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5.21.063

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 30, 2015
Subject:	Sprycel	**Page:**	1 of 6

Last Review Date: December 8, 2023

Sprycel

Description

Sprycel (dasatinib)

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).

Related policies
Ayvakit, Bosulif, Gleevec, Iclusig, Qinlock, Scemblix, Tasigna

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sprycel may be considered **medically necessary** if the conditions indicated below are met.

Sprycel may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)
    a. 1 year of age or older
2. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
    a. 1 year of age or older
3. Gastrointestinal Stromal Tumor (GIST)
    a. 18 years of age or older
    b. PDGFRA D842V mutation
    c. Prior therapy with imatinib, sunitinib or regorafenib

AND ALL of the following for Ph+ CML or Ph+ ALL diagnoses:

a. Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy
b. If the patient has had prior therapy with a TKI then **ONE** of the following requirements must be met:
    i. Member experienced resistance to prior therapy with TKI
        1) Results from mutational testing are negative for the T315I mutation
    ii. Member experienced toxicity or intolerance to prior therapy with a TKI

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)
    a. 1 year of age or older
2. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
    a. 1 year of age or older
3. Gastrointestinal stromal tumors (GIST)
    a. 18 years of age or older

AND the following for **ALL** indications:

a. Complete or partial response to therapy or lack of disease progression

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity
20 mg	180 tablets per 90 days **OR**
50 mg	180 tablets per 90 days **OR**
70 mg	180 tablets per 90 days **OR**
80 mg	90 tablets per 90 days **OR**
100 mg	90 tablets per 90 days **OR**
140 mg	90 tablets per 90 days

Maximum daily limit of any combination: 180 mg

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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; February 2023.
2. NCCN Clinical Practice Guidelines in Oncology® Chronic Myeloid Leukemia (Version 1.2024). National Comprehensive Cancer Network, Inc. August 2023. Accessed on October 12, 2023.
3. NCCN Drugs & Biologics Compendium® Dasatinib 2023. National Comprehensive Cancer Network, Inc. Accessed on October 12, 2023.

Policy History

Date	Action
October 2015	Addition to PA
December 2015	Annual review
June 2016	Annual review and reference update Policy code changed from 5.04.63 to 5.21.63
March 2017	Annual editorial review and reference update Addition of no dual therapy with another tyrosine kinase inhibitor and addition of the age requirement in the renewal section
December 2017	Addition of pediatric patients with Ph+ CML and quantity limits
March 2018	Annual editorial review Addition of “If the patient has had prior therapy with a TKI then ONE of the following requirements must be met: member experienced resistance to prior therapy with TKI and results from mutational testing are negative for the T315I mutation or member experienced toxicity or intolerance to prior therapy with a TKI”
July 2018	Update in quantities of 20 mg, 50 mg, and 70 mg to match packaging in package insert
September 2018	Annual review
January 2019	Reduction of age to 1 year and older for Ph+ CML and Ph+ ALL
March 2019	Annual review and reference update
June 2020	Annual editorial review and reference update. Removed no dual therapy with another TKI requirement
July 2020	Annual review
September 2021	Annual editorial review and reference update
March 2022	Annual editorial review and reference update
December 2022	Annual review and reference update. Changed policy number to 5.21.063
September 2023	Annual review and reference update
December 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.