



Prior Authorization Approval Criteria

Hycamtin (topotecan)

Generic name:	Topotecan, oral
Brand name:	Hycamtin capsules
Medication class:	Antineoplastic (topoisomerase I inhibitor, camptothecin)
FDA-approved uses:	Small cell lung cancer, after failure of a platinum agent and etoposide as first line therapy
Available dosage forms:	Oral capsules, 1 mg and 0.25 mg
Usual dose:	2.3 mg/m ² /day orally for 5 days every 21 days.
Approximate cost for 5-day treatment:	\$5,232.18 (orally) for small cell lung cancer
Duration of therapy:	Indeterminate

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- Clinically diagnosed with small cell lung cancer.
- Patient failed combination therapy with platinum agent and etoposide for small cell lung cancer
- Patient is unable to use IV formulation of topotecan (Hycamtin)

Criteria for continuation of therapy:

- Neutrophil count is > 1000/mm³
- Platelet count is > 100,000/mm³
- For oral topotecan, hemoglobin level should be > 9 g/dL

Caution:

- Administer under the guidance of an experienced doctor
- Severe anemia
- Neutropenia
- Thrombocytopenia
- Diarrhea, severe in some cases leading to hospitalizations
- Kidney problems leading to increased levels of topotecan
- Avoid use with CYP 450 inhibitors such as ritonavir, cyclosporine A, elacridar, saquinavir, ketoconazole, as they will increase concentration of hycamtin

Monitoring: CBC, renal function tests, bilirubin

Contraindication:

- Hypersensitive to topotecan or any of the components
- Breastfeeding
- Pregnancy
- Severe bone marrow suppression

Not approved if:

- Above criteria are not met
- Patient has any contraindications to the use of topotecan

Special considerations:

- Safety and efficacy has not been proven in pediatric patients
- \$2408.11 (injectable) for small cell lung cancer, ovarian cancer given for 5 days
- \$722.43 (injectable) for cervical cancer given for 3 days

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/10/2008