UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1096-12
Program	Prior Authorization/Notification
Medication	Sprycel® (dasatinib)
P&T Approval Date	8/2008, 6/2009, 6/2010, 9/2010, 12/2010, 9/2011, 8/2012, 8/2013, 2/2014, 2/2015, 2/2016, 11/2017, 11/2018, 10/2019, 10/2020, 10/2021, 10/2022, 10/2023
Effective Date	1/1/2024

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 the 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, in recurrent chordoma, in myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement, and in cutaneous melanoma with metastatic or unresectable tumors with activating mutations of KIT as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. <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

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. 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.

D. 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.

E. 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.

F. 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.

H. Cutaneous Melanoma

1. **Initial Authorization**

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

(1) Diagnosis of cutaneous melanoma

-AND-

(2) Tumors are metastatic or unresectable

-AND-

(3) Contains activating mutations of KIT

-AND-

(4) Used as second-line or subsequent therapy for disease progression, intolerance, and/or projected risk of progression with BRAF-targeted 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.

I. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National

Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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 Step Therapy, and/or Medical Necessity may be in place.

4. References:

1. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; February 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 29, 2023.

Program	Prior Authorization/Notification - Sprycel (dasatinib)
Change Control	
2/2014	Updated references.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
2/2015	Annual review. Updated GIST to include PDGFRA D842V mutation. Updated background and references.
2/2016	Annual review. Updated background and CML coverage criteria to include BCR-ABL1 positive diagnosis. Updated references.
11/2017	Annual review. Updated background and criteria removing acute lymphoblastic lymphoma as no longer recommended by NCCN.
11/2018	Updated background and criteria to include NCCN recommended use in chordoma and chondrosarcoma.
10/2019	Annual review. Added general NCCN recommended review criteria. 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.
10/2021	Annual review with no change to clinical coverage criteria. Updated reference.
10/2022	Annual review with no changes to clinical coverage criteria. Updated references. Added state mandate footnote.

10/2023	Annual review. Added criteria for cutaneous melanoma per NCCN Guidelines. Updated background and references.