Hycamtin® (topotecan)  
(Intravenous, Intrathecal)  

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:
   - Hycamtin 4mg powder for injection: 3 vials per 21 days

B. Max Units (per dose and over time) [Medical Benefit]:

   Cervical Cancer
   - 120 units every 21 days

   All other Indications
   - 120 units every 21 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

   Cervical Cancer†
   Ovarian Cancer†
   Small Cell Lung Cancer†
   Acute Myeloid Leukemia (AML)‡
   Bone Cancer – Ewing’s sarcoma/Osteosarcoma‡
CNS Cancers‡
Non-Melanoma Skin Cancers - Merkel Cell Carcinoma‡
Soft Tissue Sarcoma - Rhabdomyosarcoma‡
Uterine Neoplasms –Endometrial Carcinoma‡

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

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Tumor response; AND
- Absence of unacceptable toxicity from the drug

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical Cancer; Osteosarcoma;</td>
<td>0.75 mg/m²/day on days 1,2,3 : repeated every 21 days</td>
</tr>
<tr>
<td>Rhabdomyosarcoma</td>
<td></td>
</tr>
<tr>
<td>Ovarian Cancer; SCLC; CNS Cancers</td>
<td>1.5 mg/m²/day for 5 days: repeated every 21 days</td>
</tr>
<tr>
<td>All other indications</td>
<td>1.5 mg/m²/day for 5 days: repeated every 21 days</td>
</tr>
</tbody>
</table>

VI. Billing Code/Availability Information

Jcode:
J9351– Hycamtin 4 mg Injection: 1 billable unit = 0.1 mg

NDC:
Hycamtin 4mg powder for injection: 00007-4201-01 (GlaxoSmithKline)*

*Generics available from numerous manufacturers

VII. References

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Topotecan. National Comprehensive Cancer Network, 2016. 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 December 2016.

Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C33</td>
<td>Malignant neoplasm of trachea</td>
</tr>
<tr>
<td>C34.00</td>
<td>Malignant neoplasm of unspecified main bronchus</td>
</tr>
<tr>
<td>C34.01</td>
<td>Malignant neoplasm of right main bronchus</td>
</tr>
<tr>
<td>C34.02</td>
<td>Malignant neoplasm of left main bronchus</td>
</tr>
<tr>
<td>C34.10</td>
<td>Malignant neoplasm of upper lobe, unspecified bronchus or lung</td>
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<tr>
<td>C34.11</td>
<td>Malignant neoplasm of upper lobe, right bronchus or lung</td>
</tr>
<tr>
<td>C34.12</td>
<td>Malignant neoplasm of upper lobe, left bronchus or lung</td>
</tr>
<tr>
<td>C34.2</td>
<td>Malignant neoplasm of middle lobe, bronchus or lung</td>
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<td>C34.30</td>
<td>Malignant neoplasm of lower lobe, unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.31</td>
<td>Malignant neoplasm of lower lobe, right bronchus or lung</td>
</tr>
<tr>
<td>C34.32</td>
<td>Malignant neoplasm of lower lobe, left bronchus or lung</td>
</tr>
<tr>
<td>C34.80</td>
<td>Malignant neoplasm of overlapping sites of unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.81</td>
<td>Malignant neoplasm of overlapping sites of right bronchus and lung</td>
</tr>
<tr>
<td>C34.82</td>
<td>Malignant neoplasm of overlapping sites of left bronchus and lung</td>
</tr>
<tr>
<td>ICD-10</td>
<td>ICD-10 Description</td>
</tr>
<tr>
<td>--------</td>
<td>--------------------</td>
</tr>
<tr>
<td>C34.90</td>
<td>Malignant neoplasm of unspecified part of unspecified bronchus or lung</td>
</tr>
<tr>
<td>C34.91</td>
<td>Malignant neoplasm of unspecified part of right bronchus or lung</td>
</tr>
<tr>
<td>C34.92</td>
<td>Malignant neoplasm of unspecified part of left bronchus or lung</td>
</tr>
<tr>
<td>C40.00</td>
<td>Malignant neoplasm of scapula and long bones of unspecified upper limb</td>
</tr>
<tr>
<td>C40.01</td>
<td>Malignant neoplasm of scapula and long bones of right upper limb</td>
</tr>
<tr>
<td>C40.02</td>
<td>Malignant neoplasm of scapula and long bones of right upper limb</td>
</tr>
<tr>
<td>C40.10</td>
<td>Malignant neoplasm of short bones of unspecified left upper limb</td>
</tr>
<tr>
<td>C40.11</td>
<td>Malignant neoplasm of short bones of right upper limb</td>
</tr>
<tr>
<td>C40.12</td>
<td>Malignant neoplasm of short bones of left upper limb</td>
</tr>
<tr>
<td>C40.20</td>
<td>Malignant neoplasm of long bones of unspecified lower limb</td>
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<td>C40.21</td>
<td>Malignant neoplasm of long bones of right lower limb</td>
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<td>C40.22</td>
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<td>Malignant neoplasm of short bones of right lower limb</td>
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<tr>
<td>C40.32</td>
<td>Malignant neoplasm of short bones of left lower limb</td>
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<tr>
<td>C40.80</td>
<td>Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb</td>
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<tr>
<td>C40.81</td>
<td>Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb</td>
</tr>
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<td>C40.82</td>
<td>Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb</td>
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<td>C40.90</td>
<td>Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb</td>
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<td>C40.91</td>
<td>Malignant neoplasm of unspecified bones and articular cartilage of right limb</td>
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<td>Malignant neoplasm of unspecified bones and articular cartilage of left limb</td>
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<td>Malignant neoplasm of mandible</td>
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<tr>
<td>C41.2</td>
<td>Malignant neoplasm of vertebral column</td>
</tr>
<tr>
<td>C41.3</td>
<td>Malignant neoplasm of ribs, sternum and clavicle</td>
</tr>
<tr>
<td>C41.4</td>
<td>Malignant neoplasm of pelvic bones, sacrum and coccyx</td>
</tr>
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<td>Malignant neoplasm of bone and articular cartilage, unspecified</td>
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<td>Malignant neoplasm of specified parts of peritoneum</td>
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<td>Malignant neoplasm of peritoneum, unspecified</td>
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<td>Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum</td>
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<td>C49.9</td>
<td>Malignant neoplasm of connective and soft tissue, unspecified</td>
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<td>C4A.0</td>
<td>Merkel cell carcinoma of lip</td>
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<tr>
<td>C4A.10</td>
<td>Merkel cell carcinoma of unspecified eyelid, including canthus</td>
</tr>
<tr>
<td>C4A.11</td>
<td>Merkel cell carcinoma of right eyelid, including canthus</td>
</tr>
<tr>
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<td>Merkel cell carcinoma of left eyelid, including canthus</td>
</tr>
<tr>
<td>ICD-10</td>
<td>ICD-10 Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td>C4A.20</td>
<td>Merkel cell carcinoma of unspecified ear and external auricular canal</td>
</tr>
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<td>Merkel cell carcinoma of right ear and external auricular canal</td>
</tr>
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<td>C4A.22</td>
<td>Merkel cell carcinoma of left ear and external auricular canal</td>
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<td>Merkel cell carcinoma of unspecified part of face</td>
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<td>C4A.31</td>
<td>Merkel cell carcinoma of nose</td>
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<td>C4A.39</td>
<td>Merkel cell carcinoma of other parts of face</td>
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<td>Merkel cell carcinoma of anal skin</td>
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<td>Merkel cell carcinoma of skin of breast</td>
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<td>C4A.59</td>
<td>Merkel cell carcinoma of other part of trunk</td>
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<td>C4A.61</td>
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<td>Malignant neoplasm of myometrium</td>
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<td>Malignant neoplasm of corpus uteri, unspecified</td>
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<td>Malignant neoplasm of right ovary</td>
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<td>C56.2</td>
<td>Malignant neoplasm of left ovary</td>
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<td>C56.9</td>
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<td>C57.10</td>
<td>Malignant neoplasm of unspecified broad ligament</td>
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<tr>
<td>C57.11</td>
<td>Malignant neoplasm of right broad ligament</td>
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<tr>
<td>C57.12</td>
<td>Malignant neoplasm of left broad ligament</td>
</tr>
<tr>
<td>ICD-10</td>
<td>ICD-10 Description</td>
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<tr>
<td>--------</td>
<td>-------------------</td>
</tr>
<tr>
<td>C57.20</td>
<td>Malignant neoplasm of unspecified round ligament</td>
</tr>
<tr>
<td>C57.21</td>
<td>Malignant neoplasm of right round ligament</td>
</tr>
<tr>
<td>C57.22</td>
<td>Malignant neoplasm of left round ligament</td>
</tr>
<tr>
<td>C57.3</td>
<td>Malignant neoplasm of parametrium</td>
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<td>Malignant neoplasm of overlapping sites of female genital organs</td>
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<td>Secondary malignant neoplasm of right lung</td>
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<td>Secondary malignant neoplasm of left lung</td>
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<tr>
<td>C79.31</td>
<td>Secondary malignant neoplasm of brain</td>
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<tr>
<td>C79.32</td>
<td>Secondary malignant neoplasm of cerebral meninges</td>
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<tr>
<td>C79.51</td>
<td>Secondary malignant neoplasm of bone</td>
</tr>
<tr>
<td>C79.52</td>
<td>Secondary malignant neoplasm of bone marrow</td>
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<tr>
<td>C7B.1</td>
<td>Secondary Merkel cell carcinoma</td>
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<td>C83.80</td>
<td>Other non-follicular lymphoma, unspecified site</td>
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<tr>
<td>C83.81</td>
<td>Other non-follicular lymphoma, lymph nodes of head, face and neck</td>
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<tr>
<td>C83.89</td>
<td>Other non-follicular lymphoma, extranodal and solid organ sites</td>
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<td>C92.00</td>
<td>Acute myeloblastic leukemia, not having achieved remission</td>
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<td>C92.50</td>
<td>Acute myelomonocytic leukemia, not having achieved remission</td>
</tr>
<tr>
<td>C92.60</td>
<td>Acute myeloid leukemia with 11q23-abnormality not having achieved remission</td>
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<td>Acute monoblastic/monocytic leukemia, not having achieved remission</td>
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<td>C94.00</td>
<td>Acute erythroid leukemia, not having achieved remission</td>
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<tr>
<td>C94.20</td>
<td>Acute megakaryoblastic leukemia not having achieved remission</td>
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<tr>
<td>Z80.49</td>
<td>Family history of malignant neoplasm of other genital organs</td>
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<tr>
<td>Z85.118</td>
<td>Personal history of other malignant neoplasm of bronchus and lung</td>
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<tr>
<td>Z85.43</td>
<td>Personal history of malignant neoplasm of ovary</td>
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<tr>
<td>Z85.821</td>
<td>Personal history of Merkel cell carcinoma</td>
</tr>
<tr>
<td>Z85.830</td>
<td>Personal history of malignant neoplasm of bone</td>
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</tbody>
</table>

**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) and Local Coverage Determinations (LCDs) may exist and compliance with
these policies is required where applicable. They can be found at: [http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx](http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx). Additional indications may be covered at the discretion of the health plan.

**Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):**

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<thead>
<tr>
<th>Jurisdiction(s)</th>
<th>NCD/LCD Document(s)</th>
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</tr>
<tr>
<td>5, 8</td>
<td>L35053</td>
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<tr>
<td>N</td>
<td>L33752</td>
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**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

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