UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Hycamtin

Program	Prior Authorization
Medication	Hycamtin® (topotecan hydrochloride)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New York, New York EPP, Rhode Island, Pennsylvania- CHIP, New Jersey, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

Hycamtin® (topotecan hydrochloride) is a topoisomerase inhibitor indicated for the treatment of patients with relapsed small cell lung cancer. The National Cancer Comprehensive Network (NCCN) also recommends the use of Hycamtin for the treatment of disseminated, clinical M1 Merkel cell carcinoma for patients with contraindications to checkpoint immunotherapy.

2. Coverage Criteria:

A. Small cell lung cancer (SCLC)

1. Initial Authorization

Hycamtin will be approved based on **all** of the following criteria:

(1) Diagnosis of small cell lung cancer (SCLC)

-AND-

(2) Patient has experienced a relapse of disease after initial first-line chemotherapy (e.g., cisplatin with etoposide)

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Authorization will be issued for 12 months.

2. Reauthorization

a. **Hycamtin** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Hycamtin therapy

Authorization will be issued for 12 months.

B. Merkel cell carcinoma

1. Initial Authorization

Hycamtin will be approved based on **all** of the following criteria:

(1) Diagnosis of Merkel cell carcinoma

-AND-

(2) **Both** of the following:

(a) Disseminated disease
(b) Clinical M1 disease

-AND-

(3) Patient has a contraindication to checkpoint immunotherapy [e.g., Bavencio (avelumab), Keytruda (pembrolizumab), Opdivo (nivolumab)]

Authorization will be issued for 12 months.

2. Reauthorization

a. **Hycamtin** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Hycamtin therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Hycamtin** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Hycamtin** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Hycamtin therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Hycamtin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2018.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on October 2, 2020.

Program	Prior Authorization –Hycamtin (topotecan hydrochloride)
Change Control	
Date	Change
9/2013	New guideline
12/2015	Annual Review
10/1/2016	Removed prescriber requirement. Added patient has experienced a partial or complete response with first-line chemotherapy and that patient has relapsed at least 45 days from the end of first-line chemotherapy. Changed all authorization to 12 months.
12/2016	Annual review. Updated references.
11/2017	Annual review. Updated references.
11/2018	Added coverage for Merkel cell carcinoma based on NCCN guidance. Added NCCN Recommended Regimen review criteria. Updated background and references.
11/2019	Annual review. Updated references.
11/2020	Annual review. Updated background to reflect package insert. Updated SCLC criteria to reflect package insert. Updated references. Added Additional Clinical Rules section.