

Applicable Drugs: Hycamtin (topotecan)

Preferred: Hycamtin capsules, topotecan for injection

Non-preferred: Hycamtin (brand) injection

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 7/23/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documentation of one of the following FDA-approved diagnosis AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

- A. Small cell lung cancer and meets criteria i or ii:
 - i. Request is for Hycamtin capsules
 1. Documented relapse after a complete or partial response at least 45 days from the end of first-line chemotherapy
 2. Hycamtin capsules will be used as a single agent
 - ii. Request is for topotecan injection
 1. Documented progression at least 60 days after initiation of first-line chemotherapy
 2. Topotecan injection will be used as a single agent
- B. Ovarian cancer
 - i. Request is for topotecan injection
 - ii. Documentation of metastatic disease
 - iii. Documentation disease has progressed on or after previous treatment
- C. Cervical cancer
 - i. Request is for topotecan injection
 - ii. Documentation of Stage IV-B, recurrent, or persistent disease
 - iii. Documentation cancer is not amenable to curative treatment
 - iv. Documentation topotecan injection will be used in combination with cisplatin

Other Uses With Supportive Evidence

- D. Bone cancer (Ewing sarcoma and osteosarcoma)

- E. Cervical cancer
 - F. Leptomeningeal metastases
 - G. Merkel cell carcinoma
 - H. Neuroblastoma
 - I. Pediatric medulloblastoma
 - J. Rhabdomyosarcoma
 - K. Uterine cancer
 - L. Vaginal cancer
- II. Minimum age requirement: 18 years old.
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A..
- V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Hycamtin capsules
 - Quantity limited to a maximum of a 30-day supply
 - Recommended dose:
 - Maximum dose: 2.3 mg/m²/day once daily for 5 consecutive days repeated every 21 days
 - The calculated oral daily dose should be rounded to the nearest 0.25 mg
 - Use the minimum number of 1 mg and 0.25 mg capsules

- The same number of capsules should be prescribed for each of the 5 dosing days
- Topotecan injection
 - Quantity limited to a maximum of a 30-day supply
 - Recommended dose:
 - Ovarian cancer and small cell lung cancer (SCLC): 1.5 mg/m² via intravenous infusion daily for 5 consecutive days starting on day 1 of a 21-day cycle
 - Cervical cancer: 0.75 mg/m² via IV infusion daily for 3 consecutive days starting on day 1 of a 21-day cycle with cisplatin 50mg/m² on day 1

APPROVAL LENGTH

- **Authorization:** 1 year
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease .

APPENDIX

N/A

REFERENCES

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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.