UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Sprycel

Program	Prior Authorization
Medication	Sprycel® (dasatinib)
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

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). Lastly, it is FDA-labeled for treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia with resistance or intolerance to prior therapy. The National Comprehensive Cancer Network (NCCN) also recommends the use of Sprycel in the following: BCR-ABL1 positive CML, and in gastrointestinal stromal tumor in patients with a PDGFRA D842V mutation.

2. Coverage Criteria:

A. Philadelphia Chromosome-Positive or BCR-ABL1-Positive Chronic Myelogenous / Myeloid Leukemia

1. Initial Authorization

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

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

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) (off-label)

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.

3. References:

1. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; August 2015.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 6, 2017.

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.