

## Hycamtin® (topotecan) (Intravenous, Intrathecal)

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### I. Length of Authorization

Coverage will be provided for six months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC Unit]:

- Hycamtin 4 mg powder for injection: 2 vials per 7 days

#### B. Max Units (per dose and over time) [HCPCS Unit]:

##### **Cervical Cancer**

- 120 units every 21 days

##### **Bone Cancer – Ewing Sarcoma and Osteosarcoma & Soft Tissue Sarcoma – Non-Pleomorphic Rhabdomyosarcoma**

- 200 units every 21 days

##### **Leptomeningeal Metastases**

- Induction: 80 units weekly x 6 weeks
- Consolidation: 40 units weekly x 6 weeks
- Maintenance: 80 units monthly x 4 months
- Extended Maintenance: 40 units monthly

##### **All other Indications**

- 200 units every 21 days

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

**Cervical Cancer †<sup>1,2</sup>**

**Ovarian Cancer (including Epithelial, Primary Peritoneal and Fallopian Tube Cancers) † ‡<sup>1,2</sup>**

Small Cell Lung Cancer (SCLC) †<sup>1,2</sup>

Bone Cancer – Ewing Sarcoma and Osteosarcoma ‡<sup>2</sup>

CNS Cancers – Leptomeningeal Metastases ‡<sup>2</sup>

Merkel Cell Carcinoma ‡<sup>2</sup>

Soft Tissue Sarcoma – Non-Pleomorphic Rhabdomyosarcoma ‡<sup>2</sup>

Uterine Neoplasms – Endometrial Carcinoma ‡<sup>2</sup>

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

#### IV. Renewal Criteria<sup>1</sup>

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelosuppression (neutropenia, thrombocytopenia, anemia), interstitial lung disease, extravasation and tissue injury, etc.

#### V. Dosage/Administration<sup>1,7-12</sup>

| Indication   | Dose   |
|--|--|
| Cervical Cancer  | 0.75 mg/m <sup>2</sup> /day IV on days 1-3 of every 21-day cycle   |
| Bone Cancer – Ewing Sarcoma and Osteosarcoma; Soft Tissue Sarcoma – Non-Pleomorphic Rhabdomyosarcoma | 0.75 mg/m <sup>2</sup> /day IV on days 1-5 of every 21-day cycle   |
| Ovarian Cancer; SCLC; Uterine Neoplasms – Endometrial Carcinoma                                      | 1.5 mg/m <sup>2</sup> /day IV on days 1-5 days of every 21-day cycle   |
| CNS Cancer – Leptomeningeal Metastases   | 400 mcg, administered intrathecally, twice weekly (every 3–4 days) for 6 weeks during induction, weekly for 6 weeks during consolidation, and twice monthly for 4 months and then monthly thereafter during maintenance. |
| All other indications  | 1.5 mg/m <sup>2</sup> /day IV for 5 days; repeated every 21 days   |

#### VI. Billing Code/Availability Information

HCPCS Code:

- J9351– Injection, topotecan, 0.1 mg: 1 billable unit = 0.1 mg.

NDC:

- Hycamtin 4 mg powder for injection, single-dose vial – 00078-0674-xx \*

*\*Generics available from numerous manufacturers*

## VII. References

1. Hycamtin [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; October 2019. Accessed November 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Topotecan. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2021.
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rhabdomyosarcoma study. J Clin Oncol. 2001 Jan 1;19(1):213-9. doi: 10.1200/JCO.2001.19.1.213.

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12. Miller DS, Blessing JA, Lentz SS, et al. A phase II trial of topotecan in patients with advanced, persistent, or recurrent endometrial carcinoma: a gynecologic oncology group study. Gynecol Oncol. 2002 Dec;87(3):247-51. doi: 10.1006/gyno.2002.6804.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description  |
|--------|---|
| C21.0  | Malignant neoplasm of anus, unspecified                                 |
| C33    | Malignant neoplasm of trachea   |
| C34.00 | Malignant neoplasm of unspecified main bronchus                         |
| C34.01 | Malignant neoplasm of right main bronchus                               |
| C34.02 | Malignant neoplasm of left main bronchus                                |
| C34.10 | Malignant neoplasm of upper lobe, unspecified bronchus or lung          |
| C34.11 | Malignant neoplasm of upper lobe, right bronchus or lung                |
| C34.12 | Malignant neoplasm of upper lobe, left bronchus or lung                 |
| C34.2  | Malignant neoplasm of middle lobe, bronchus or lung                     |
| C34.30 | Malignant neoplasm of lower lobe, unspecified bronchus or lung          |
| C34.31 | Malignant neoplasm of lower lobe, right bronchus or lung                |
| C34.32 | Malignant neoplasm of lower lobe, left bronchus or lung                 |
| C34.80 | Malignant neoplasm of overlapping sites of unspecified bronchus or lung |
| C34.81 | Malignant neoplasm of overlapping sites of right bronchus and lung      |
| C34.82 | Malignant neoplasm of overlapping sites of left bronchus and lung       |
| C34.90 | Malignant neoplasm of unspecified part of unspecified bronchus or lung  |
| C34.91 | Malignant neoplasm of unspecified part of right bronchus or lung        |
| C34.92 | Malignant neoplasm of unspecified part of left bronchus or lung         |
| C40.00 | Malignant neoplasm of scapula and long bones of unspecified upper limb  |
| C40.01 | Malignant neoplasm of scapula and long bones of right upper limb        |
| C40.02 | Malignant neoplasm of scapula and long bones of left upper limb         |
| C40.10 | Malignant neoplasm of short bones of unspecified upper limb             |
| C40.11 | Malignant neoplasm of short bones of right upper limb                   |
| C40.12 | Malignant neoplasm of short bones of left upper limb                    |
| C40.20 | Malignant neoplasm of long bones of unspecified lower limb              |
| C40.21 | Malignant neoplasm of long bones of right lower limb                    |

| ICD-10  | ICD-10 Description   |
|---------|--|
| C40.22  | Malignant neoplasm of long bones of left lower limb  |
| C40.30  | Malignant neoplasm of short bones of unspecified lower limb                                    |
| C40.31  | Malignant neoplasm of short bones of right lower limb  |
| C40.32  | Malignant neoplasm of short bones of left lower limb   |
| C40.80  | Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb    |
| C40.81  | Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb          |
| C40.82  | Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb           |
| C40.90  | Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb            |
| C40.91  | Malignant neoplasm of unspecified bones and articular cartilage of right limb                  |
| C40.92  | Malignant neoplasm of unspecified bones and articular cartilage of left limb                   |
| C41.0   | Malignant neoplasm of bones of skull and face  |
| C41.1   | Malignant neoplasm of mandible   |
| C41.2   | Malignant neoplasm of vertebral column   |
| C41.3   | Malignant neoplasm of ribs, sternum and clavicle   |
| C41.4   | Malignant neoplasm of pelvic bones, sacrum and coccyx  |
| C41.9   | Malignant neoplasm of bone and articular cartilage, unspecified                                |
| C48.0   | Malignant neoplasm of retroperitoneum  |
| C48.1   | Malignant neoplasm of specified parts of peritoneum  |
| C48.2   | Malignant neoplasm of peritoneum, unspecified  |
| C48.8   | Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum                      |
| C49.0   | Malignant neoplasm of connective and soft tissue of head, face and neck                        |
| C49.10  | Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder |
| C49.11  | Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder       |
| C49.12  | Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder        |
| C49.20  | Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip      |
| C49.21  | Malignant neoplasm of connective and soft tissue of right lower limb, including hip            |
| C49.22  | Malignant neoplasm of connective and soft tissue of left lower limb, including hip             |
| C49.3   | Malignant neoplasm of connective and soft tissue of thorax                                     |
| C49.4   | Malignant neoplasm of connective and soft tissue of abdomen                                    |
| C49.5   | Malignant neoplasm of connective and soft tissue of pelvis                                     |
| C49.6   | Malignant neoplasm of connective and soft tissue of trunk, unspecified                         |
| C49.8   | Malignant neoplasm of overlapping sites of connective and soft tissue                          |
| C49.9   | Malignant neoplasm of connective and soft tissue, unspecified                                  |
| C4A.0   | Merkel cell carcinoma of lip   |
| C4A.10  | Merkel cell carcinoma of unspecified eyelid, including canthus                                 |
| C4A.111 | Merkel cell carcinoma of right upper eyelid, inc canthus                                       |
| C4A.112 | Merkel cell carcinoma of right lower eyelid, inc canthus                                       |

| ICD-10  | ICD-10 Description  |
|---------|---|
| C4A.121 | Merkel cell carcinoma of left upper eyelid, inc canthus               |
| C4A.122 | Merkel cell carcinoma of left lower eyelid, inc canthus               |
| C4A.20  | Merkel cell carcinoma of unspecified ear and external auricular canal |
| C4A.21  | Merkel cell carcinoma of right ear and external auricular canal       |
| C4A.22  | Merkel cell carcinoma of left ear and external auricular canal        |
| C4A.30  | Merkel cell carcinoma of unspecified part of face                     |
| C4A.31  | Merkel cell carcinoma of nose   |
| C4A.39  | Merkel cell carcinoma of other parts of face                          |
| C4A.4   | Merkel cell carcinoma of scalp and neck                               |
| C4A.51  | Merkel cell carcinoma of anal skin                                    |
| C4A.52  | Merkel cell carcinoma of skin of breast                               |
| C4A.59  | Merkel cell carcinoma of other part of trunk                          |
| C4A.60  | Merkel cell carcinoma of unspecified upper limb, including shoulder   |
| C4A.61  | Merkel cell carcinoma of right upper limb, including shoulder         |
| C4A.62  | Merkel cell carcinoma of left upper limb, including shoulder          |
| C4A.70  | Merkel cell carcinoma of unspecified lower limb, including hip        |
| C4A.71  | Merkel cell carcinoma of right lower limb, including hip              |
| C4A.72  | Merkel cell carcinoma of left lower limb, including hip               |
| C4A.8   | Merkel cell carcinoma of overlapping sites                            |
| C4A.9   | Merkel cell carcinoma, unspecified                                    |
| C53.0   | Malignant neoplasm of endocervix                                      |
| C53.1   | Malignant neoplasm of exocervix                                       |
| C53.8   | Malignant neoplasm of overlapping sites of cervix uteri               |
| C53.9   | Malignant neoplasm of cervix uteri, unspecified                       |
| C54.0   | Malignant neoplasm of isthmus uteri                                   |
| C54.1   | Malignant neoplasm of endometrium                                     |
| C54.2   | Malignant neoplasm of myometrium                                      |
| C54.3   | Malignant neoplasm of fundus uteri                                    |
| C54.8   | Malignant neoplasm of overlapping sites of corpus uteri               |
| C54.9   | Malignant neoplasm of corpus uteri, unspecified                       |
| C55     | Malignant neoplasm of uterus, part unspecified                        |
| C56.1   | Malignant neoplasm of right ovary                                     |
| C56.2   | Malignant neoplasm of left ovary                                      |
| C56.9   | Malignant neoplasm of unspecified ovary                               |
| C57.00  | Malignant neoplasm of unspecified fallopian tube                      |
| C57.01  | Malignant neoplasm of right fallopian tube                            |

| ICD-10  | ICD-10 Description   |
|---------|--|
| C57.02  | Malignant neoplasm of left fallopian tube                        |
| C57.10  | Malignant neoplasm of unspecified broad ligament                 |
| C57.11  | Malignant neoplasm of right broad ligament                       |
| C57.12  | Malignant neoplasm of left broad ligament                        |
| C57.20  | Malignant neoplasm of unspecified round ligament                 |
| C57.21  | Malignant neoplasm of right round ligament                       |
| C57.22  | Malignant neoplasm of left round ligament                        |
| C57.3   | Malignant neoplasm of parametrium                                |
| C57.4   | Malignant neoplasm of uterine adnexa, unspecified                |
| C57.7   | Malignant neoplasm of other specified female genital organs      |
| C57.8   | Malignant neoplasm of overlapping sites of female genital organs |
| C57.9   | Malignant neoplasm of female genital organ, unspecified          |
| C63.2   | Malignant neoplasm of scrotum                                    |
| C78.00  | Secondary malignant neoplasm of unspecified lung                 |
| C78.01  | Secondary malignant neoplasm of right lung                       |
| C78.02  | Secondary malignant neoplasm of left lung                        |
| C79.31  | Secondary malignant neoplasm of brain                            |
| C79.32  | Secondary malignant neoplasm of cerebral meninges                |
| C79.51  | Secondary malignant neoplasm of bone                             |
| C79.52  | Secondary malignant neoplasm of bone marrow                      |
| C7A.1   | Malignant poorly differentiated neuroendocrine tumors            |
| C7B.1   | Secondary Merkel cell carcinoma                                  |
| Z85.43  | Personal history of malignant neoplasm of ovary                  |
| Z85.830 | Personal history of malignant neoplasm of bone                   |
| Z85.831 | Personal history of malignant neoplasm of soft tissue            |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

| Jurisdiction | Applicable State/US Territory   | Contractor  |
|--------------|---|---|
| E (1)        | CA, HI, NV, AS, GU, CNMI  | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)    | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ  | Noridian Healthcare Solutions, LLC                |
| 5            | KS, NE, IA, MO  | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6            | MN, WI, IL  | National Government Services, Inc. (NGS)          |
| H (4 & 7)    | LA, AR, MS, TX, OK, CO, NM  | Novitas Solutions, Inc.                           |
| 8            | MI, IN  | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)        | FL, PR, VI  | First Coast Service Options, Inc.                 |
| J (10)       | TN, GA, AL  | Palmetto GBA, LLC                                 |
| M (11)       | NC, SC, WV, VA (excluding below)  | Palmetto GBA, LLC                                 |
| L (12)       | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                           |
| K (13 & 14)  | NY, CT, MA, RI, VT, ME, NH  | National Government Services, Inc. (NGS)          |
| 15           | KY, OH  | CGS Administrators, LLC                           |