SPRYCEL
(dasatinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Sprycel is an orally administered kinase inhibitor used to treat patients with either Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Patients with either condition are classified into three groups that help predict outlook: chronic phase, accelerated phase or blast phase. Treatment with Sprycel can be used in any of these three phases in patients who failed prior therapy but in newly diagnosed patients with CML, Sprycel may only be used as initial therapy for patients in chronic phase (1).

Regulatory Status
FDA-approved indication: Sprycel is a kinase inhibitor indicated for treatment of: (1)
1. Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase
2. Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib
3. Adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy
4. Pediatric patients with Ph+ CML in chronic phase

Off-label Uses:
Sprycel can be used in the treatment of patients with advanced phase CML with the Philadelphia chromosome and BCR-ABL fusion gene (accelerated phase or blast crisis), follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT), follow-up therapy for CML patients resistant or intolerant to primary treatment with alternative tyrosine kinase inhibitors, Ph+ ALL as a single agent or in combination with chemotherapy or corticosteroids, gastrointestinal stromal tumor (GIST) in patients with PDGFRA D842V mutation (2-3).

Treatment may result in severe myelosuppression requiring dose interruption, dose adjustment or discontinuation of therapy. Routine monitoring of CBC is recommended (1).

Patients should also be monitored for signs and symptoms of cardiac dysfunction (including arrhythmias/QT prolongation), cardiopulmonary disease, SJS, erythema multiforme and TLS (1).
The safety and efficacy of Sprycel in patients less than 2 years of age have not been established for Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) (1).

The safety and efficacy of Sprycel in patients less than 18 years of age have not been established for BCR-ABL 1 positive chronic myeloid leukemia (BCR-ABL 1+ CML), Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL), or Gastrointestinal Stromal Tumor with PDGFRA D842V mutation (1-3).

Summary
Sprycel is a kinase inhibitor that is indicated for the treatment of Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML), BCR-ABL 1 positive chronic myeloid leukemia (BCR-ABL 1+ CML), Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL), or Gastrointestinal Stromal Tumor. Sprycel may cause cardiac dysfunction, fluid retention, cardiopulmonary disease, TLS and/or skin reactions. Routine monitoring for myelosuppression is warranted during therapy (1-3).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Sprycel while maintaining optimal therapeutic outcomes.

References