

Corporate Medical Policy

Topotecan Hydrochloride (Hycamtin)

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| File Name: | topotecan_hydrochloride_hycamtin |
| Origination: | 9/2016 |
| Last CAP Review: | 8/2020 |
| Next CAP Review: | 8/2021 |
| Last Review: | 8/2020 |

Description of Procedure or Service

Hycamtin (topotecan hydrochloride) is a semi-synthetic derivative of camptothecin and is an anti-tumor drug with topoisomerase I-inhibitory activity.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Topotecan Hydrochloride (Hycamtin) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Topotecan Hydrochloride (Hycamtin) is covered

Topotecan Hydrochloride (Hycamtin) is considered medically necessary for the treatment of patients with:

- Acute Myeloid Leukemia: Induction therapy in combination with cytarabine for individuals less than 60 years of age with impaired cardiac function (NCCN 2A)
- Bone cancer (NCCN 2A)
 - Ewing's sarcoma family of tumors (excluding mesenchymal chondrosarcoma), when used in combination with cyclophosphamide, with or without vincristine, with growth factor support, for relapsed or progressive disease
 - Osteosarcoma, as second line therapy in combination with cyclophosphamide, with growth factor support
- Cervical cancer
 - In combination with cisplatin as first line therapy for recurrent, persistent or metastatic disease not amenable to curative treatment.
 - In combination with paclitaxel with or without bevacizumab for first line treatment of recurrent or metastatic disease. (NCCN 1)

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- Lymphoma, primary Central Nervous System (Primary CNS Lymphoma)
 - As a single agent to treat progressive or recurrent disease
- Merkel Cell Skin Cancer
 - to treat distant metastases or disseminated recurrence
- Ovarian cancer, epithelial (includes fallopian tube cancer and primary peritoneal cancer), for recurrent or persistent disease on or after initial or subsequent chemotherapy
 - As a single agent, **OR**
 - In combination with bevacizumab
- Small cell lung cancer
 - As a single agent, to treat platinum-sensitive disease (FDA) or primary progressive disease (NCCN 2A) in patients who progressed after first line chemotherapy;
 - To treat metastatic brain lesions or leptomeningeal metastases
- Soft tissue sarcoma: non-pleomorphic rhabdomyosarcoma, as a single agent or in combination with cyclophosphamide
- Uterine cancer: endometrial carcinoma, as a single agent.

When Topotecan Hydrochloride (Hycamtin) is not covered

Topotecan Hydrochloride (Hycamtin) is considered not medically necessary and therefore not covered when above criteria are not met.

Policy Guidelines

Ovarian cancer and small cell lung cancer: 1.5mg/m² by intravenous infusion over 30 minutes daily for 5 consecutive days, starting on day one of a 21-day course.

Cervical cancer: 0.75mg/m² by intravenous infusion over 30 minutes on days 1, 2, and 3 followed by cisplatin 50mg/m² by intravenous infusion on day 1 repeated every 21 days.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J9351, S0353, S0354

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration (FDA). Available at:
http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020671s016s0171bl.pdf

Gordon AN, Tonda M, Sun S, Rackoff W; Doxil Study 30-49 Investigators. Long-term survival advantage for women treated with pegylated liposomal doxorubicin compared with topotecan in a

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phase 3 randomized study of recurrent and refractory epithelial ovarian cancer. *Gynecol Oncol*. 2004 Oct;95(1):1-8. [PMID: 15385103](#)

Abushahin F, Singh DK, Lurain JR, Grendys EC, Rademaker AW, and Schink JC. Weekly topotecan for recurrent platinum resistant ovarian cancer. *Gynecol Oncol*. 2008 Jan;108(1):53-7. [PMID: 17904208](#)

Poveda AM, Selle F, Hipert F, et al. Bevacizumab Combined With Weekly Paclitaxel, Pegylated Liposomal Doxorubicin, or Topotecan in Platinum-Resistant Recurrent Ovarian Cancer: Analysis by Chemotherapy Cohort of the Randomized Phase III AURELIA Trial. *J Clin Oncol*. 2015 Nov 10;33(32):3836-8. [PMID: 26282651](#)

O'Brien ME, Ciuleanu TE, Tsekov H, et al. Phase III trial comparing supportive care alone with supportive care with oral topotecan in patients with relapsed small-cell lung cancer. *J Clin Oncol*. 2006 Dec 1;24(34):5441-7. [PMID: 17135646](#)

Eckardt JR, von Pawel J, Pujol JL, et al. Phase III study of oral compared with intravenous topotecan as second-line therapy in small-cell lung cancer. *J Clin Oncol*. 2007 May 20;25(15):2086-92. [PMID: 17513814](#)

von Pawel J, Schiller JH, Shepherd FA, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. *J Clin Oncol*. 1999 Feb;17(2):658-67. [PMID: 10080612](#)

National Comprehensive Cancer Network (NCCN). www.nccn.org

Medical Director review 9/2016

Specialty Matched Consultant Advisory Panel review 8/2017

Specialty Matched Consultant Advisory Panel review 8/2018

Specialty Matched Consultant Advisory Panel review 8/2019

Specialty Matched Consultant Advisory Panel review 8/2020

Policy Implementation/Update Information

- 12/30/16 New policy developed. Topotecan Hydrochloride (Hycamtin) is considered medically necessary for the treatment of patients with: acute myeloid leukemia, bone cancer, cervical cancer, lymphoma of CNS, Merkel cell skin cancer, small cell lung cancer, soft tissue sarcoma, uterine cancer, endometrial cancer. Reference added. Medical director review 9/2016. Added HCPCS codes S0353, S0354 to Billing/Coding section. Notification given 12/30/16 for effective date 4/1/17. (lpr)
- 9/29/17 Specialty Matched Consultant Advisory Panel review 8/30/2017. No change to policy statement. (lpr)
- 10/12/18 Specialty Matched Consultant Advisory Panel review 8/22/2018. No change to policy statement. (krc)

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10/1/19 Specialty Matched Consultant Advisory Panel review 8/21/2019. No change to policy statement. (krc)

11/24/20 Specialty Matched Consultant Advisory Panel review 8/2020. No change to policy intent. (krc)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.