of platinum-sensitive recurrent ovarian cancer.

Status

Funding available through Cancer Care Ontario's New Drug Funding Program.

Highlights of Recommendation:

- Topotecan (Hycamtin) is a drug often used in combination with other drugs to treat cancer. In this case, it is used alone to treat patients with ovarian cancer who cannot tolerate platinum-based drugs, when their ovarian cancer has recurred within six months.
- Topotecan (Hycamtin) is administered intravenously.
- There is no substantial difference in the way topotecan (Hycamtin), paclitaxel or pegylated liposomal doxorubicin work when given alone. Physicians may choose one of the three drugs based on previous drug exposure, patient preference, ease of administration, availability, and likeliness of side effects.
- Although the Committee noted that evidence for the use of topotecan (Hycamtin) in this treatment is weak, ovarian cancer patients have few treatment options if they cannot take a platinum-based drug.
- **Overall, the Committee noted that patients whose ovarian cancer has recurred more than six months since their last treatment and who cannot tolerate platinum should have access to topotecan (Hycamtin) used as a single agent.**
- The CED recommended topotecan (Hycamtin) for the single-agent treatment of platinum-sensitive recurrent ovarian cancer be listed on the New Drug Funding Program Formulary, according to specific criteria. Please refer to the "Detailed Discussion" section for details of the criteria.
- The CED worked jointly with a subcommittee involving cancer experts to review this cancer drug, as is done for all other cancer drug treatments.

Background:

Ovarian cancer is the fifth-leading cause of death from cancer in Canadian women. When a person is first diagnosed with ovarian cancer, treatment usually involves a combination of chemotherapy and surgery. When the ovarian cancer recurs, women are usually treated with chemotherapy. The type of drug used depends on when the patient last received chemotherapy, side effects of the medication, ease of administration and patient preference.

If patients require further chemotherapy, they should be offered the opportunity to participate in available clinical trials. If a clinical trial is not available or suitable, and if re-treatment with platinum-based chemotherapy is not appropriate, then it is reasonable to consider using single-agent topotecan (Hycamtin), paclitaxel or pegylated liposomal doxorubicin for these patients.

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Detailed Discussion:

- The Cancer Care Ontario's (CCO's) Gynecology Disease Site Group requested that the Ministry of Health and Long-Term Care consider listing paclitaxel, pegylated liposome doxorubicin and topotecan (Hycamtin) in the treatment of platinum-sensitive recurrent ovarian cancer on the New Drug Funding Program (NDFP) Formulary.
- The Committee reconsidered the use of topotecan (Hycamtin) as a single agent to treat platinum-sensitive recurrent ovarian cancer, after previously reviewing it (in Spring 2005), because current clinical management of platinum-sensitive and platinum-resistant diseases is not clear.
- The CCO's Program in Evidence-Based Care (PEBC) guideline recommends using non-platinum drugs including topotecan (Hycamtin), paclitaxel and pegylated liposomal doxorubicin to treat recurrent ovarian cancer if patients cannot tolerate platinum-based chemotherapy.
- Studies report improved response rates in patients using these drugs as single agents.
- Common side effects of topotecan (Hycamtin) may include neutropenia, thrombocytopenia, alopecia and gastrointestinal disturbances.
- Selecting one of the non-platinum based cancer drugs is based on prior drug exposure, patient preference, toxicity profile, ease of administration and availability.
- The submitted pharmacoeconomic evidence was conducted in the Stage 3 and Stage 4 ovarian cancer population. Thus, it is not relevant to the indication currently under discussion.
- Overall, the Committee noted that although the evidence base is weak, and the pharmacoeconomic data are incomplete, ovarian cancer patients who cannot take platinum-based chemotherapy have few treatment options. The Committee also noted that these patients should have access to single-agent paclitaxel, and one of either topotecan (Hycamtin) or pegylated liposomal doxorubicin. The Committee recommended topotecan (Hycamtin) be funded through CCO's NDFP under the following specific criteria:
  - Patients with recurrent ovarian cancer who cannot tolerate further platinum therapy should have access to paclitaxel and one of either topotecan (Hycamtin) or pegylated liposomal doxorubicin, according to specific circumstances;
  - Selection of the non-platinum based therapy can be based on patient preference, toxicity profile, ease of administration, and availability.

Cancer Care Ontario (CCO) Information:

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

The Gynecology Cancer Disease Site Group (DSG) Program in Evidence-based Care (PEBC) guideline for the use of chemotherapy in ovarian cancer is available at: http://www.cancercare.on.ca/index_gynecologyCancerguidelines.htm

Ontario

Ministry of
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