UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Sprycel

Program	Prior Authorization
Medication	Sprycel® (dasatinib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New York, New York EPP, Rhode Island, Pennsylvania- CHIP, New Jersey, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

1. Background:

Sprycel® (dasatinib) is a tyrosine kinase inhibitor indicated for newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. Sprycel is also indicated for treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including Gleevec® (imatinib), for treatment of adults with Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy, for the treatment of pediatric patients 1 year of age and older with Ph+ CML in chronic phase, and for the treatment of pediatric patients 1 year of age and older with Ph+ ALL in combination with chemotherapy. The National Comprehensive Cancer Network (NCCN) also recommends the use of Sprycel in the following: BCR-ABL1 positive CML, in gastrointestinal stromal tumor in patients with a PDGFRA D842V mutation, metastatic chondrosarcoma, and in recurrent chordoma and in myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement.

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2. Coverage Criteria:

A. <u>Philadelphia Chromosome-Positive or BCR-ABL1-Positive Chronic Myeloid Leukemia</u>

1. <u>Initial Authorization</u>

a. **Sprycel** will be approved based on the following criterion:

(1) Diagnosis of Philadelphia chromosome-positive or BCR-ABL1-Positive chronic myeloid leukemia

-AND-

(2) **<u>One</u>** of the following:

(a) Patient is not a candidate for imatinib as attested by physician

-OR-

(b) Patient is currently on Sprycel therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. **Sprycel** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sprycel therapy

Authorization will be issued for 12 months.

B. Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ALL)

1. Initial Authorization

a. **Sprycel** will be approved based on the following criterion:

(1) Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Sprycel** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sprycel therapy

Authorization will be issued for 12 months.

C. Gastrointestinal Stromal Tumor (GIST)

1. Initial Authorization

a. **Sprycel** will be approved based on the following criterion:

(1) Diagnosis of gastrointestinal stromal tumor (GIST) with PDGFRA D842V mutation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sprycel** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sprycel therapy

Authorization will be issued for 12 months.

D. Chondrosarcoma

1. **Initial Authorization**

a. Sprycel will be approved based on the following criterion:

(1) Diagnosis of metastatic chondrosarcoma

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Sprycel will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sprycel therapy

Authorization will be issued for 12 months.

E. Chordoma

1. **Initial Authorization**

a. Sprycel will be approved based on the following criterion:

(1) Diagnosis of recurrent chordoma

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Sprycel will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sprycel

therapy

Authorization will be issued for 12 months.

G. Myeloid/Lymphoid Neoplasms with Eosinophilia

1. **Initial Authorization**

a. **Sprycel** will be approved based on **both** of the following:

(1) Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

-AND-

(2) Patient has an ABL1 rearrangement

Authorization will be issued for 12 months.

2. Reauthorization

a. **Sprycel** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sprycel therapy.

Authorization will be issued for 12 months.

F. NCCN Recommended Regimens

1. Initial Authorization

a. **Sprycel** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Sprycel** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Sprycel therapy

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Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; December 2018.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 28, 2020.

Program	Prior Authorization/Notification - Sprycel (dasatinib)
Change Control	
9/19/2013	New guideline; individual guideline created to replace the general Oral Chemotherapy guideline
12/17/2015	Annual review, no change
10/2016	Separated Tasigna and Sprycel into individual policies to align with Employer and Individual notification policies and updated policy template
11/2017	Updated background and criteria removing acute lymphoblastic lymphoma as no longer recommended by NCCN.
11/2018	Updated background and criteria to include chordoma and chondrosarcoma. Added NCCN Recommended Regimen review criteria. Added step through imatinib for CML only.
10/2019	Annual review. Updated background and references.
10/2020	Annual review. Updated background and coverage criteria to include NCCN recommended use in myeloid/lymphoid neoplasms with eosinophilia. Updated references. Added Additional Clinical Rules section.