Clinical Policy: Topotecan (Hycamtin)

Reference Number: PA.CP.PHAR.64
Effective Date: 06.01.11
Last Review Date: 04.2019

Coding Implications
Revision Log

Description
Topotecan (Hycamtin®) is a topoisomerase inhibitor.

FDA Approved Indication(s)
Hycamtin capsules are 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.

Hycamtin for injection is indicated:

- As a single agent for the treatment of patients with metastatic carcinoma of the ovary after disease progression on or after initial or subsequent chemotherapy
- As a single agent for the treatment of patients with small cell lung cancer with platinum-sensitive disease who progressed at least 60 days after initiation of first line chemotherapy
- In combination with cisplatin for the treatment of patients with Stage IV-B, recurrent, or persistent carcinoma of the cervix not amenable to curative treatment

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria

It is the policy of health plans affiliated with PA Health & Wellness that Hycamtin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ovarian Cancer (must meet all)**:**

1. Diagnosis of ovarian cancer;
2. Request is for topotecan for injection;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Disease progression on or after initial or subsequent chemotherapy;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 1.5 mg/m^{2}per day for 5 consecutive days every 21 days;
   b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 6 months

B. Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of small cell lung cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;

4. Member has received prior chemotherapy;
5. Request meets one of the following (a or b):
   a. Dose does not exceed the following:
      i. Injection: 1.5 mg/m^{2}per day IV for 5 consecutive days every 21 days;
      ii. Capsule: 2.3 mg/m^{2}per day orally for 5 consecutive days every 21 days;
   b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label *use (prescriber must submit supporting evidence).*

Approval duration: 6 months

C. Cervical Cancer (must meet all)**:**
1. Diagnosis of cervical cancer;
2. Request is for topotecan for injection;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 0.75 mg/m^2 on days 1-3 every 21 days;
   b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 6 months

D. NCCN Recommended Uses(off-label) (must meet all)**:**
1. Prescribed for one of the following diagnoses:
   a. Request is for topotecan for injection:
      i. Ewing sarcoma;
      ii. Osteosarcoma;
      iii. Primary CNS lymphoma;
      iv. Leptomeningeal metastases and route of administration is intrathecal;
      v. Rhabdomyosarcoma;
      vi. Endometrial carcinoma;
   b. Request is for topotecan for injection or topotecan capsules:
      Merkel cell carcinoma and member has contraindications to checkpoint immunotherapy (e.g., avelumab, pembrolizumab, nivolumab);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Dose is within FDA maximum limit for any FDA approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 6 months

E. Other diagnoses/indications
1. Refer to PA.CP.PMN.53.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit, or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed the following:
      i. Ovarian cancer: 1.5 mg/m^2/day IV for 5 consecutive days every 21 days;
      ii. Small cell lung cancer: 1.5 mg/m^2/day IV *or* 2.3 mg/m^2/day orally for 5 consecutive days repeated every 21 days;
      iii. Cervical cancer: 0.75 mg/m^2 IV on days 1-3 every 21 days;
   b. Requested dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): History of hypersensitivity reactions to topotecan
- Boxed warning(s): Myelosuppression

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Ovarian cancer	IV infusion dosage: 1.5 mg/m^2 IV over 30 minutes daily for 5 consecutive days, starting on Day 1 of a 21-day course	4 mg/dose if IV infusion, otherwise refer to regimen
Small cell lung cancer	IV infusion dosage: 1.5 mg/m^2 IV over 30 minutes daily for 5 consecutive days, starting on Day 1 of a 21-day course	4 mg/dose if IV infusion, otherwise refer to regimen

Indication	Dosing Regimen	Maximum Dose
	Oral dosage: 2.3 mg/m^2/day orally once daily for 5 consecutive days repeated every 21 days	
Cervical cancer	IV infusion dosage: 0.75 mg/m^2 IV over 30 minutes on Days 1, 2, and 3 repeated every 21 days in combination with cisplatin 50 mg/m^2 on Day 1	4 mg/dose if IV infusion, otherwise refer to regimen

V. Product Availability

- Capsules: 0.25 mg, 1 mg
- Lyophilized powder in single use vial for injection: 4-mg (free base)

VI. References

1. Hycamtin for Injection Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; September 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed February 8, 2019.
2. Hycamtin capsules Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; September 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed February 8, 2019.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed February 8, 2019.

Coding Implications –
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J8705	Topotecan, oral, 0.25 mg
J9351	Injection, topotecan, 0.1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.13.18	04.18.18
2Q 2019 annual review: capsules added as an option for Merkel cell carcinoma and intrathecal route notated for leptomeningeal metastasis per NCCN; references reviewed and updated.	04.2019	