UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3025-14
Program	Step Therapy
Medication	Sprycel® (dasatinib)
P&T Approval Date	8/2013, 2/2014, 2/2015, 2/2016, 10/2016, 10/2017, 10/2018, 10/2019, 10/2020, 10/2021, 4/2022, 4/2023, 4/2024
Effective Date	7/1/2024

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a patient trial, or physician consideration of imatinib, and a trial of or contraindication to Tasigna® (nilotinib) before providing coverage for Sprycel in the setting of Philadelphia chromosome-positive or BCR-ABL1-positive chronic myelogenous/myeloid leukemia.

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,b]:

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 Myelogenous / Myeloid Leukemia</u>

1. **Sprycel** will be approved based **<u>all</u>** of the following criteria:

   a. Diagnosis of Philadelphia chromosome-positive or BCR-ABL1-positive chronic myelogenous / myeloid leukemia

   -AND-

   b. **<u>One</u>** of the following:

      (1) **<u>Both</u>** of the following:

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

-AND-

(b) Provider attests the patient has a contraindication to, history of intolerance to, or that the patient is not an appropriate candidate (document reason, e.g., pre-existing cardiovascular, hepatic disease to a degree therapy would not be an option) for Tasigna (nilotinib) therapy

-OR-

(2) **Both** of the following:

(a) Patient is currently on Sprycel therapy

-AND-

(b) Patient has not received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from a Bristol-Myers Squibb sponsored Sprycel Assist Program™ (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Sprycel*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a Bristol-Myers Squibb sponsored Sprycel Assist Program™ **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months

C. Other Indications

1. **Sprycel** will be approved

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

[b] Coverage of oncology medications may be approved based on state mandates.

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 and/or Notification may be in place.
- Coverage of oncology medications may be approved based on state mandates.

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 February 26, 2024.
3. Schiffer CA, Atallah E. Initial treatment of chronic myeloid leukemia in chronic phase. In: UpToDate, Waltham, MA, 2021.

Program	Step Therapy - Sprycel (dasatinib)
Change Control	
8/2013	New step therapy criteria.
2/2014	Review with no change to Coverage Criteria.
2/2015	Annual review. Added sample pack language. Updated background and references.
2/2016	Annual review with no change to coverage criteria. Updated background and references. Added Maryland coverage information.
7/2016	Added Indiana and West Virginia coverage information.
10/2016	Updated criteria to include imatinib as preferred first line option. Added additional toxicity criteria to bypass Tasigna requirement. Updated references
11/2016	Added California coverage information.
10/2017	Annual review. Updated sample pack and state mandate verbiage. Updated reference.
10/2018	Annual review with no changes to coverage criteria. Updated reference.
10/2019	Annual review with no changes to coverage criteria. Updated references.
10/2020	Annual review with no changes to coverage criteria. Updated references.
10/2021	Annual review. Added coverage criteria for diagnosis of BCR-ABL1-positive chronic myelogenous / myeloid leukemia. Updated references.
4/2022	Added oncology medications state mandate note.
4/2023	Annual review with no changes to coverage criteria. Updated references.
4/2024	Annual review. Updated Tasigna step therapy wording with no change to clinical intent. Updated references.