

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2021 P 1042-10
Program	Prior Authorization/Notification
Medication	Hycamtin® (topotecan hydrochloride)
Date Approved	1/12/2010, 9/2010, 12/2010, 7/2011, 8/2012, 2/2014, 2/2015, 2/2016, 12/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021
Date Revised	2/1/2022; Oxford only: 2/1/2022

**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 and uterine neoplasms.

**Coverage Information:**

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria:**

**A. Patients less than 19 years of age**

1. Hycamtin will be approved based on the following criterion:

a. Patient is less than 19 years of age

**Authorization will be issued for 12 months.**

**B. Small cell lung cancer (SCLC)**

1. **Initial Authorization**

a. 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)

**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**

- a. **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. Uterine Neoplasms**

#### **1. Initial Authorization**

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

(1) Diagnosis of endometrial carcinoma

**-AND-**

(2) Used as adjuvant treatment for uterine-confined disease

**-AND-**

(3) Disease is recurrent, metastatic, or high-risk

**Authorization will be issued for 12 months.**

#### **2. Reauthorization**

b. **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.**

### **D. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

**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.  
The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [http://www.nccn.org/professionals/drug\\_compendium/content/contents.asp](http://www.nccn.org/professionals/drug_compendium/content/contents.asp). Accessed on September 20, 2021.

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<b>Change Control</b>	
2/2014	Annual review. No change to coverage criteria.
2/2015	Annual review. Added additional criteria to SCLC indication. Updated references.
2/2016	Annual review. Changed all authorization to 12 months. Updated references.
12/2016	Annual review. Updated references.
11/2017	Annual review. Updated references.
11/2018	Annual review. Added coverage for Merkel cell carcinoma based on NCCN guidelines. Updated background and references.
11/2019	Annual review. Added NCCN recommended regimens criteria. Updated references.
11/2020	Annual review. Updated background to reflect package insert. Updated SCLC criteria to reflect package insert. Updated references.
11/2021	Annual review. Added clinical criteria for uterine neoplasms per NCCN recommendations. Updated reference.