

Policies Repository



Policy Title Topotecan capsule (Hycamtin®)

Policy Number FS.CLIN.88

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This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Topotecan capsule (Hycamtin®)** is indicated for the treatment of relapsed small cell lung cancer in patients with a prior complete or partial response and who are at least 45 days from the end of first-line chemotherapy.

The use of topotecan capsule (Hycamtin®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description **Topotecan capsule (Hycamtin®)** is a semi-synthetic derivative of camptothecin and is an anti-tumor drug. The anti-tumor activity of topotecan involves the inhibition of topoisomerase-I, an enzyme intimately involved in DNA replication as it relieves the torsional strain introduced ahead of the moving replication fork. Topotecan inhibits topoisomerase-I by stabilizing the covalent complex of enzyme and strand-cleaved DNA, which is an intermediate of the catalytic mechanism. The cellular sequel of inhibition of topoisomerase-I by topotecan is the induction of protein-associated DNA single-strand breaks. The cytotoxicity of topotecan is thought to be due to double strand DNA damage produced during DNA synthesis, when replication enzymes interact with the ternary complex formed by topotecan, topoisomerase I, and DNA. Mammalian cells cannot efficiently repair these double strand breaks.

Policy Guideline Inclusion **Topotecan capsule (Hycamtin®)** is approved when **all** of the following inclusion criteria are met:

- Documentation of diagnosis of small cell lung cancer
- Documentation of complete or partial response to one of the following first-line chemotherapy agents:
 - Cisplatin
 - Carboplatin

- Etoposide
- Irinotecan
- Cyclophosphamide
- Doxorubicin
- Vincristine
- Intravenous Topotecan
- Ifosfamide
- Paclitaxel
- Docetaxel
- Gemcitabine

Policy Guideline Exclusion

Topotecan capsule (Hycamtin®) is denied when **any** of the following exclusion criteria is present:

- No documentation of diagnosis of small cell lung cancer
- No documentation of complete or partial response to one of the following first-line chemotherapy agents:
 - Cisplatin
 - Carboplatin
 - Etoposide
 - Irinotecan
 - Cyclophosphamide
 - Doxorubicin
 - Vincristine
 - Intravenous Topotecan
 - Ifosfamide
 - Paclitaxel
 - Docetaxel
 - Gemcitabine

Policy List of Applicable Drugs

Brand Name	Generic Name
Hycamtin	topotecan

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

Topotecan capsule (Hycamtin®)[package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2008.

Topotecan capsule (Hycamtin®) In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed October 2008.

Topotecan capsule (Hycamtin®) In: Drugdex [online through Micromedex Healthcare Series]. Greenwood Village, CO: Thomson Micromedex. Accessed October 2008.

Policy Link to Related Policies

Printed

09/07/2010 13:21:40

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