BCCA Protocol Summary for DOXOrubicin for Adjuvant Use for Patients with Non-Metastatic Operable Large High Grade Soft Tissue Sarcoma

**Protocol Code:** SAAJA

**Tumour Group:** Sarcoma

**Contact Physician:** Dr Meg Knowling

**ELIGIBILITY/TESTS:**
- Adult (greater than or equal to 17 years of age) patients with:
  - localized, operable non-metastatic soft tissue sarcoma of the extremity but not rhabdomyosarcoma, Ewing’s Family of Tumours (EWFT) in adults.
  - or
  - high grade aggressive histologies with known poor prognosis
  - In certain instances for young patients with aggressive primitive histologies, locally advanced disease or large high grade synovial sarcomas, SAAI may be used - as before
- Patients must have normal cardiac function.
- Radiation therapy will generally follow chemotherapy – but can be given concurrently for selected patients.

**TESTS**
- Baseline: full clinical evaluation including recent (within 3 months) CT chest, CBC and diff, platelets, LFT’s and bilirubin.
- Before each treatment: CBC and diff, platelets
- If clinically indicated: bilirubin, ECG and measure of LVEF

**TREATMENT:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>BCCA Administration Guideline</th>
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</thead>
<tbody>
<tr>
<td>DOXOrubicin (ADRIAMYCIN®)</td>
<td>75 mg/m²</td>
<td>IV push</td>
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Repeat every 3 weeks x 5 cycles only (total dose 375 mg/m²).
DOSE MODIFICATIONS:

1. **Hematologic Toxicity**: Treatment day counts

<table>
<thead>
<tr>
<th>ANC* (x 10^9/L)</th>
<th>Platelets (x 10^9/L)</th>
<th>Dose</th>
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<tbody>
<tr>
<td>greater than 1.5 and greater than 100</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>1 to 1.5 or 70 to 100</td>
<td></td>
<td>80%</td>
</tr>
<tr>
<td>less than 1 or less than 70</td>
<td></td>
<td>delay one week</td>
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</table>

* Absolute neutrophil count

2. **Mucositis**: Grade 3 or 4 give 80%
3. **Nausea & Vomiting**: Grade 4 - not helped by antiemetics give 80% of dose or QUIT.
4. **Neutropenic Fever**: with ANC less than 0.5 (x 10^9/L), give 80% of dose.
5. **Bilirubin**: 1.5 - 2 times normal, reconsider advisability of adjuvant chemotherapy.

**PRECAUTIONS:**

1. **Cardiomyopathy** is a well known toxicity of DOXOrubicin with cumulative dose of the drug over 400 mg/m². Occasionally this may occur with less drug – patients should be screened for any symptoms or signs of arrhythmia or congestive heart failure during therapy and on follow-up.

Call Dr. Meg Knowling or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

**Date Activated**: 1 Nov 2002

**Date revised**: 1 Mar 2013 (TALLman lettering)

**Reference:**