



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** dasatinib

**Brand Name:** Sprycel

**Medication Class:** Antineoplastic Agent

**FDA Approved Uses:** - Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.  
-Chronic, accelerated, or myeloid or lymphoid blast phase chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy, including imatinib.  
-Philadelphia chromosome positive acute lymphoblastic leukemia with resistance or intolerance to prior therapy (Ph + ALL)

**Available Dosage Forms:** 20mg, 50mg and 70mg tablets

**Usual Dose:** 70mg orally twice daily

**Duration of Therapy:** Until disease progression or until no longer tolerated by the patient.

**Approximate monthly cost** (based on AWP 2006): \$3,900 per month for 140mg/day. (\$47,000.00/year)

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

- Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
- Or
- Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib.
- Or
- Adults with Ph+ ALL with resistance or intolerance to prior therapy.
  
- Resistance to Gleevec (imatinib). Defined as failure to achieve a complete hematologic response within 3-6 months or major cytogenetic response by month 12 or progression of disease after a previous cytogenetic or hematologic response.
- Intolerance to Gleevec (imatinib). Defined as the inability to tolerate 400 mg or more of imatinib per day or discontinuation of imatinib because of toxicity.

**Criteria for Continuation of Therapy:**

- Elimination of detectable leukemia cells.
- Or
- Significant reduction in the number of leukemia cells (by at least 65%)



**Cautions:**

- Risk of pleural effusions\*
- Cardiovascular events^

**Monitoring:**

- Fluid retention, cough or shortness of breath due to risk of pleural effusion\*\*

**Contraindications:**

- None known

**Not Approved if:**

- Does not meet the above stated criteria

**Special Considerations:**

- Most patients who had a response remained so six months after they began taking dasatinib.
- Most cytogenetic responses occurred after 12 weeks of treatment.
- 2/3 of patients have significant severe adverse effects on dasatinib.

\*In phase II trials, 17% of dasatinib patient's experienced pleural effusions, with 5% exhibiting grade ¾ pleural effusions.

\*\*Bristol-Meyers Squibb suggest using a diuretic or steroid if fluid retention is seen

^4% of dasatinib patients experienced a cardiovascular event.

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_