UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1042-14
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, 11/2022, 11/2023, 11/2023, 11/2025
Date Revised	2/1/2026

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 Hycamtin may be considered as single-agent treatment (useful in certain circumstances) for M1 disseminated or regional N+ disease with or without surgery and/or radiation therapy if anti-PD-L1 or anti-PD-1 therapy is contraindicated or disease has progressed on anti-PD-L1 or anti-PD-1 therapy.

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]:

A. <u>Patients less than 19 years of age</u>

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. <u>Small cell lung cancer (SCLC)</u>

1. **<u>Initial Authorization</u>**

   a. **Hycamtin** will be approved based on **<u>all</u>** 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

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(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.

C. 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) Patient has a contraindication to or disease has progressed on anti-PD-L1 or anti-PD-1 therapy.

-AND-

(3) **One** of the following:

i. Disease is regional N+
ii. Disease is M1 disseminated

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.

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.

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[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 1, 2025.

Program	Prior Authorization/Notification - Hycamtin (topotecan hydrochloride)
Change Control	
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.
11/2022	Annual review. Removed criteria for uterine neoplasms since dosage form for treatment is IV. Added state mandate footnote. Updated reference.
11/2023	Annual review. Updated Merkel cell carcinoma criteria based on current NCCN recommendations. Updated background and reference.
11/2024	Annual review with no changes to coverage criteria.

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11/2025	Annual review. Updated Merkel cell carcinoma criteria based on current NCCN recommendations. Updated background.

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