**Doxorubicin liposomal (Doxil®, Lipodox®)**
(Intravenous)

**I. Length of Authorization**

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

Use in the treatment of Mycosis Fungoides or Sezary Syndrome will be limited to 8 cycles.

Use in the treatment of Hodgkin Lymphoma, will be limited to 6 cycles.

**II. Dosing Limits**

A. **Quantity Limit (max daily dose) [Pharmacy Benefit]:**
   - Lipodox/Doxil 20mg injection: 2 vials every 28 days
   - Lipodox/Doxil 50mg injection: 3 vials every 28 days

B. **Max Units (per dose and over time) [Medical Benefit]:**
   - **AIDS-related Kaposi sarcoma (KS):**
     - 5 units every 21 days
   - **Multiple myeloma/Non-Hodgkin Lymphoma:**
     - 8 units every 21 days
   - **Ovarian cancer/Sarcoma/MF-SS/PTLD:**
     - 10 units every 28 days
   - **Breast/Uterine Cancer:**
     - 12 units every 28 days
   - **Hodgkin Lymphoma:**
     - 8 units every 21 days

**III. Initial Approval Criteria**

Coverage is provided in the following conditions:

- AIDS-related Kaposi sarcoma (KS)†
- Multiple Myeloma†
- Ovarian Cancer (including Fallopian Tube and Primary Peritoneal Cancers‡)†
• Breast Cancer‡
• Hodgkin Lymphoma‡
• Non-Hodgkin’s Lymphoma‡
  o B-Cell Lymphomas
    ▪ Follicular Lymphoma
    ▪ Diffuse Large B-cell Lymphoma
    ▪ Castleman’s Disease – Multicentric
    ▪ Mycosis Fungoides/Sezary Syndrome
  o T-Cell Lymphomas
    ▪ Peripheral T-Cell Lymphoma
    ▪ Adult T-Cell Leukemia/Lymphoma
    ▪ Hepatosplenic Gamma-Delta T-Cell Lymphoma
• Soft Tissue Sarcoma‡
  o Extremity/Superficial Trunk, Head/Neck
  o Retroperitoneal/Intra-Abdominal
  o Angiosarcoma
  o Rhabdomyosarcoma
  o Desmoid Tumors (Aggressive Fibromatosis)
• Uterine Sarcoma (including stromal, undifferentiated and leiomyosarcoma) ‡
• Uterine Endometrial Carcinoma (including Adenocarcinoma, Carcinosarcoma, Clear Cell Carcinoma, Serous Carcinoma, Undifferentiated/dedifferentiated carcinoma) ‡
• Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders ‡

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

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

• Patient continues to meet criteria identified in section III: AND
• Tumor response with 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 some of the following: hand-foot syndrome, cardiomyopathy, secondary oral neoplasms, severe infusion related reactions, etc.

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS-related Kaposi sarcoma (KS)</td>
<td>20 mg/m²/dose given intravenously every 3 weeks until disease progression or unacceptable toxicity</td>
</tr>
<tr>
<td>Multiple myeloma/ NHL</td>
<td>30 mg/m²/dose given intravenously every 3 weeks (on day 4) for eight cycles or until disease progression or unacceptable toxicity</td>
</tr>
</tbody>
</table>
MF/SS, PTLD | 20-40 mg/m²/dose given intravenously every 4 weeks for up to 8 cycles.
---|---
Ovarian cancer/ Sarcoma/ Uterine | 50 mg/m²/dose given intravenously every 4 weeks until disease progression or unacceptable toxicity
Breast Cancer | 45-50 mg/m²/dose given intravenously every 4 weeks until disease progression or unacceptable toxicity
Hodgkin Lymphoma | 10-15 mg/m²/dose given intravenously on days 1 and 8 every 21 days for 2 to 6 cycles

VI. Billing Code/Availability Information

**HCPCS code:**
- Q2049 – Injection, doxorubicin hydrochloride, liposomal, imported Lipodox, 10 mg: 1 billable unit = 10mg
- Q2050 - Injection, doxorubicin hydrochloride, liposomal, not otherwise specified, 10 mg : 1 billable unit = 10mg

**NDC:**
- Lipodox 20 mg/10 ml single dose vial: 47335-0082-xx
- Lipodox 50 mg/25 ml single dose vial: 47335-0083-xx
- Doxil 20 mg/10 ml single dose vial: 59676-0960-xx
- Doxil 50 mg/25 ml single dose vial: 59676-0960-xx

*Generic available from various manufacturers*

VII. References

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Doxorubicin liposomal. National Comprehensive Cancer Network, 2018. 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 2018.


**Appendix 1 – Covered Diagnosis Codes**

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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</thead>
<tbody>
<tr>
<td>C46.0</td>
<td>Kaposi's sarcoma skin</td>
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<tr>
<td>C46.1</td>
<td>Kaposi's sarcoma soft tissue</td>
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<tr>
<td>C46.2</td>
<td>Kaposi's sarcoma palate</td>
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<tr>
<td>C46.3</td>
<td>Kaposi's sarcoma of lymph nodes</td>
</tr>
<tr>
<td>C46.4</td>
<td>Kaposi's sarcoma gastrointestinal sites</td>
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<tr>
<td>C46.50</td>
<td>Kaposi's sarcoma of unspecified lung</td>
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<tr>
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<td>C46.7</td>
<td>Kaposi's sarcoma of other sites</td>
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<tr>
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<td>Kaposi's sarcoma of unspecified site</td>
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<td>C47.0</td>
<td>Malignant neoplasm of peripheral nerves of head, face and neck</td>
</tr>
<tr>
<td>C47.10</td>
<td>Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder</td>
</tr>
<tr>
<td>C47.11</td>
<td>Malignant neoplasm of peripheral nerves of right upper limb, including shoulder</td>
</tr>
<tr>
<td>C47.12</td>
<td>Malignant neoplasm of peripheral nerves of left upper limb, including shoulder</td>
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<tr>
<td>C47.20</td>
<td>Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip</td>
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<td>Malignant neoplasm of peripheral nerves of right lower limb, including hip</td>
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<td>Malignant neoplasm of peripheral nerves of left lower limb, including hip</td>
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<td>Malignant neoplasm of peripheral nerves of thorax</td>
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<td>C47.5</td>
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<td>C47.6</td>
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<td>Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system</td>
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<td>ICD-10</td>
<td>ICD-10 Description</td>
</tr>
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<tr>
<td>C47.9</td>
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<td>C48.0</td>
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<td>Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder</td>
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<td>Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder</td>
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<td>Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder</td>
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<td>Malignant neoplasm of connective and soft tissue of left lower limb, including hip</td>
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<td>ICD-10 Description</td>
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<td>Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb</td>
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<tr>
<td>C81.16</td>
<td>Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes</td>
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<td>C81.17</td>
<td>Nodular sclerosis Hodgkin lymphoma, spleen</td>
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<tr>
<td>C81.18</td>
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<td>Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites</td>
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<td>Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes</td>
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<td>Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes</td>
</tr>
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<td>Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb</td>
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ICD-10 | ICD-10 Description
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C85.88 | Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89 | Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C86.1 | Hepatosplenic T-cell lymphoma
C86.2 | Enteropathy-type (intestinal) T-cell lymphoma
C86.6 | Primary cutaneous CD30-positive T-cell proliferations
C90.00 | Multiple myeloma not having achieved remission
C90.02 | Multiple myeloma, in relapse
C90.10 | Plasma cell leukemia not having achieved remission
C90.12 | Plasma cell leukemia in relapse
C90.20 | Extramedullary plasmacytoma not having achieved remission
C90.22 | Extramedullary plasmacytoma in relapse
C90.30 | Solitary plasmacytoma not having achieved remission
C90.32 | Solitary plasmacytoma in relapse
C91.50 | Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.52 | Adult T-cell lymphoma/leukemia (HTLV-1-associated) in relapse
D36.0 | Benign neoplasm of lymph nodes
D47.2 | Castleman disease
D48.1 | Neoplasm of uncertain behavior of connective and other soft tissue
R59.0 | Localized enlarged lymph nodes
R59.1 | Generalized enlarged lymph nodes
R59.9 | Enlarged lymph nodes, unspecified
Z85.3 | Personal history of malignant neoplasm of breast
Z85.43 | Personal history of malignant neoplasm of ovary
Z85.71 | Personal history of Hodgkin lymphoma
Z85.79 | Personal history of other malignant neoplasm of lymphoid hematopoietic and related tissues
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) 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):**
Jurisdiction(s): N  
NCD/LCD Document (s): L33722


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