RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Sprycel (dasatinib) is an orally administered kinase inhibitor indicated for the treatment of 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 indications: 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 1 year of age and older with Ph+ CML in chronic phase
5. Pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy

Off-Label Uses: (2-3)

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, and gastrointestinal stromal tumor (GIST) in patients with PDGFRA D842V mutation.

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, Stevens-Johnson syndrome (SJS), erythema multiforme and tumor lysis syndrome (TLS) (1).

Sprycel can cause fetal harm when administered to a pregnant woman. Adverse pharmacologic effects of Sprycel including hydrops fetalis, fetal leukopenia, and fetal thrombocytopenia have been reported with maternal exposure to Sprycel. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with Sprycel and for 30 days after the last dose.

The safety and effectiveness of Sprycel in patients less than 1 year of age with Ph+ CML or Ph+ ALL have not been established. The safety and effectiveness of Sprycel in patients less than 18 years of age with GIST have not been established (1-3).

Summary

Sprycel (dasatinib) is a kinase inhibitor used in the treatment of Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML), Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), and gastrointestinal stromal tumor (GIST). Patients should also be monitored for signs and symptoms of cause cardiac dysfunction, fluid retention, cardiopulmonary disease, tumor lysis syndrome, skin reactions and myelosuppression. The safety and effectiveness of Sprycel in patients less than 1 year of age with Ph+ CML or Ph+ ALL have not been established. The safety and effectiveness of Sprycel in patients less than 18 years of age with GIST have not been established (1-3).

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

References

1. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; July 2024.
2. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 3.2025). National Comprehensive Cancer Network, Inc. November 2024. Accessed on January 13, 2025.
3. NCCN Drugs & Biologics Compendium® Dasatinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 13, 2025.