Prior Authorization Approval Criteria
Sprycel (dasatinib)

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
Approximate monthly cost: $9,700/month for 70mg twice daily (based on AWP 2012)

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

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
  Or
- Clinically diagnosed with Ph + ALL with resistance or intolerance to prior therapy.
  Or
- Clinically diagnosed with CML
- 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

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

Caution:
- Risk of pleural effusions*
- Cardiovascular events^
Monitoring:
- Fluid retention, cough or shortness of breath due to risk of pleural effusion**

Contraindication:
- 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.

FCHP Pharmacy and Therapeutics Committee approval: ________________________________

Date: ______________________

Adopted: 09/13/06
Revised: 09/2011