



## Prior Authorization Approval Criteria

### *Adriamycin (doxorubicin)*

<b>Generic name:</b>	Doxorubicin
<b>Brand name:</b>	Adriamycin
<b>Medication class:</b>	Antineoplastic (anthracycline)
<b>FDA-approved uses:</b>	Regression of disseminated neoplastic conditions: <ul style="list-style-type: none"><li>• Acute lymphoblastic leukemia</li><li>• Acute myeloblastic leukemia</li><li>• Wilms' tumor</li><li>• Neuroblastoma</li><li>• Soft tissue and bone sarcomas</li><li>• Breast carcinoma</li><li>• Ovarian carcinoma</li><li>• Transitional cell bladder carcinoma</li><li>• Thyroid carcinoma</li><li>• Gastric carcinoma</li><li>• Hodgkin's disease</li><li>• Malignant lymphoma</li><li>• Bronchogenic carcinoma (small-cell histologic type)</li></ul>
<b>Available dosage forms:</b>	Lyophilized powder for injection or solution for injection (2 mg/ml)
<b>Usual dose range:</b>	IV infusion in 50 ml over 15 min. or IVP over 3-5 min. every 21-28 days, depending on clinical response
<b>Duration of therapy:</b>	Indeterminate; dependent upon clinical response
<b>Approximate yearly cost:</b> (based on ASP 7/20/06)	\$1,067

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- Clinically diagnosed with one of the above diseases
- Patient is not hypersensitive to doxorubicin or any of the formulation's components
- Patient does not have pre-existing myelosuppression
- Lifetime anthracycline cumulative doses does not exceed 450-550 mg/m<sup>2</sup>

**Criteria for continuation of therapy:**

- No signs of cardiotoxicity
- Patient is not intolerant to treatment regimen

**Caution:**

- Administered only under the supervision of a physician who is experienced in the use of cancer chemotherapeutic agents
- Extravasation can occur
- Possibility of myocardial toxicity (fatal CHF) and severe myelosuppression
- Dose reduction for hepatic impaired patients

**Monitoring:** CBC, ECG changes, ECHO, liver function

**Contraindications:**

- Hypersensitivity to doxorubicin or any of the components
- Rotavirus vaccine, live
- Marked myelosuppression induced by previous treatment with other antitumor agents or by radiotherapy
- Previous treatment with complete cumulative doses of doxorubicin, daunorubicin, idarubicin, and/or other anthracyclines and anthracenes

**Not approved if:**

- Above criteria are not met
- Lifetime cumulative dose of doxorubicin does not exceed 450-550 mg/m<sup>2</sup> (taking into account previous treatment with other anthracyclines as well)

**Special considerations:**

- Red coloration of the urine for 1 to 2 days after administration

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 10/8/2008