



Commercial/Healthcare Exchange PA Criteria

Effective: November 2, 2016

Prior Authorization: Hycamtin

Products Affected: Hycamtin (topotecan) oral capsules

Medication Description:

Hycamtin capsules are indicated for treatment of patients with relapsed small cell lung cancer. Hycamtin is a topoisomerase inhibitor. Topoisomerase I relieves torsional strain in DNA by inducing reversible single-strand breaks. Topotecan binds to the topoisomerase I-DNA complex and prevents re-ligation of these singlestrand breaks. The cytotoxicity of topotecan is thought to be due to double-strand DNA damage produced during DNA synthesis, when replication enzymes interact with the ternary complex formed by topotecan, topoisomerase I, and DNA. Mammalian cells cannot efficiently repair these double-strand breaks.

Hycamtin has a Boxed Warning for bone marrow suppression. Hycamtin can cause severe myelosuppression. According to the Boxed Warning, Hycamtin should only be administered to patients with a baseline neutrophil count greater than or equal to 1,500 cells/mm³ and a platelet count greater than or equal to 100,000 cells/mm³.

Covered Uses:

1. Relapsed Small cell lung cancer

Exclusion Criteria:

Hycamtin has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances:

1. Treatment naïve patients

Required Medical Information:

1. Diagnosis
2. Previous therapies tried
3. Dose and frequency

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by, or in consultation with an oncologist

Coverage Duration: 12 months

Other Criteria:

1. **Small cell lung cancer.** Approve if the patient meets the following criteria (a, b, c, d, and e):
 - a. Patient has relapsed small cell lung cancer; AND
 - b. Patient has platinum-sensitive disease; AND
 - c. Patient has disease progression after initial chemotherapy; AND
 - d. Patient had a prior complete or partial response; AND
 - e. Patient is at least 45 days from the end of first-line chemotherapy

Last Res.10.15.2019



Confidential Information

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References:

1. Hycamtin [prescribing information]. New York, NY: GlaxoSmithKline; August 2016.
2. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 1.2017). © 2015 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 10, 2016

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	8/16/2016
2	Policy Update	CCI Adopted EH Policy, removed from CCI Oncology Policy Added Age Restriction Added Prescriber Restriction	Age Restriction Prescriber Restriction	10/15/2019