Doxorubicin Hydrochloride Liposome Injection

<table>
<thead>
<tr>
<th>Override</th>
<th>Approval Duration</th>
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<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 year</td>
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</tbody>
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**Medications**
- Doxil
- Doxorubicin hydrochloride (HCL) liposome
- Lipodox

**APPROVAL CRITERIA**

Requests for Doxorubicin Liposome (Doxil, Lipodox) may be approved if the following criteria are met:

I. Individual has a diagnosis of one of the following:
   A. Breast cancer when used as monotherapy for recurrent or metastatic disease (NCCN 2A); OR
   B. Kaposi’s sarcoma, AIDS-related; OR
   C. Hodgkin’s Lymphoma (e.g. classical Hodgkin lymphoma or nodular lymphocytic predominant Hodgkin lymphoma) when used as second-line or subsequent therapy for refractory or relapsed disease (NCCN 2A); OR
   D. Non-Hodgkin lymphoma (NCCN 2A); OR
   E. Multiple myeloma when agent used as second-line or later line of therapy; OR
   F. Non-melanoma, dermatofibrosarcoma protuberans metastatic disease (NCCN 2A); OR
   G. Ovarian cancer (including epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer) that is persistent or recurrent disease when one of the following is met:
      1. Agent used as monotherapy; OR
      2. Agent used in combination with carboplatin or cisplatin (NCCN 2A); OR
      3. Agent used in combination with bevacizumab, if bevacizumab was not previously used for treatment of ovarian cancer (NCCN 2A); OR
   H. Sarcomas, soft tissue when one of the following is met (NCCN 2A):
      1. Angiosarcoma when used as monotherapy; OR
      2. Desmoid tumors; OR
      3. Retroperitoneal/Intra-abdominal sarcomas when used as monotherapy; OR
      4. Rhabdomyosarcoma when used as monotherapy; OR
      5. Soft tissue sarcoma of the extremity, superficial trunk, head or neck when used as monotherapy;

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0457-19
Market Applicability

<table>
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<th>Market</th>
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<tbody>
<tr>
<td>Applicable</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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OR
I. Uterine neoplasm when one of the following is met (NCCN 2A):
   1. Endometrial carcinoma when used as monotherapy; OR
   2. Uterine sarcoma when used as monotherapy for advanced or metastatic disease.

Requests for Doxorubicin Liposome (Doxil, Lipodox) may not be approved for the following:
I. All other indications not included above; OR
II. For the treatment of endometrioid adenocarcinoma for isolated metastases.

State Specific Mandates

<table>
<thead>
<tr>
<th>State Name</th>
<th>Date effective</th>
<th>Mandate details (including specific bill if applicable)</th>
</tr>
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<tbody>
<tr>
<td>N/A</td>
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</table>

Key References:

5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.