

SPECIALTY GUIDELINE MANAGEMENT

HYCANTIN CAPSULES (topotecan)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Hycamtin capsules are indicated for the treatment of relapsed small cell lung cancer (SCLC) in patients with a prior complete or partial response and who are at least 45 days from the end of first-line chemotherapy.

B. Compendial Uses

1. Small Cell Lung Cancer (SCLC)
2. Merkel Cell Carcinoma (MCC)

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. **Small Cell Lung Cancer (SCLC)**

Authorization of 12 months may be granted for treatment of small cell lung cancer.

B. **Merkel Cell Carcinoma (MCC)**

Authorization of 12 months may be granted for treatment of Merkel cell carcinoma when all of the following criteria are met:

1. Member has metastatic disseminated disease.
2. Member has contraindications to or member has disease that has progressed on anti-PD-L1 or anti-PD-1 monotherapy [e.g., Bavencio (avelumab), Keytruda (pembrolizumab)].
3. The medication will be used as a single agent.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Hycamtin Capsules [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; September 2018.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed March 7, 2024.

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