



Horizon BCBSNJ
 Medical Necessity Guideline

Section Drugs
Policy Number
Effective Date 2/29/08
Review Date 11/24/08

Subject:
BRAND NAME Hycamtin
(Generic) (topotecan capsules)

IMPORTANT NOTE:

*The purpose of this policy is to provide general information applicable to the administration of outpatient prescription drug benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. **Outpatient prescription drugs are not covered under all Horizon benefit plans.** If the member's contract benefits differ from the pharmacy guideline, the contract prevails. Although a service, supply drug or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply drug or procedure is not covered and the member proceeds to obtain the service, supply drug or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's or pharmacist's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.*

Horizon BCBSNJ pharmacy guidelines do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, contract or guarantee of payment.

BLACK BOX WARNINGS

Bone marrow suppression: Administer topotecan only to patients with baseline neutrophil counts of 1,500 cells/mm³ or more and a platelet count of 100,000 cells/mm³ or more. In order to assess the occurrence of bone marrow suppression, monitor blood cell counts.

FDA-APPROVED INDICATIONS

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.

CRITERIA FOR APPROVAL

- | | | | |
|----|--|-----|----|
| 1. | Does the patient have one of the following diagnoses?
<ul style="list-style-type: none"> • relapsed small cell lung cancer • non-small-cell lung cancer (NSCLC) [If the answer to this question is no, then no further questions are required.] | Yes | No |
| 2. | Will Hycamtin therapy be initiated and managed consistent with all of the following?
<ul style="list-style-type: none"> • a baseline neutrophil count of > 1,500 cells/mm³ • a baseline platelet count ≥ 100,000 cells/ mm³ • patient's blood cell counts (hematocrit/hemoglobin, leukocyte and platelet counts) will be monitored frequently during Hycamtin therapy [If the answer to this question is no, then no further questions are required.] | Yes | No |
| 3. | If applicable, are the physician and patient aware that this drug must not be taken if the | Yes | No |

patient is pregnant or may become pregnant?	
Guidelines for Approval	
Duration of Approval	6 Months
Set 1:	
YES to question(s)	NO to question(s)
1	None
2	
3	

Horizon BCBSNJ Pharmacy Guideline Development Process: This Horizon BCBSNJ Pharmacy Guideline (the "Pharmacy Guideline") has been developed by Horizon BCBSNJ's Pharmacy Drug Policy Subcommittee, Clinical Issues Subcommittee, and Quality Improvement Committee which include practicing physicians and pharmacists. This guideline is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ's view of the subject health care services, supplies drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Guideline also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Guideline considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

RATIONALE

The intent of the criteria is to ensure that patients follow selection elements established by Horizon BCBS New Jersey's medical policies.

REFERENCES

1. Hycamtin® (topotecan) Capsules prescribing information. GlaxoSmithKline. October 2007.
2. O'Brien M, Ciuleanu T, 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 Oncology*. 2006;24:5441-47.

Pharmacy Guidelines can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.

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